TREATING THE PROBLEM: ADDRESSING ANTICOMPETITIVE CONDUCT AND CONSOLIDATION IN HEALTHCARE MARKETS

HEARING

BEFORE THE

SUBCOMMITTEE ON ANTITRUST, COMMERCIAL, AND ADMINISTRATIVE LAW

OF THE

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TREATING THE PROBLEM: ADDRESSING ANTICOMPETITIVE CONDUCT AND CONSOLIDATION IN HEALTHCARE MARKETS

Thursday, April 29, 2021

HOUSE OF REPRESENTATIVES

SUBCOMMITTEE ON ANTITRUST, COMMERCIAL, AND ADMINISTRATIVE LAW

COMMITTEE ON THE JUDICIARY
Washington, DC

The Subcommittee met, pursuant to call, at 1:04 p.m., in Room 2141, Rayburn House Office Building, Hon. David Cicilline [Chair of the Subcommittee] presiding.

Present: Representatives Cicilline, Nadler, Jones, Deutch, Jeffries, Raskin, Jayapal, Demings, Scanlon, Dean, Johnson of Georgia, Buck, Issa, Johnson of Louisiana, Steube, Bishop, Fischbach, Spartz, Fitzgerald, and Owens.

Staff Present: Cierra Fontenot, Chief Clerk; John Williams, Parliamentarian; Amanda Lewis, Counsel; Joseph Van Wye, Professional Staff Member; Slade Bond, Chief Counsel; Phillip Berenbroick, Counsel; Ella Yates, Minority Member Services Director; Douglas Geho, Minority Chief Counsel for Administrative Law; and Kiley Bidelman, Minority Clerk.

Mr. CICILLINE. The Subcommittee will come to order without objection. The Chair is authorized to declare a recess of the Subcommittee at any time. Good morning, and welcome to today's hearing to examine consolidation and anticompetitive conduct in the healthcare industry.

I am truly honored by my colleagues' presence, along with our esteemed Witnesses on the second panel.

I would like to extend an especially warm welcome to my counterpart on the Senate Antitrust Subcommittee, Senator Klobuchar, who has been a real leader on these issues.

I also want to extend a warm welcome to Senator Blumenthal, Senator Cornyn, and Senator Grassley, and to thank them for all their work to lower prescription drug costs and on several of the bills under discussion today. Of course, we may have to move the order around, depending on the schedule of the Senators.

It is also a pleasure to welcome Senator Lee, the Ranking Member of the Senate Antitrust Subcommittee.

Finally, I am very pleased to be joined today by our colleague in the House, Chair Maloney, who has led a serious and effective in-

vestigation into drug prices as the Chair of the Committee on Oversight.

Before we begin, I would like remind Members that we have established an email address and distribution list dedicated to circulating exhibits, motions, or other written materials that Members might want to offer as part of today's hearing. If you would like to submit materials, please send them to the email address that has been previously distributed to your offices, and we will circulate the materials to Members and staff as quickly as we can.

I would also like to remind all Members and our Witnesses that guidance from the Office of the Attending Physician states that face coverings are required for all meetings in an enclosed space, such as Committee hearings. I expect all Members on both sides of the aisle to wear a mask for the duration of today's hearing.

I now recognize myself for an opening statement. Prior to the onset of the COVID–19 pandemic, our healthcare system was in a State of crisis. The cost of prescription medicine has increased by 200 percent in a short period of time, while Kaiser Health reported that a quarter of cancer patients in the United States could not afford their medicine. They had resorted to cutting their pills in half or skipping drug treatment entirely. Despite decades of rising costs, the United States ranked dead last in health outcomes among similar countries.

In the wake of the pandemic, the healthcare sector has undergone a wave of consolidation across the entire industry, and all the while the cost of healthcare continues to skyrocket.

In the second half of 2020, there were five mega-mergers in the pharmaceutical marketplace alone, adding up to nearly $100 billion. Within the decade, the Centers for Medicare and Medicaid Services project that spending on healthcare in the United States will surpass $6 trillion, equal to nearly 20 percent of U.S. gross domestic product.

Despite ample evidence of rising costs and anticompetitive conduct in the pharmaceutical sector, the FTC has not attempted to block any of these deals, including the combination of Pfizer and Mylan's generic drug business into what is now the largest manufacturer of generics in the world.

As then Commissioner Chopra and Acting Chair Rebecca Kelly Slaughter noted in a dissenting statement, there has not been a single instance in recent history where the agency has filed a complaint in Federal court seeking to halt a prescription drug merger. Under the leadership of Acting Chair Slaughter, the FTC recently launched an international working group to rethink the FTC's approach, which is a very promising step. In the hospital markets, the FTC has been more active in seeking to block mergers. The time and expense of bringing these cases over the past few years has stretched the FTC's razor thin resources to the breaking point.

At the same time, executive compensation at healthcare firms continues to soar. The CEO of Tenet Healthcare, a for-profit hospital giant with $399 million in profit last year, was paid $16.7 million in the same year that the company furloughed about 11,000 workers and received hundreds of millions in bailout funds. According to reports by The Washington Post, Genesis Healthcare—one of the largest nursing home chains in the country—rewarded their

CEO with a multimillion dollar bonus, despite shortages of medical equipment for workers at their facilities and a higher COVID mortality rate than its major competitors. Finally, *The New York Times* reported earlier this week that the CEO of a chain of primary care physicians was paid $199 million last year alone.

In other words, we are not seeing better care or more innovation as a result of consolidation and anticompetitive practices in the healthcare sector. It is far more likely that monopoly profits are contributing to a CEO's mega yacht than bringing new lifesaving drugs to market.

As our Nation recovers from both the public health and economic effects of the pandemic, it is more essential than ever that we take these issues head-on. Our competition system is the backbone of promoting open and fair markets, and that is especially true here.

In the pharmaceutical marketplace, the entry of generic drug competitors can reduce the cost of branded drugs exponentially. In hospital and healthcare insurance markets, competition not only lower prices, but it also improves the quality, availability, and affordability of care.

In far too many cases, effective antitrust enforcement takes too long to deliver meaningful results to people in need. For example, some branded drug companies have abused safety protocols to delay generic entry, preserving their monopoly power for more than the decade. As Professor Robin Feldman has noted, even months of delay could be worth hundreds of millions of dollars in additional monopoly revenues as the generic sits on the sideline.

While this anticompetitive conduct should violate the antitrust laws, even successful cases often take long to provide effective relief. In response to this crisis, we enacted the CREATES Act in December 2019, legislation I introduced with Senator Leahy, that will lower drug prices by billions of dollars. This law will help end the abuse of FDA safety protocols by branded drug companies and spur the entry of numerous lower cost alternatives. According to a recent report by the FDA, the CREATES Act has already increased generic and biosimilar competition to lower drug prices and simplified the process for market entry.

In the final days of the 116th Congress, we also enacted the Competitive Health Insurance Act, legislation that repeals the longstanding exemption for the business of health insurance that has been on the books since 1945.

In this Congress, we plan to build on these successes by moving legislation to address other forms of anticompetitive conduct and promote competition to healthcare markets.

Yesterday, I reintroduced the Affordable Prescriptions for Patients through Competition Act together with Subcommittee Ranking Member Buck and Senators Cornyn and Blumenthal. This legislation addresses product hopping, a particular abusive form of conduct used by drug manufacturers to extend their monopolies by preemptively switching the market for a drug prior to the expiration of the patent. As the National Institute for Health has noted, there is often little or no therapeutic advantage for the switch. It only exists to block competitors from entering the market.

For example, several years ago, the pharmaceutical company Actavis attempted to remove its blockbuster treatment for Alz-

heimer's disease and replace it with a "new and improved," version in order extend its monopoly until 2029. The new version was simply a once daily dose instead of a twice daily dose, which may be helpful but does not warrant decades of additional exclusivity. This is not true innovation, and it is costing hardworking Americans.

According to a recent report by Matrix Global Advisors, just five instances of product hopping alone cost working Americans $4.7 billion annually.

My distinguished colleagues on the first panel will discuss several other proposals that address additional abuse of conduct from pay-for-delay agreements to citizen petition abuse.

As Chair Maloney will testify today, her committee's drug pricing investigation uncovered new evidence of anticompetitive conduct underscoring the urgency for congressional action.

In closing, the American people deserve a government that is in their corner fighting for them to take on drug profiteering and other barriers to affordable healthcare. Since the beginning of the 116th Congress, ending this moral crisis has been a top priority of mine as Chair of this Subcommittee, and a top priority for House Democrats to keep our promise to the American people to lower their healthcare costs.

With that, it is my pleasure now to recognize the Ranking Member of the Subcommittee Mr. Buck for the purposes of making an opening statement.

Mr. Buck, you may still be on mute.

Mr. BUCK. Does that work.

Mr. CICILLINE. It does indeed.

Mr. BUCK. I wanted to assure the Chair that I am going to go maskless, and I am socially distanced, approximately, 1,400 miles away from Capitol Hill at this point. So, I appreciate the Chair's indulgence.

Today's hearing focuses on the issues that are important to every American. Healthcare is a very large and important sector of our economy that accounts for almost ⅕ of the United States GDP. According to the Centers for Medicare and Medicaid Services, America spends almost $3.8 trillion, or almost $12,000 per person, on healthcare. These sky-high costs are a result of many factors, including the misguided Obamacare legislation, a patchwork of often contradictory and burdensome Federal and State laws, and anticompetitive conduct by a host of actors in the healthcare sector but especially the pharmaceutical industry.

I want to start by thanking our Witnesses today. It is always a pleasure to interact with our Senate colleagues and see the bipartisan nature of a legislation we will be considering in the future.

I also want to thank Chair Cicilline for arranging this hearing and my friend from Colorado, Congressman Joe Neguse, for highlighting abuses in the pharmaceutical industry and finding ways to lower drug cost for consumers.

Obamacare was sold to the American people as a means to make healthcare affordable and protect patients. Over the past decade, the exact opposite has materialized. Obamacare has resulted in the loss of doctors and insurance options, skyrocketing costs, and increasing consolidation and monopolization of insurance and hospital markets across the country. As we heard in Martin Gaynor's

testimony before this Subcommittee last Congress, the two largest insurers have 70 percent of the market in over one-half of all local insurance markets. There have been almost 1,600 hospital mergers over the past two decades, and there were nearly 31,000 physician practice acquisitions by hospitals from 2008–2012. At least a third of all doctors are now in hospital-owned practices.

One particularly pernicious result of this failed law is the consolidation and closing of hospitals, especially in rural areas. This leaves people in rural America, like most of the people in my home district, with few options other than driving to facilities that are often hours away.

A second factor that is driving up prices, destroying competition, and leaving patients with fewer choices is the web of inconsistent and often contradictory Federal and State laws and regulations. We all know the Federal system is a virtually unnavigable morass of laws, regulations, and guidance documents. This seems to increasingly be the case at the State level as well.

The pandemic has shown the need for a more nimble and responsive healthcare system. That is not what we have in either the Federal or State level. Instead, we have an ossified system that seemingly can't get out of its own way.

For example, the Trump Administration took critical steps to cut red tape and allow companies to develop extremely effective and safe vaccines to stop the pandemic in under one year. This previously unheard-of timeline highlights the need for permanent regulatory reform, as promising drugs for other diseases like cancer, cystic fibrosis, and multiple sclerosis continue to languish for years in a bureaucratic approval process.

Further, many of the largest players use this regulatory framework to stifle smaller competitors, who rely on getting new medication to market to become profitable and remain in business. These smaller companies frequently end up bought by giant competitors because they do not have the funds to survive a decade-long FDA approval process.

Lastly and probably more egregiously in terms of driving up costs and decreasing patient options are the examples of anticompetitive conduct and abuse of government process we have seen from the pharmaceutical industry.

The three bills we are considering today will result in more competition and lower prices for patients.

I want to thank Senators Grassley, Cornyn, and Klobuchar, and Blumenthal for their work on these important issues and for being here today to discuss these bills.

In summary, the bills we are looking at today authorize regulators to investigate the abuse of citizen petitions which artificially delay the entry of generic competitors, curb the practice of using anticompetitive pay-for-delay tactics that artificially inflate prices for patients, and stop the brand-name pharmaceuticals from playing games with their patents to extend the period of their monopoly while destroying the market for generics. These bills address the gamesmanship and abusive process we have seen in this market, they will help curb the price increases, and provide more options to the American supervisor. In sum, the underlying issue in each

of these markets is the lack of competition and anticompetitive conduct exhibited by the biggest players.

Our healthcare system is based on markets, and the system only works as well as the markets that underpin it.

Mr. Chair, I am proud to cosponsor these three bills with you that will result in more competition, lower prices, and greater choice for patients.

I yield back.

Mr. CICILLINE. Thank you to the Ranking Member.

I now recognize the Chair of the Full Committee, the gentleman from New York, Mr. Nadler, for an opening statement.

Chair NADLER. Thank you. The Judiciary Committee has a strong bipartisan tradition of promoting competition in healthcare markets. We have done this work to make healthcare services, particularly prescription drugs, more affordable for patients. We continue that tradition with today's hearing which will examine anticompetitive practices in this market, along with legislation to address it. I am pleased that we are joined by our distinguished colleagues from the Senate, and I thank them for their hard work on a bipartisan basis on the important legislation we introduced yesterday to lower prescription drug costs. I want to take this opportunity to congratulate Senator Klobuchar on her new book "Antitrust," and to wish her well on its sales.

All these bills are essential to help stop pharmaceutical companies from engaging in anticompetitive conduct, such as so-called pay-for-delay agreements, citizen petition abuse, and product hopping. This conduct blocks or delays access to affordable medications without any offsetting benefits.

I also want to extend a warm welcome to Chair Maloney, who has led one of the most comprehensive and in-depth investigations of drug prices in congressional history as Chair of the Oversight and Reform Committee. The investigation, which was originally launched by our late colleague, Chair Elijah Cummings, has already uncovered significant new evidence of pharmaceutical companies exploiting their market power at every turn, all at the expense of the patient.

Today, one-quarter of Americans report that it is difficult to afford their medicines. In fact, exorbitant medical bills are one of the major causes of why Americans seek bankruptcy relief. It is painfully clear that the soaring cost of healthcare is also bad for the health and well-being of American families. It is unacceptable that many seniors cannot afford the arthritis medication they need to perform everyday tasks, such as buttoning their coat or opening a jar, without excruciating pain. It is unacceptable that hundreds of thousands of cancer patients are reportedly delaying lifesaving care, cutting their pills in half, or skipping treatment entirely because of high drug prices. It is unacceptable that people suffering from diabetes must worry about life-threatening consequences of not being able to afford insulin because of its exorbitant costs.

These trends have only worsened in the wake of the pandemic, which has brought tremendous economic hardship to our communities. It is time for this to change. As many experts have noted, including some of the Witnesses who will testify here today, the

lack of competition in healthcare markets is one of the primary causes of escalating costs.

In recent years, under Republican and Democratic leadership, the Subcommittee has held numerous hearings in this area, examining the topics of consolidation in the market for health insurance, competition in the drug supply chain, and anticompetitive practices by prescription drug companies. I am pleased that we are continuing that essential work today. One focus of our efforts should be lowering prescription drug costs by strengthening competition from lower priced generic drugs.

According to the Federal Trade Commission, the first generic competitor to brand the product is typically offered at a price 20–30 percent below the brand price. Subsequent generic entry creates greater price competition with price drops reaching 85 percent or more off the brand price. In response to the threat of generic entry, which of course threatens the ability of branded drug companies to charge monopoly prices, branded companies have engaged in numerous anticompetitive tactics.

This Committee has been and will continue to be active in stopping drug companies from reaping monopoly profits at the expense of patients' health. For example, I am proud to have reintroduced the Preserve Access to Affordable Generics and Biosimilars Act, which Senator Klobuchar, Chair Cicilline, and Ranking Member Buck to ban so-called pay-for-delay settlements. These anticompetitive agreements allow branded drug companies to pay off a generic competitor to delay entering the market with a lower cost generic product. As a result of this abuse of conduct, a brand name drug company gets to keep its monopoly, and the generic gets paid off with a portion of the monopoly profits, but the consumers inevitably lose.

Although the Supreme Court in *FTC* v. *Actavis* held that pay-for-delay agreements could violate the antitrust laws, the FTC has spent significant resources challenging what appear to be clear violations. This legislation would address that problem by requiring courts to view such agreements as presumptively unlawful.

According to the nonpartisan Congressional Budget Office, this legislation would save American taxpayers at least hundreds of millions of dollars over 10 years due to the high costs imposed on our healthcare system by this anticompetitive conduct.

I was pleased that this legislation passed unanimously out of the Committee in the last Congress, with strong support from then Ranking Member Collins. I hope it will receive similar support from my colleagues on the Committee in this Congress.

I also look forward to addressing this issue together with our colleagues on the Energy and Commerce Committee in the weeks ahead.

In closing, I thank the Chair for holding today's important hearing, and I welcome all our esteemed colleagues and panelists. I look forward to hearing their testimony, and I yield back the balance of my time.

Mr. CICILLINE. Thank you, Mr. Chair.

It is now my pleasure to introduce the Witnesses on our first panel. Our first Witness is the Senior Senator from Minnesota and Chair of the Senate Judiciary Subcommittee on Competition Policy,

Antitrust, and Consumer Rights, Amy Klobuchar, and soon to be an award-winning author.

Additionally, Senator Klobuchar is Chair of the Democratic Steering and Outreach Committee as well as the Rules and Administration Subcommittee. She has served Minnesota for more than 20 years, first as a Hennepin County attorney from 1998–2006, and since as United States Senator.

Prior to entering public service, Chair Klobuchar was a partner at both Dorsey & Whitney and Gray, Plant, and Mooty, specializing in regulatory work in the areas of telecommunications.

Chair Klobuchar received her bachelor's degree from Yale University and her J.D. from the University of Chicago Law School.

Today's second Witness is Senator Charles Grassley, former Chair of the Senate Judiciary Committee, President Pro Tempore of the Senate, and Senior Senator from Iowa. Additionally, Mr. Grassley has Chaired the Senate Finance, Narcotics, and Aging Committees in his four decades in the United States Senate.

Prior to being elected to the Senate in 1980, Mr. Grassley served in the Iowa House of Representatives from 1959–975 and the United States House of Representatives from 1975–1980.

Before entering public service, Mr. Grassley worked farms and on factory floors in Iowa, first as a sheet metal shearer and then as an assembly line worker. Mr. Grassley received both his bachelor's and master's degrees from the University of Northern Iowa.

Our third Witness is the Senior Senator from the State of Connecticut, Richard Blumenthal. He was elected in 2010 and is currently serving his second term. Prior to his election to the Senate, Mr. Blumenthal served Connecticut as Attorney General for 20 years, from 1991–2011—the longest tenure in the State's history—as a State Senator from 1987–1991, in the Connecticut House from 1984–1987, and as United States Attorney for the district of Connecticut from 1977–1981.

He is also a 6-year veteran of the United States Marine Corps Reserves where he attained the rank of sergeant. Mr. Blumenthal received his bachelor's degree from Harvard College and his J.D. from Yale Law School.

Our fourth Witness, Senator John Cornyn, is Chair of the Senate Judiciary Committee on Border Security and Immigration and the Senior Senator from the State of Texas. Senator Cornyn is currently serving his fourth term and was first elected to the Senate in 2002. He has served his State of Texas in a number of elected positions, including as Bexar County district judge, Texas Supreme Court, and Texas Attorney General. In the 114th, 115th, and 116th Congresses, Mr. Cornyn served as a Senate Majority Whip. Senator Cornyn received his bachelor's degree from Trinity University, his J.D. from St. Mary's Law School, and his Master of Laws from the University of Virginia.

Our fifth Witness, Senator Mike Lee, is the Ranking Member of the Senate Judiciary Subcommittee on Antitrust Competition and Policy and Consumer Rights, and a senior Senator from Utah. Mr. Lee is also the Ranking Member of the Joint Economic Committee. He was elected to the Senate in 2010 and is currently serving his third term. He spent years at the law firm Sidley Austin as an attorney specializing in appellate and Supreme Court litigation, and

then as assistant United States attorney in Salt Lake City. He has clerked for Supreme Court Justices Samuel Alito on both the U.S. Court of Appeals Third Circuit and on the Supreme Court.

Mr. Lee received both his bachelor's degree and his J.D. from Brigham Young University.

The final Witness on our first panel is my distinguished colleague, the Chair of the House Committee on Oversight and Government Reform, Carolyn Maloney. Chair Maloney has represented New York's 12th district since 1992 and has served as Chair of the Committee on Oversight and Government Reform since 2019.

A lifelong public servant, she worked for the people of her State at the New York City Board of Education and in the New York State legislature. In 1982, Chair Maloney was elected to the New York City Council, where she served for 10 years until her election to Congress.

She has also served at various times as Vice Chair of the Joint Economic Committee, regional whip of the Democratic Caucus, and a Vice Chair of the House Democratic Steering and Policy Committee.

Chair Maloney received her bachelor's degree from Greensboro College.

We welcome all our very distinguished Witnesses on our first panel, and we thank them for their participation. I will ask the Witnesses to summarize your testimony in 5 minutes. To help you stay within that time, there is a timing light in Webex. When the light switches from green to yellow, you will have 1 minute to conclude your testimony. When the light turns red, it signals that your 5 minutes have expired. Of course, your full written testimony will be made a part of the record.

With that, I now recognize the distinguished Senator from Minnesota, Senator Klobuchar for 5 minutes.

STATEMENT OF THE HON. AMY KLOBUCHAR, A SENATOR FROM THE STATE OF MINNESOTA

Senator KLOBUCHAR. Well, thank you very much, Mr. Chair, Ranking Member. I assure you, Mr. Chair, if they ever make a movie out of my book, dream on, you will have a starring role.

Thank you for your work on digital platforms, the bipartisan work in this Committee, and this incredible gathering you have put together to make the point that it is not just tech where we see this kind of consolidation. It is healthcare. It is everything from cat food to caskets.

So, I got involved on the pharma side when I got a call in 2008 from a pharmacist at Minneapolis Children's Hospital who said: "You know, the price of this lifesaving drug for heart defects for kids, babies, newborn babies, has gone up from $85 a treatment to $1,600 a treatment."

I am thinking that is impossible. I called the head of the hospital. I start looking into it. What happened was one company bought that drug, and then they cornered the market. They bought the other drug. Those were the only two drugs available, and they went to town and made a whole bunch of money.

Even the FTC, they tried to take it on. We tried to take it on in Congress. AGs across the country tried to take it on. They ultimately failed. It took years—years—for a generic to develop.

That is what we are dealing with. When newborn babies and their parents and all the hospitals in a country can't win a case, we better do something about it. I think you know some of the answers because they have come right out of the House.

First, I would suggest negotiation of drug prices under Medicare, a bill that I lead with Representative Welch. I think it is a great idea. The President mentioned it last night. Doing something when it comes to drug reimportation is something that I know, Chair, many people have worked on over on this side. I also have worked on that bill with Senator Grassley. I know he is coming up next. That is a pretty important effort. There are efforts over here as well.

Second, is protecting drug price competition and doing something about generics. You mentioned the CREATES Act, and the work we have to do to stop pay-for-delay. That is ripe for action. It is outrageous that we still have this practice going on where pharmaceuticals are paying their competitors to keep their products off the market, and there is more we can do on that, and you mentioned a few of those efforts, Mr. Chair.

Finally, antitrust competition policy. Incredible consolidation has been going on. I am focused here—there are other aspects of healthcare—but on pharma. What I am thinking is when you look at what we are dealing with, when we have got the biggest companies the world has ever known in Facebook and Google now being sued by the FTC and by the Justice Department, this was a good thing. I am glad that Makan Delrahim and Chair Simons under the Trump Administration brought these suits. Now, they are being carried on by the Biden Administration.

You can't just do that and expect these healthcare pharma issues to be taken care of without funding those agencies. Senator Grassley and I—he can mention this—have a bill to finally update our nation's antitrust laws regarding fees when it comes to mergers. This merger filing fee bill almost got done, as you know, Mr. Chair, at the end of the year in the budget with support from the White House. We need to get that done immediately. That will add significant resources to the two agencies, plus the appropriations policy.

You cannot take on Big Pharma and Big Tech with Band-Aids and duct tape. You have got to give our enforcers the resources to do it.

Then I would finally add the work we are all doing on going after exclusionary conduct, going after these mergers, changing the standards, and making sure that our laws are as sophisticated as the companies that are supposed to be serving consumers. Thank you, Mr. Chair.

[The statement of Senator Klobuchar follows:]

Statement of U.S. Senator Amy Klobuchar

Before The U.S. House of Representatives
Committee on the Judiciary
Subcommittee on Antitrust, Commercial, and Administrative Law

Hearing on "Treating the Problem: Addressing Anticompetitive Conduct and Consolidation in Health Care Markets"

April 29, 2021

Introduction

Good afternoon Chairman Cicilline, Ranking Member Buck, and Members of the Subcommittee on Antitrust, Commercial, and Administrative Law. As Chair of the Senate's Competition Policy Subcommittee, I appreciate your invitation to testify today.

I would also like to thank you for focusing much-needed attention on competition in health care markets. We are all aware of the ground-breaking bipartisan work that this Subcommittee has done to explore the serious competition issues raised by dominant digital platforms, and I look forward to working with you and members of the Senate to address those issues.

America's competition problems are not limited to just one industry. We have a market power problem that cuts across our entire economy, from pharma to online travel, from cat food to caskets. And that is certainly true for the health care markets we will be discussing today.

Rising Health Care Costs

According to the Centers for Medicare and Medicaid Services, health care spending accounted for 17.7 percent of U.S. Gross Domestic Product in 2019—that is more than one-sixth of the American economy. That figure pre-dates the COVID-19 pandemic, and it is projected to rise to 19.7 percent by 2028.

These rising costs are driven by increases in the three largest sources of healthcare spending—hospital care, physician and clinical services, and prescription drugs, which together account for more than 60 percent of healthcare spending. Unfortunately, all of these markets are highly consolidated. We continue to see large pharmaceutical mergers and serial acquisitions of smaller providers by major health systems. And we repeatedly hear complaints of anticompetitive conduct in these markets.

Every American should have access to affordable health care. But nearly 20 percent of older adults report not taking their medicines as prescribed because of the cost. This means seniors are not filling their prescriptions, or they are cutting pills in half or skipping doses, because of high

costs. And excessive consolidation is hurting consumers and contributing to the rising costs of care.

Allowing Medicare Part D to Negotiate Drug Prices

To help bring down the cost of prescription drugs, I believe we must allow Medicare to negotiate the prices of prescription drugs directly with pharmaceutical companies.

For this reason, I introduced the *Empowering Medicare Seniors to Negotiate Drug Prices Act* with Representative Peter Welch to give direct negotiation authority to the Department of Health and Human Services to address the high out-of-pocket costs too many Medicare beneficiaries are facing. With this authority, Medicare will be equipped to negotiate for the best possible price to help save money for the nearly 46 million seniors enrolled in the Part D program.

Promoting Competition through Importation

In Minnesota, we know that our friends across the border in Canada often pay much less for prescription drugs than we do. That's why we should allow people to import safe, less expensive prescription drugs from an approved Canadian pharmacy, and I've worked with Senator Grassley to introduce the *Safe and Affordable Drugs from Canada Act* which will allow just that.

More competition in the marketplace will lead to more affordable prescription drugs for Americans, and I've also worked with Senator Mike Lee to introduce the *Short on Competition Act* to help lower drug prices by giving Department of Health and Human Services the authority to prioritize approvals and safely allow temporary importation of prescription drugs to address markets that lack competition.

Protecting Drug Price Competition

Over the years, I have also worked with a number of Senators on this panel and with members of this Subcommittee to protect and foster competition in prescription drug markets. That includes our work on the *CREATES Act*, signed into law in 2019, which is helping deter pharmaceutical companies from withhold testing samples from companies that are developing alternative generic drugs and biosimilars. This Congress, I look forward to making further progress.

The availability of generic drugs and biosimilars is critical to reducing drug costs. But branded drug companies have powerful financial incentives to delay the introduction of these more affordable alternatives to their own high-priced products. Senator Grassley and I have two bills to deter pharmaceutical companies from engaging in strategies to delay the entry of competing drug products.

We have reintroduced the *Preserve Access to Affordable Generics and Biosimilars Act* in the Senate to strengthen the Federal Trade Commission's (FTC) ability to prevent anticompetitive pay-for-delay patent settlement agreements, in which branded pharmaceutical companies compensate generic drug and biosimilar manufacturers for delaying the introduction of competing products. Although it is helpful that the Supreme Court and the Fifth Circuit have acknowledged that these agreements can be anticompetitive, legislation is still necessary as

companies continue enter into these deals and enforcement requires years of litigation at great expense. Chairman Nadler and Ranking Member Buck have sponsored this legislation in the House.

We have also reintroduced the *Stop STALLING Act* in the Senate with Senator Blumenthal to help prevent anticompetitive abuse of the Food and Drug Administration (FDA) petitioning process. For too long, some pharmaceutical companies have been abusing this process by submitting sham petitions that are groundless or filed at the last minute to attempt to delay the approval of competing generic drugs. This legislation will help deter branded companies from filing unfounded petitions to delay the approval of generic drugs, preserve limited FDA resources currently wasted on reviewing baseless petitions, and bolster FTC enforcement efforts. Representative Jeffries and Ranking Member Buck have introduced this legislation in the House.

Together these bills would save the government and consumers hundreds of millions of dollars. We look forward to working with this Subcommittee to make these bills law.

Competition Policy and Health Care

In addition to targeted legislation addressing anticompetitive conduct in drug markets, Congress must update our antitrust laws to prevent the excessive consolidation and exclusionary conduct that we see across the health care sector and across our economy.

This February, I introduced the *Competition and Antitrust Law Enforcement Reform Act* with Senator Blumenthal and others. The bill would strengthen the current legal standard for reviewing mergers under the *Clayton Act* to help stop harmful consolidation, shifting the legal burden to merging parties for several categories of mergers that pose significant risks to competition. The bill also reinvigorates enforcement against anticompetitive conduct by shifting the burden to dominant firms to prove that their exclusionary conduct does not risk harming competition.

This legislation would empower enforcers to crack down on anticompetitive conduct and excessive consolidation in pharmaceutical and hospital markets. We plan to examine some of these issues in the Senate Competition Policy Subcommittee next month in a hearing on hospital competition.

In the short term, we urgently need to ensure that the enforcement agencies have the financial and human resources they need to hold some of the most powerful companies in our economy accountable when they harm competition. We cannot expect the FTC and the Antitrust Division to take on Big Pharma, Big Tech, and others when they are significantly underfunded.

Senator Grassley and I have introduced the *Merger Filing Fee Modernization Act*, which would fund a $135 million budget increase for antitrust enforcement—split between the FTC and the Antitrust Division—by raising merger filing fees for the largest transactions. This is a proposal that I would encourage all of the members of this Subcommittee to support.

Finally, in light of the hundreds of millions of dollars in consumer redress that the FTC has recovered for consumers harmed by anticompetitive conduct in health care and related markets, I urge support for legislation to restore the FTC's authority to recover equitable monetary relief for

competition violations, as well as consumer protection violations. The Supreme Court's decision in *AMG Capital Management*[1] is nothing less than a call to action for lawmakers who are serious about protecting competition. And Congress must act swiftly.

I look forward to working with you all to address the serious competition policy problems in the health care sector and throughout our economy.

Thank you.

[1] *AMG Capital Mgmt., LLC v. FTC*, No. 19-508, 593 U.S. ___, slip op. (Apr. 22, 2021), *available at* https://www.supremecourt.gov/opinions/20pdf/19-508_l6gn.pdf.

Mr. CICILLINE. Thank you, Senator.

I now recognize the distinguished Senator from Iowa, Senator Grassley, for 5 minutes.

STATEMENT OF THE HON. CHUCK GRASSLEY, A SENATOR FROM THE STATE OF IOWA

Senator GRASSLEY. Thank you very much for the invitation, Mr. Chair. Millions of Americans started their day with a dose of prescription medication. Unfortunately, for many patients, those drugs aren't affordable, prescriptions are left at the pharmacy counter, and doses are skipped or rationed until the next paycheck. That is unacceptable.

As Chair of the Finance Committee last Congress, I explored several approaches to reduce healthcare costs. Senator Wyden and I started by investigating insulin pricing. We found that the business practices in competitive relationships between manufacturers and middlemen, the pharmacy benefit managers, or PBMs, whatever you want to call them, have created a vicious cycle of pricing increases. PBM's spur drug makers to hike list prices to secure prime formulary placement and greater rebates.

I also investigated the debt collection practices of nonprofit hospitals. I examined how these hospitals make financial assistance plans available to patients, and the patients can't even afford to pay. Nonprofit hospitals enjoy certain tax benefits because they are supposed to serve the needs of their communities and, particularly, patients with limited means. It is only fair that we ensure compliance with the laws if they get special treatment.

I have worked with Senator Wyden on a prescription drug bill that would lower drug costs and at the same time save the taxpayers $95 billion. Our bill would cap out-of-pocket drug costs for seniors at $3,100. It would slow the growth of drug costs in the future while protecting innovation by keeping government out of the business of setting prices. The key part of the bill limits year-over-year increases to CPI, or approximately 2 percent today, as opposed to the usual increases of 5–10 percent every year. It is the only prescription drug bill that can get 60 votes in the United States Senate.

I also believe that the importation of safe and affordable prescription drugs from Canada would lower healthcare costs. As you heard, Senator Klobuchar and I worked together on several bills. We have a bill to allow this, creating savings for consumers and injecting more competition into the pharmaceutical market.

When I chaired the Judiciary Committee, I conducted an investigation into EpiPen's misclassification in the Medicaid Drug Rebate Program. My investigation started when a constituent contacted me about high EpiPen costs. Those constituent contacts and the resulting congressional investigation ultimately contributed to the implementation of the bipartisan bill that we call the Right Rebate Act.

We must deter companies from engaging in activities that aim to reduce competition, including regulatory interference, pay-for-delay, product hopping, and rebate bundling, just to name a few. Again, Senator Klobuchar and I reintroduced our bill to combat

anticompetitive pay-for-delay deals where brand drug companies pay their generic competitors not to compete.

Senator Klobuchar and I also reintroduced our bill to reduce the incentives for branded drug companies to interfere with the regulatory approval of generics and biosimilars that would compete with their own products. The largest PBMs have merged with insurance companies. These conglomerates often own other players in the healthcare industry. It is important to determine whether consolidation helps patients, or as I believe, creates anticompetitive behavior and increased costs.

I have also introduced a bill with Senator Cantwell to bring transparency to the PBM industry by requiring the Federal Trade Commission to study the effects of consolation on pricing and potential anticompetitive behavior.

Further, Congress should codify regulations requiring hospitals and insurers to disclose their low discounted cash prices and negotiated rates to consumers before they receive medical care.

We should pass Senator Braun's Price Transparency Act, which I cosponsored. We should work in a bipartisan, bicameral fashion to tackle the problems of rising healthcare costs. This hearing proves in a bicameral way that we are doing it.

Thank you again for the opportunity to testify.

[The statement of Senator Grassley follows:]

House Judiciary Committee Subcommittee on Antitrust, Commercial, And Administrative Law
"Treating the Problem: Addressing Anticompetitive Conduct and Consolidation in Health Care Markets"
Senator Chuck Grassley of Iowa
April 29, 2021

I appreciate the invitation to testify today.

Millions of Americans started their day with a dose of prescription medication. Unfortunately, for many patients, those drugs aren't affordable. Prescriptions are left at the pharmacy counter. Doses are skipped or rationed until the next paycheck.

That's unacceptable.

As Chairman of the Finance Committee last Congress, I explored several approaches to reduce health care costs. Senator Wyden and I started by investigating insulin pricing. We found that the business practices and competitive relationships between manufacturers and middlemen, the Pharmacy Benefit Managers (PBMs), have created a vicious cycle of price increases. PBMs spur drug makers to hike list prices in order to secure prime formulary placement and greater rebates.

I also investigated the debt collection practices of non-profit hospitals. I examined how these hospitals make financial-assistance plans available to patients who can't afford to pay. Non-profit hospitals enjoy certain benefits under the tax code because they're supposed to serve the needs of their communities, including patients with limited means. It's only fair that we ensure compliance with the law if they get special treatment.

I've worked with Senator Wyden on a prescription drug bill that would lower drug costs and save taxpayers $95 billion. Our bill would cap out-of-pocket drug costs for seniors at $3,100. It would slow the growth of drug costs in the future while protecting innovation by keeping government out of the business of setting prices. It's the only prescription drug bill that can get 60 votes in the Senate.

I also believe that the importation of safe and affordable prescription drugs from Canada would lower health care costs. Senator Klobuchar and I have a bill to allow this, creating savings for consumers and injecting more competition into the pharmaceutical market.

When I chaired the Judiciary Committee, I conducted an investigation into EpiPen's misclassification in the Medicaid Drug Rebate Program. My investigation started when a constituent contacted me about high EpiPen costs. Those constituent contacts, and its resulting congressional investigation, ultimately contributed to implementation of the bipartisan Right Rebate Act.

We must deter companies from engaging in activities that aim to reduce competition, including regulatory interference, pay for delay, product-hopping and rebate bundling, just to name a few.

Senator Klobuchar and I re-introduced our bill to combat anti-competitive pay for delay deals, where brand drug companies pay their generic competitors not to compete. We've also re-introduced our bill to reduce the incentives for brand drug companies to interfere with the regulatory approval of generics and biosimilars that would compete with their own products.

The largest PBMs have merged with insurance companies, and these conglomerates often own other players in the health care industry. It's important to determine whether consolidation helps patients, or creates anticompetitive behavior and increased costs.

I've introduced a bill with Senator Cantwell to bring transparency to the PBM industry by requiring the Federal Trade Commission to study the effect of consolidation on pricing and potential anti-competitive behavior.

Further, Congress should codify regulations requiring hospitals and insurers to disclose their low, discounted cash prices and negotiated rates to consumers before they receive medical care. We should pass Senator Braun's PRICE Transparency Act, which I've cosponsored.

We should work in a bipartisan and bicameral fashion to tackle the problem of rising healthcare costs.

Thank you again for the opportunity to testify today.

Mr. CICILLINE. Thank you very much, Senator Grassley.

I now recognize Senator Blumenthal, the distinguished Senator from the State of Connecticut for 5 minutes.

STATEMENT OF THE HON. RICHARD BLUMENTHAL, A SENATOR FROM THE STATE OF CONNECTICUT

Senator BLUMENTHAL. Thanks so much, Mr. Chair.

I want to begin by really very enthusiastically thanking you for your leadership on antitrust issues. What you and the Committee have done, along with the other Members, on the tech monopoly and predatory pricing and conduct issues is truly remarkable. I am sure that you will be doing the same here. I am proud to be a cosponsor with you of many of the measures that are coming before the Committee today.

I just want to say how honored I am to join in sponsoring the No Stalling Act and to support the Preserve Access to Affordable Generics and Biosimilars Act led by Senator Klobuchar.

Speaking of Senator Klobuchar, here is the book. Buy it. It is a big book. Serious. As the title indicates, it covers taking on monopoly power from the Gilded Age to the Digital Age.

Now, in the Gilded Age, as you know, they divided up territory, and they fixed prices in smoked-filled rooms. Now, monopoly and predatory conduct are much more sophisticated and less visible because we live in the Digital Age. The effects are a matter of life and death. I am very much in favor of conduct remedies or misconduct remedies, the behavioral standards that we are going to hopefully write into law, including importing more drugs, requiring negotiation of Medicare pricing, other kinds of steps. One of them, by the way, is the bipartisan Affordable Prescription for Patients Act, which I have joined with Senator Cornyn on cosponsoring.

At the end of the day, what is really needed here is a structural remedy. Break them up. That is the remedy that I have advocated on some of the Big Tech companies. Break them up. They have grown too big. It has given them monopoly power. They are misusing that power. I know what it is like to sue based on antitrust law, a monopolistic predatory power. I did it as Attorney General against Microsoft. It had an enormously important positive effect for consumers.

So, I respectfully suggest that we need stronger enforcement of the laws we have. We also need to enhance and improve the laws with regard to our power of enforcement and provide more resources to the enforcers. In the FTC, in the Department of Justice, they need to be empowered to enforce the law more aggressively and effectively. We have seen too little of it in past years.

Let me speak on the bipartisan Affordable Prescription for Patients Act. I thank Senator Cornyn for sponsoring this bill. It would eliminate the abuses of product hopping, which, for example, was demonstrated by Actavis when it feared that its patent would run out on an Alzheimer's disease medication. Instead of facing the fact that it would no longer have exclusivity, it issued a new product, supposedly, but really it was the old product, with an extended-release mechanism. It pulled the old drug from the market. It was able to continue charging monopoly prices as a result of it.

This kind of practice is used with respect to countless drugs. They inflate prices. They deprive people of lifesaving medication. I am also pleased to be in partnership with Representatives Johnson and Issa in a House companion to a bill that shuts down the abuses of the patent dance, the product hopping patent dance. They have colorful names, but they are abhorrent to consumers.

Patent dancing involves, in effect, resolving patent litigation quickly before a biosimilar is introduced on the market, which creates a pattern dispute resolution process and enables the manufacturer to continue with a lock on the market.

So, I recommend tougher, more aggressive enforcement and structural remedies, but in the meantime these kinds of efforts to eliminate abuses of monopolistic power must be advanced. I thank you, Mr. Chair, and I yield.

[The statement of Senator Blumenthal follows:]

Statement of Senator Richard Blumenthal
"Treating the Problem: Addressing Anticompetitive Conduct and Consolidation in Health Care Markets"
Testimony before the House Judiciary Committee
April 29, 2021

We've seen some alarming trends in the health care industry lately. One trend: drug prices are too high.

Americans spend more on prescription drugs than citizens of any other country in the world, at an average cost of $1200 per person each year.[1] The costs of prescription drugs continues to grow at alarming rates. In 2019 alone, Americans spent nearly $370 billion on prescription drugs, up more than 5% since 2018, and more than 40% since 2013—and the prices continue to climb.[2]

Generic drugs and biosimilars play a critical role in making drugs more affordable. When generics and biosimilars enter the market, more expensive branded drugs are forced to compete on price. According to the Federal Trade Commission, if a single generic drug competitor enters the market, it can reduce drug prices by up to 30%. If another generic competitor enters the market, it can further reduce drug prices, with discounts of 85% or more.[3]

Paving the way for generics and biosimilars to enter the market is essential to lowering drug prices for all Americans. That is why I'm proud to reintroduce the bipartisan Affordable Prescriptions for Patients Act with Senator Cornyn, which does just that. Our bill puts an end to two key abuses of our patent system designed to inhibit generic entry.

First, our bill—along with Representative Cicilline and Representative Buck's companion in the House—puts an end to "product hopping," a tactic in which large, branded pharmaceutical companies abuse our patent system, raise prices on drugs, and block access to generic alternatives.

A prominent instance of product hopping featured a branded Alzheimer's treatment produced by Actavis. Knowing that its market exclusivity was running out, Actavis sought to replace its twice-daily dosage of the Alzheimer's treatment with a new extended release, once-daily version. After the FDA approved the new drug, Actavis strategically waited three years to introduce the new extended release version, with the goal of extending its exclusivity in the U.S. market. Once introduced, Actavis used the patent system to "hop" from the old product to the new, pushing all of its customers onto the new drug while pulling the old drug from the market. As a result, Actavis was able to continue charging monopoly prices long after their market exclusivity for the original version was expected to expire.

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[1] Robert Langreth, *Drug Prices*, Bloomberg (Sep. 16, 2020), https://www.bloomberg.com/quicktake/drug-prices.
[2] Anne B. Martin, Micah Hartman, David Lassman, Aaron Catlin, and The National Health Expenditure Accounts Team, *National Health Care Spending In 2019: Steady Growth For The Fourth Consecutive Year*, Ctrs. for Medicare and Medicaid Services (2021) at 3.
[3] Statement of Markus H. Meier, Acting Director, Bureau of Competition, Fed. Trade Comm'n (July 2017), at 3.

I am deeply troubled by instances like these, where pharmaceutical companies risk their customers' health and access to critical medication to improve their own profits. The Affordable Prescriptions for Patients Act would put an end to this anticompetitive practice. Our bill would prohibit branded drug manufacturers like Actavis from artificially extending their monopolies on certain prescription drugs, and removing a barrier to entry for generics and biosimilars.

Second, in partnership with Representatives Johnson and Issa's House companion, our bill also shuts down abuses of the "patent dance." In 2010, Congress enacted a law designed to resolve any patent litigation quickly before a biosimilar is introduced to the market, creating a patent dispute resolution process known as the patent dance. Under current law, however, there are no limits on the number of patents that a branded manufacturer of biologics can assert during the patent dance. Our bill imposes a reasonable limit to deter pharmaceutical companies from using gaming tactics to abuse a process designed to facilitate biosimilar entry, not hinder it.

Abuses of our patent system may have colorful names, like "product hopping" and the "patent dance," but make no mistake: these tactics are designed to crush competition and stifle access to cheaper generic drugs. By putting an end to product hopping and addressing delay tactics in the patent dance process, our bill will pave the way for generics and biosimilars to enter the market as competitors, and aggressively lower drug prices for hardworking Americans.

Mr. CICILLINE. Thank you very much, Senator Blumenthal.

Now, I recognize Senator Cornyn, who is the co-lead of the Affordable Prescription for Patients Act, along with Senator Blumenthal, Ranking Member Buck, and myself.

Welcome to the Committee. You are now recognized for 5 minutes.

STATEMENT OF THE HON. JOHN CORNYN, A SENATOR FROM THE STATE OF TEXAS

Senator CORNYN. Well, thank you, Chair Cicilline and Ranking Member Buck and Members of the Subcommittee. It is unusual to have this many Members of the Senate testifying in the House, but we are grateful for your invitation and the opportunity.

After more than a year battling COVID–19, the light at the end of the tunnel is rapidly growing brighter and larger because of the astonishing scientific achievements that led to multiple, effective vaccines. As you know, more than half of the adults in America have received at least one dose. I look forward to the time when this vaccine helps put this virus to bed once and for all.

I say this because it is important to recognize that American ingenuity, creativity, and innovation are remarkable qualities that has led to lifesaving discoveries. Alongside this innovation, we also have to have smart public policies that protect both the creators and the beneficiaries of these discoveries. There is no better example than prescription drug prices.

As the cost of many prescription drugs have skyrocketed in recent years, countless of my constituents in Texas have reached out to share stories about the impossible decisions their families have had to make, which have only become more heart-wrenching over the last year. Not paying some of their bills, cutting pills in half, skipping doses, or not filling prescriptions altogether because they are simply too expensive. No family should have to make these types of difficult choices. That is why Senator Blumenthal and I have offered up the Affordable Prescriptions for Patients Act in the Senate. We have been proud to work with a bipartisan group of colleagues on both sides of the Capitol, and the strong bipartisan, bicameral support of this bill demonstrates just how commonsense these reforms are.

Now, I know most of us haven't heard of the terms "product hopping" or "patent thicketing" in the past, but as you heard from Senator Blumenthal, this is the core of the problem that this bill attempts to solve.

Product hopping occurs when a company develops a reformulation of a product that is about to lose its patent exclusivity and then pulls the original product off the market. This isn't done because the new formula is more effective but because it prevents generic competition. This simply needs to stop. The FTC should be able to bring antitrust suits against bad actors who deliberately game the patent system. This legislation will ensure that that is possible.

Second is patent thicketing. This occurs when an innovator uses multiple overlapping patents with identical claims to make it nearly impossible for competitors to come to market. This abuse of the patent system comes at a high cost for patients. To solve this, our

legislation would streamline the way drug manufacturers resolve patent disputes so lengthy legal processes don't stand in the way of competition. We are protecting patents rights, which are critical, but we are not letting these important issues get bogged down in the sludge of time-consuming and expensive litigation.

We know companies are unlikely to pour extensive time, money, and resources into discovering new cures if, at the end of it, they can't recoup their costs. We can't allow bad actors to abuse the system for their financial gain either.

We know there is bipartisan support for this bill, as I said, on both ends of the Capitol. I hope we can achieve the same success we did last year when this bill passed with bipartisan support, unanimous support in both the House and Senate Judiciary Committees.

So, I am proud to be here with my colleague Senator Blumenthal to advocate for these proposals, and we look forward to working with all of you to bring down drug prices for American families.

[The statement of Senator Cornyn follows:]

Testimony of U.S. Senator John Cornyn
House Judiciary Committee: Subcommittee on Antitrust, Commercial and Administrative Law
Treating the Problem: Addressing Anticompetitive Conduct and Consolidation in Health Care Markets
April 29, 2021

[As prepared for delivery]

Thank you Chairman Cicilline, Ranking Member Buck, and members of the Subcommittee for the invitation to join you today.

After more than a year battling the COVID-19 pandemic, the light at the end of the tunnel is growing rapidly because of the astonishing scientific achievements that led to multiple effective vaccines. More than half of adults in America have received at least one dose of the vaccine, and I look forward to a time in the not-so-distant future when this vaccine helps us put this virus to bed once and for all.

I say this because I think it's important to recognize that American ingenuity, creativity, and innovation are remarkable qualities that lead to lifesaving discoveries.

But alongside this innovation we must also have smart public policies that protect both the creators and beneficiaries of those discoveries. There is no better example than prescription drug prices.

As the cost of many prescription drugs have skyrocketed in recent years, countless Texans have reached out to share stories about the impossible decisions their families have had to make, which have only become more heart wrenching over the past year. Not paying certain bills… Cutting pills in half… Skipping doses… Or not filling prescriptions altogether because they're simply too expensive. No family should have to make these types of decisions.

That's why America needs the *Affordable Prescriptions for Patients Act* to be signed into law. I've been proud to work with a bipartisan group of colleagues on this important issue, including my friend from Connecticut, Senator Blumenthal, and members of this subcommittee. The strong bipartisan, bicameral support for this bill demonstrates just how commonsense these reforms are.

Some unfair practices have encouraged these high prices, and the *Affordable Prescriptions for Patients Act* would solve two of the most concerning.

First is something called product hopping. This occurs when a company develops a reformulation of a product that is about to lose exclusivity, and then pulls the original product off the market. This isn't done because the new formula is more effective, but because it prevents generic competitors. That needs to stop.

The Federal Trade Commission should be able to bring antitrust suits against the bad actors who deliberately game the patent system, and this legislation will ensure the bad guys are held accountable.

Second is a practice known as patent thicketing. This occurs when an innovator uses multiple overlapping patents or patents with identical claims to make it nearly impossible for competitors to come to market. This abuse of the patent system comes at a high cost for patients who rely on these drugs.

To solve this, our legislation will streamline the way drug manufacturers resolve patent disputes so lengthy legal processes don't stand in the way of competition. We're protecting patent rights, which are critical, but not letting these important issues get bogged down in the sludge of litigation.

Our country offers robust protections for intellectual property, which is why we are ground zero for innovation. We know companies are unlikely pour extensive time, money, and resources into discovering new cures if at the end of it, they can't even recoup their own costs. But we can't allow some bad actors to abuse the system for their own financial gain.

This legislation doesn't stifle innovation. It doesn't limit patent rights. And it doesn't cost taxpayers a dime – in fact, in 2019 the Congressional Budget Office estimated it would lower federal spending by more than half a billion dollars over ten years.

And we already know this bill has bipartisan support. Last Congress, it passed both the House and Senate Judiciary Committees with unanimous support. I hope we can achieve the same success this Congress, and finally get the bill to the President's desk for his signature.

I'm proud to be here to advocate for this legislation alongside my colleagues, and I look forward to working with members of the Committee to bring down drug prices for American families.

Mr. CICILLINE. Thank you very much, Senator Cornyn.

I now recognize Senator Lee for 5 minutes. I believe he is on the—

STATEMENT OF THE HON. MIKE LEE, A SENATOR FROM THE STATE OF UTAH

Senator LEE. Thank you so much. Thank you, Mr. Chair, and Ranking Member Buck, esteemed Members of the Subcommittee, thanks to all of you for asking me to speak today.

As the leading Republican on the Senate's sister Subcommittee to this body, over the last decade, I have developed a tremendous appreciation for our country's antitrust laws and for the importance of competition policy to our national economy.

Rising healthcare costs and limited healthcare options are leading concerns for Americans of all stripes, making competition in the healthcare markets particularly important. Now, I share the commitment of my colleagues who have joined you today in ensuring and protecting competition across the healthcare space. In 2016, I was honored to introduce, along with Senators Grassley, Leahy, and Klobuchar the CREATES Act, which was timely passed by Congress and signed into law by President Trump in 2019.

As you know, the CREATES Act was designed to protect competition and to lower drug costs by ensuring that generic competitors have access to samples of certain brand-name drugs for the purpose of establishing bioequivalence for the FDA. The Congressional Budget Office estimated that the law will save taxpayers $3.8 billion over 10 years. Industry participants tell me that it is already improving generic competition.

As this Subcommittee considers additional legislation aimed at ways to improve competition across various healthcare markets, I would urge you to follow the model that we made with the CREATES Act and that helped make the CREATES Act so successful. Light-touch reform to help align private incentives to benefit competition rather than government intervention that displaces competition with regulation.

We should all examine our history to find the root causes of consolidation in America's healthcare industry and tackle the issue with incremental targeted fixes rather than a massive, one-size-fits-all approach. That in turn will require taking up a widened view of the factors that impact competition in healthcare markets, including existing Federal and State laws and regulations.

If there is anything worse than a monopolist using its power to squelch competition and squeeze consumers, it is when that monopolist is a creature of government policy and power.

We as elected representatives of the people, entrusted with enacting the laws, hopefully, in pursuit of justice and equality, have to always be vigilant against allowing the democratic process to be corrupted, even if inadvertently, to pick winners and losers.

If we want to make reforms in this area, we sadly have no shortage of opportunities. At the State level, entry into hospital markets is frequently restrained by State certificate of need laws. These laws require potential market entrants and existing competitors to obtain approval or permission in advance from the State to build new hospitals or to expand current facilities. In some states, in-

cumbent hospitals even have veto power over granting certificates to new entrants. This is crony capitalism, pure and simple. Patients everywhere have suffered for it where these laws have been in place.

It is no wonder that the pandemic saw at least 24 states suspend or loosen their certificate of need laws. Imagine the benefits to healthcare and competition within healthcare if states just repealed those laws. Which we don't need anyway and harm people, in any event.

Another common restriction at the State level are limitations on nurse practitioners, some of which make little to no sense and provide little to no benefit or additional safety to the patient. The conflict of interest is obvious. For many basic needs, nurse practitioners offer a comparable skill in service at a lower price. This is something that increases access to the healthcare for the most economically vulnerable.

So, removing those sorts of restrictions would inevitably generate price and quality competition between nurse practitioners and physicians and improve costs and outcomes for patients across the country. This is one of those many areas in which we should just allow for people to do what they do best. Here in the case of nurse practitioners, take care of people without excessive government intervention. We would be better off without that intervention.

Government intervention in healthcare has also had disastrous effects at the Federal level. Medicare has used Federal clout to strong-arm healthcare providers into agreeing to low reimbursement rates. Now, ordinarily, we should cheer lower prices. In this case, these so-called savings are really just subsidies paid for by insured and self-paid patients. This isn't healthcare reform. It is sort of Ponzi scheme. Medicare-for-all would mean that there was no one left to pay the subsidy, and everyone would suffer. These artificial pricing pressures also mean that healthcare markets are not able to fully respond to competitive pressure and would have fewer resources to invest in expansion and innovation. As a result, consumers would have fewer options. Quality would go down; prices would go up.

Obamacare has had a similar effect.

Mr. CICILLINE. Senator, if I could just ask you to conclude your testimony. You are well over time, but I wanted to accommodate you as much as I can.

Senator LEE. Great. Thank you. So, we are all familiar with the promise that if you like your plan, you can keep it. This has turned out not to be true. So, it is always tempting in all of this to retrench into tribalism and push forward encompassing reforms, all-encompassing solutions that might only require floor time once. Our constituents deserve better. Then deserve a free-market approach where providers can respond to needs and demand.

Antitrust enforcement and competition policy have historically been areas of bipartisan agreement. We know that vigorous competition is necessary. So, thanks for your close attention to keeping America's healthcare markets competitive. I thank you again for inviting me to join you today. I look forward to working with you today.

[The statement of Senator Lee follows:]

Testimony before the House Judiciary
Subcommittee on Antitrust, Commercial, and Administrative Law

Hearing On:
"Treating the Problem: Addressing Anticompetitive Conduct and Consolidation in Healthcare Markets"

Senator Mike Lee

April 29, 2021

Chairman Cicilline, Ranking Member Buck, and esteemed members of the Subcommittee: thank you for inviting me to speak today.

As the leading Republican on the Senate's sister subcommittee to this body for the last decade, I have developed a great appreciation for our country's antitrust laws and the importance of competition policy to our national economy.

Rising healthcare costs and limited healthcare options are leading concerns of Americans of all stripes, making competition in the healthcare markets particularly important. I share the commitment of my colleagues who have joined you today in ensuring and protecting competition across the healthcare space.

In 2016, I was honored to introduce—along with Senators Grassley, Leahy, and Klobuchar—the CREATES Act, which was finally passed by Congress and signed into law by President Trump in 2019. As you know, the CREATES Act was designed to protect competition and lower drug costs by ensuring that generic competitors have access to samples of certain brand name drugs for the purpose of establishing bioequivalence for the FDA. The Congressional Budget Office estimated that the law will save taxpayers $3.8 billion dollars over 10 years, and industry participants tell me it is already improving generic competition.

As this Subcommittee considers additional legislation aimed at improving competition across various healthcare markets, I urge you to follow the model that made the CREATES Act successful: light touch reform to help align private incentives to benefit competition, rather than government intervention that displaces competition with regulation.

We should all examine our history to find the root causes of consolidation in America's healthcare industry, and tackle the issue with incremental, targeted fixes rather than a massive, one-size-fits-all approach. That will require taking a wide view of all of the factors that impact competition in healthcare markets, including existing federal and state laws and regulations.

If there is anything worse than a monopolist using its power to squelch competition and squeeze consumers, it is when that monopolist is a creature of government policy and power. We—as representatives of the people entrusted to enact laws that pursue justice and equality—must always be vigilant against allowing the democratic process to be corrupted, even inadvertently, to pick winners and losers.

If we wish to make reforms in this area, we sadly have no shortage of opportunities. At the state level, entry into hospital markets is frequently restrained by state certificate of need laws. These laws require potential market entrants and existing competitors to obtain approval from the state to build new hospitals or expand current facilities. In some states, incumbent hospitals even have veto power over granting certificates to new entrants. This is crony capitalism, pure and simple, and patients have suffered for it. It's no wonder that the pandemic saw at least 24 states suspend or loosen their certificate-of-need laws. Imagine the benefits to healthcare and competition if states repealed those laws.

Another common restriction at the state level are limitations on nurse practitioners, some of which make little to no sense and provide little to no benefit or additional safety to the patient. The conflict of interest is obvious: for many basic needs, nurse practitioners offer comparable skill and service at a lower price, increasing access to healthcare for the most economically vulnerable. Removing these sorts of restrictions would generate price and quality competition between nurse practitioners and physicians, and improve costs and outcomes for patients across the country.

Government intervention in healthcare has also had disastrous effects at the federal level. Medicare has used federal clout to strong-arm healthcare providers into agreeing to low reimbursement rates. Ordinarily, we should cheer lower prices, but in this case the "savings" are really just subsidies paid for by insured and self-pay patients. This isn't healthcare reform; it's a Ponzi scheme. "Medicare for all" would mean there was no one left to pay the subsidy, and everyone would suffer. These artificial pricing pressures also mean that healthcare markets are not able to fully respond to competitive pressure and have fewer resources to invest in expansion and innovation.

Obamacare has had a similar effect. We're all familiar with the infamous promise that, "if you like your plan, you can keep it." It turned out that the largest expansion of government regulation of healthcare and health insurance had the opposite effect. The aftermath of Obamacare saw sudden and significant increases in consolidation among providers and reduced output from insurers. This is just one more example of why a belief in the benefits of competition needs to be paired with skepticism of government intervention.

My criticism of these specific approaches, however, should not be taken as criticism of the underlying goals. Just as Democrats and Republicans are united in our desire to protect consumers, we are also united in our desire to ensure that everyone has access to affordable quality healthcare. The devil is in the details, as they say. The best way to improve healthcare in the future is to return to what has worked in the past: procompetitive measures that prioritize patient freedom and choice and prevent the government from tipping the scales.

It is tempting to retrench into tribalism and push for all encompassing reforms that might only require floor time once. But, our constituents deserve better. They deserve a free market approach, where providers—whether they be doctors, insurers, pharmaceutical companies, hospitals, etc.—respond to their needs and demands. Antitrust enforcement and competition policy have historically been areas of bipartisan agreement. For all the differences between our

two parties, we are united in our desire to protect consumers and ensure Americans have access to affordable, high-quality care. We know that vigorous competition is essential to both.

Thank you for your close attention to keeping America's healthcare markets competitive, and thank you again for inviting me to join you today. I look forward to working with each of you.

Mr. CICILLINE. Thank you, Senator Lee.

Now, at the risk of offending our colleagues in the other Chamber, we did save the best for last.

Chair Maloney, you are recognized for 5 minutes.

STATEMENT OF THE HON. CAROLYN B. MALONEY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

Ms. MALONEY. Thank you so much, Chair Cicilline, Chair Nadler, Ranking Member Buck, and Members of the Subcommittee, thank you for holding this important hearing today and inviting me to testify about the Oversight Committee's findings of anticompetitive conduct in the pharmaceutical industry.

At the onset, I want to commend the Subcommittee for its groundbreaking work on antitrust issues and also acknowledge the historic work of my friend and colleague in the Senate, Senator Klobuchar, and her heroic work in fighting rising prescription drug prices.

The former Chair of my Committee, the late Elijah Cummings, cared deeply, as I do, about the issue of rising prescription drug prices. He understood that drug companies' exorbitant prices have devastated patients across our country, forcing many to make gut-wrenching choices between affording their medications and paying rent, buying food, or saving for retirement.

For this reason, at the beginning of the 116th Congress, Chair Cummings launched an in-depth investigation into some of the largest and most profitable drug companies in the world. This investigation has remained one of my highest priorities since I took over as Chair.

Over the last 2 years, we have reviewed over 1.3 million pages of internal company documents. Last fall, the Committee held hearings with six CEOs and released five staff reports summarizing our initial findings. Before I describe some of these findings, I want to recognize that we rely on the pharmaceutical industry to develop critical new therapies, cures, and vaccines. In exchange, our system grants these companies the exclusive right to sell their products for a limited number of years without facing competition from lower priced generic and biosimilar drugs.

Unfortunately, brand-name drug companies have abused this system by engaging in blatantly anticompetitive strategies to extend their monopoly pricing for far longer than our system intended. Our Committee's investigation found that these strategies, combined with laws restricting Medicare's ability to negotiate directly for lower prices, have emboldened drug companies to target the United States for price increases while cutting prices in the rest of the world. Our system, in essence, is leading to higher and less affordable drug prices right here in the United States.

In addition, our investigation found that pharmaceutical companies dedicate significant portions of their research budgets to coming up with new ways to suppress generic and biosimilar competition, rather than focusing on developing new therapies.

By allowing these anticompetitive tactics to continue, we are paying more money and getting less innovation. Our investigation ex-

posed the inner workings of the types of anticompetitive conduct your Subcommittee is seeking to combat.

Here are just a few examples. One drug company, Teva, engaged in what is known as product hopping, using its monopoly market power to shift patients from one dose of its blockbuster MS drug Copaxone to another dose before generic competition for the first dose comes to market. Experts estimate this one product hop cost the U.S. Health System $4.3 billion.

In another example, companies such as Amgen and Novartis entered into patent settlement agreements with potential generic competitors to delay their entry into the market. Amgen internally estimated that it collected $202 million in extra sales of the kidney drug Sensipar by delaying generic entry by just 10 weeks. Experts estimate that Novartis' delay of generic competition for its cancer drug Gleevec cost the U.S. market over $700 million.

In my last example, executives at another company Celgene discussed how to leverage the high price of their cancer drug Revlimid to prevent other competitors from conducting productive cancer research.

Our Committee's investigation also revealed damning details about other abuses like patent thickets, misuse of the Orphan Drug Act, and exclusionary contracting with pharmacy benefit managers. I encourage Members and the public to use these reports as a resource as they seek to combat rising drug prices in our country.

I want to end by emphasizing that we are not done. My Committee is continuing to investigate abuses by the pharmaceutical industry. On May 18th, the Committee will hold a hearing with the CEO of AbbVie. AbbVie sells Humira, the highest grossing drug in the United States and the world. The Committee has obtained internal documents, previously not public, that show the tactics AbbVie has used to suppress competition for Humira and other drugs that maintain monopoly pricing in the U.S.

I hope the Oversight Committee's findings are helpful to the Judiciary Committee as you consider legislation to address the pharmaceutical industry's anticompetitive practices and unsustainable, unfair, deceptive price increases. Thank you. I appreciate the opportunity to appear before you today and congratulate you on all your hard work in this area. I yield back.

[The statement of Ms. Maloney follows:]

CAROLYN B. MALONEY, NEW YORK
CHAIRWOMAN

ONE HUNDRED SEVENTEENTH CONGRESS

JAMES COMER, KENTUCKY
RANKING MINORITY MEMBER

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Opening Statement
Chairwoman Carolyn B. Maloney
House Committee on Oversight and Reform

Hearing Before House Committee on the Judiciary
Subcommittee on Antitrust, Commercial, and Administrative Law
"Treating the Problem: Addressing Anticompetitive Conduct and Consolidation in Health Care Markets."

April 29, 2021

Chairman Cicilline, Ranking Member Buck, and members of the Subcommittee, thank you for holding this important hearing today and for inviting me to testify about the Oversight Committee's findings of anticompetitive conduct in the pharmaceutical industry.

At the outset, I want to commend this subcommittee for its groundbreaking work on antitrust issues.

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Over the last two years, we have reviewed over 1.3 million pages of internal company documents. Last fall, the Committee held hearings with six CEOs and released five staff reports summarizing our initial findings.

Before I describe some of these findings, I want to recognize that we rely on the pharmaceutical industry to develop critical new therapies, cures, and vaccines. In exchange, our system grants these companies the exclusive right to sell their products for a limited number of years without facing competition from lower-priced generic and biosimilar drugs.

Unfortunately, brand name drug companies have abused this system by engaging in blatantly anticompetitive strategies to extend their monopoly pricing for far longer than our system intended.

Our Committee's investigation found that these strategies, combined with laws restricting Medicare's ability to negotiate directly for lower prices, have emboldened drug companies to target the United States for price increases while cutting prices in the rest of the world. Our system, in essence, is leading to higher—and less affordable—drug prices right here in the U.S.

In addition, our investigation found that pharmaceutical companies dedicate significant portions of their research budgets to coming up with new ways to suppress generic and biosimilar competition, rather than focusing on developing new therapies.

By allowing these anticompetitive tactics to continue, we are paying more money and getting less innovation.

Our investigation exposed the inner workings of the types of anticompetitive conduct your Subcommittee is seeking to combat. Here are just a few examples:

- Companies such as Amgen and Novartis entered into patent settlement agreements with potential generic competitors to delay their entry into the market. Amgen internally estimated that it collected $202 million in extra sales of the kidney drug Sensipar by delaying generic entry by just ten weeks. Experts estimate that Novartis' delay of generic competition for its cancer drug Gleevec cost the U.S. market $700 million.

- Executives at another company, Celgene, discussed how to leverage the high price of its cancer drug Revlimid to prevent their competitors from conducting productive cancer research.

- Another company, Teva, engaged in what is known as "product hopping": using its monopoly market power to shift patients from one dose of its blockbuster MS drug Copaxone to another dose before generic competition for the first dose came to market.

I want to provide you with more detail about our findings regarding Teva, as these findings show why we need legislative reform to prohibit similar product hopping in the future.

In 1997, Teva began selling Copaxone as a 20-milligram dose administered once a day. For 18 years, Teva enjoyed monopoly pricing for its drug, raising its price from $9,000 per year to over $60,000 per year. As the 20-milligram dose of Copaxone approached the loss of market exclusivity and the possibility of competition from lower-priced generics, Teva introduced a new

40-milligram version of the drug to be administered three times a week. According to internal emails, Teva's executives referred to the new dose as a "generic defense strategy."

Internal documents revealed how Teva used its market power to shift patients to the new 40-milligram dose. Teva exerted pressure on pharmacy benefit managers to add 40-milligram Copaxone to their formularies by tying such action to contractual rebates on 20-milligram Copaxone. Teva used information collected during sales of 20-milligram Copaxone to lobby doctors to prescribe 40-milligram Copaxone. Teva even considered discontinuing its patient financial assistance program for 20-milligram Copaxone to pressure patients to switch to the 40-milligram version of the drug.

Teva's strategy was incredibly successful. By the time a lower-priced generic version of 20-milligram Copaxone entered the market in 2015, Teva had shifted over 75% of patients to its 40-milligram version. Experts estimate that Teva's product hop strategy cost the U.S. health care system over $4.3 billion in excess expenditures. We cannot allow this type of abuse in the future. That is why I am honored to co-sponsor the Affordable Prescriptions for Patients Act of 2021, which seeks to combat product hopping. I thank many of the Senators and Representatives in this room for their leadership on this bill.

Our Committee's investigation also revealed damning details about other abuses like patent thickets, misuse of the Orphan Drug Act, and exclusionary contracting with pharmacy benefit managers. I encourage Members and the public to use these reports as a resource as they seek to combat rising drug prices in our country.

I hope the Oversight Committee's findings are helpful as the Judiciary Committee considers legislation to address the pharmaceutical industry's anticompetitive practices and unsustainable price increases.

Thank you. I appreciate the opportunity to appear before you today.

Mr. CICILLINE. I thank the gentlelady for her testimony and can assure her that the extraordinary work of your Committee is very supportive of the work of this Subcommittee. So, we thank you.

With that, I would like to thank each of our distinguished Witnesses on our first panel for their very valuable testimony today. You are now excused. We will hold briefly while staff will make the necessary accommodations for our second panel. We should just take a couple of minutes.

Mr. CICILLINE. The Committee will come back to order.

It's now my pleasure to introduce the Witnesses on our second panel. Our first Witness is Dr. Leemore Dafny. Dr. Dafny currently serves as the Bruce V. Rauner Professor of Business Administration at the Harvard Business School and Harvard Kennedy School where she teaches courses on healthcare strategy and policy. Her research focuses on competitive interactions between patients and providers of healthcare, with a focus on antitrust competitive strategy and public policy.

Dr. Dafny is a research associate of the National Bureau of Economic Research and is on the panel of health advisers to the Congressional Budget Office. From 2002–2013, she served as the deputy director for healthcare and antitrust at the FTC's Bureau of Economics, and has been published in various journals, including the American Economic Review and The New England Journal of Medicine. Dr. Dafny received her bachelor's degree from Harvard College and her Ph.D. from the Massachusetts Institute of Technology.

The second Witness on our panel is Michael Carrier, Distinguished Professor and Codirector of the Rutgers Institute for Policy and Law. Professor Carrier has served at Rutgers since 2001 and was named codirector of the Institute for Information Policy & Law in 2013. He's widely published and has been featured in many journals, including the Chicago Law Review, the Michigan Law Review, the Columbia Law Review, and CPI Antitrust Chronicle. Professor Carrier is currently on the board of advisers to the American Antitrust Institute and is a contributing editor for the Antitrust Law Journal.

Before joining the faculty of Rutgers, Professor Carrier spent 4 years at the firm of Covington & Burling, where he focused on antitrust, intellectual property, sports, and civil litigation. Professor Carrier received his bachelor's degree from Yale University and his J.D. from the University of Michigan Law School.

The third Witness on our panel is the Arthur J. Goldberg Distinguished Professor of Law at the University of California Hastings College of Law, Professor Robin Feldman. She is also the director of the UC Hastings Center for Innovation. Professor Feldman has been published in many well-respected journals, including the New England Journal of Medicine and the Stanford Technology Law Review. She was elected to the American Law Institute in 2012 and has received both the William Rutter Award for Excellence in Teaching and the 1066 Foundation Award for Scholarship.

Professor Feldman received both her bachelor's degree and her J.D. at Stanford University.

Our last Witness today is Alden Abbott, the Senior Research Fellow at George Mason University's Mercatus Center. Before joining

Mercatus, Mr. Abbot served as the Federal Trade Commission's General Counsel, representing the Commission in court. He has a long career of serving the Federal government at the FTC, the Department of Justice, and the Department of Commerce. He's also worked at The Heritage Foundation and BlackBerry Limited. Mr. Abbott was an adjunct professor at George Mason University's Antonin Scalia Law School for almost 20 years and is widely published on competition, regulation, international trade.

Mr. Abbott received his bachelor's degree from the University of Virginia, his master's in economics from Georgetown University, and his J.D. from Harvard Law School.

We welcome all our distinguished Witnesses on our second panel and we thank you for your participation.

I will begin by swearing in our Witnesses, and I ask our Witnesses that are testifying in person to rise. I ask our Witnesses testifying remotely to turn on their audio and make sure that we can see your face and your raised right-hand while I administer the oath.

Do you swear or affirm under penalty of perjury that the testimony you're about to give is true and correct to the best of your knowledge, information, and belief, so help you God?

Let the record show the Witnesses answered in the affirmative.

Thank you and please be seated. Please note that your written statements will be entered into the record in their entirety. Accordingly, I ask that you summarize your testimony in 5 minutes. To help you stay within that timeframe, there's a timing light in Webex. When the light switches from green to yellow, you have 1 minute to conclude your testimony. When the light turns red, it signals that your 5 minutes have expired.

I now recognize Dr. Dafny for 5 minutes.

TESTIMONY OF DR. LEEMORE DAFNY

Dr. DAFNY. Chair Cicilline, Ranking Member Buck, and distinguished Members of the Subcommittee, I thank you for holding this hearing and giving me the opportunity to testify on the subject of healthcare consolidation. My name is Leemore Dafny, and I'm an academic health economist with long-standing research interests in competition and consolidation. I'm a professor at the Harvard Business School and the Harvard Kennedy School, and I previously served as the deputy director for healthcare and antitrust in the Bureau of Economics at the Federal Trade Commission while on university leave. I'm on the panel of health advisers to the Congressional Budget Office, and I engage with regulators, policymakers, and businesses in my role as a faculty member and a healthcare antitrust expert.

The United States spends a larger share of its GDP, nearly 18 percent, on healthcare in any other country. Studies show that high prices, not the type or quantity of services consumed, nor the health of our population, are the primary driver of higher U.S. spending. International comparisons also show the U.S. lags other leading developed countries on most dimensions of healthcare quality. We are not receiving the highest possible value for our dollars, far from it.

My focus today is healthcare providers, such as hospitals and physicians who jointly account for about half our healthcare spending. As you're aware, government programs like Medicare set prices for provider services like hospital admissions, but the private sector relies on market-based prices, and those prices are high and growing.

Back in the late nineties, private prices were about 10 percent higher than Medicare prices. By 2012, they were 75 percent higher. Today, privately insured patients pay on average two times what Medicare pays for hospital care. These higher prices hurt patients and they hurt our economy.

As a response to high prices, health insurance premiums and deductibles are rising. High deductibles mean people pay thousands of dollars out of pocket when they are unlucky enough to require care. Higher insurance premiums mean smaller paychecks.

The key questions I'm here to answer is whether consolidation is driving these higher prices and what we can do about it. My answer to the first question is yes, studies show horizontal or same market consolidation results in higher prices for hospitals. It is also true for physician groups and for insurance premiums. The evidence on nonhorizontal healthcare mergers, such as mergers across providers or firms in different geographies or service categories, also shows prices in spending increased post-merger, in particular, after hospital systems acquire additional hospitals in the same State and after hospitals acquire physician practices. Antitrust enforcers regularly challenge horizontal margins, but challenges of nonhorizontal mergers are very rare, and in my recommendations, I suggest ways to enable such challenges.

Let me be clear. The bad guys in healthcare are not hospitals or doctors or even insurers. The bad guy is a lack of competition, driven by consolidation.

The COVID pandemic has shown us what is magnificent about our healthcare providers. They rose to the occasion and did all they could to meet patients' needs. They collaborated with one another in resourceful ways, but that doesn't mean they need to merge with one another now. If the pandemic stimulates even more consolidations, we'll face a different type of long-haul symptom of COVID, higher prices.

To protect competition, I have three recommendations.

First, strengthen our Federal enforcement agencies' ability to identify and review potentially anticompetitive conduct in mergers. You can do that by requiring more healthcare transactions to be reported, mandating insurers share healthcare claims data with Federal agencies, and increasing agency budgets.

In real terms, appropriations in 2018 were 18 percent lower than in 2010. The recent increase has only kept up with inflation. Restoring and increasing funding will yield a return for years to come.

Second, amend and strengthen the antitrust statutes. Ensure the statutes prohibit healthcare mergers that enable providers to exploit existing market power and are likely to harm consumers. The current wording or interpretation of that wording is enabling scores of transactions that are harmful to consumers to proceed.

Third, ask the agencies to issue healthcare guidelines that set forth their interpretation of antitrust statutes in healthcare today. Regulators, private parties, and courts pay close heed to agency guidelines, so this has potential for real impact.

Our healthcare providers have so many people working hard to help people live better lives. My recommendations are not aimed at making their work more difficult; they are aimed at creating a market context that brings out their best and rewards them for it.

Thank you.

[The statement of Dr. Dafny follows:]

TESTIMONY OF LEEMORE S. DAFNY, Ph.D

Bruce V. Rauner Professor of Business Administration
Harvard Business School
Harvard Kennedy School

Before the

U.S. House Committee on the Judiciary
Subcommittee on Antitrust, Commercial and Administrative Law

On

"How Health Care Consolidation Is Contributing to Higher Prices and Spending, and Reforms That Could Bolster Antitrust Enforcement and Preserve and Promote Competition in Health Care Markets"

April 29, 2021

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I. High and Rising Provider Prices are Driving Higher Health Care Spending
II. Health Care Markets a Decade After the ACA: Bigger, but Probably Not Better
III. The Pandemic Should Not Delay Actions to Prevent Anticompetitive Consolidation
IV. Current State of Enforcement
V. Reforms to Bolster Antitrust Enforcement and Preserve and Promote Competition in Health Care Markets
VI. Conclusion

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I. High and Rising Provider Prices are Driving Higher Health Care Spending

The United States spends a larger share of its GDP (nearly 18 percent) on health care than any other country. The key driver is high prices, and the result is that we are not getting enough value for our spending.[1] These conclusions are supported by decades of research and hard data. U.S. provider prices are extremely high by international standards (see Figure 1), and studies show that these high *prices*, not the quantity of services consumed nor the underlying health of our population, are the primary driver of higher spending in the U.S. International comparisons of health care quality also show the U.S. lags other leading OECD nations on most dimensions.[2] We are not receiving the highest possible value for our dollars – far from it.

Figure 2 depicts where we spend our health care dollars. My focus today is health care providers, such as hospitals, physicians, and clinics, who jointly account for just over half of health care spending. When discussing the effects of consolidation on this spending, we must consider the bifurcated insurance market. Health care providers are reimbursed differently by public insurance programs (like Medicare and Medicaid) and commercial insurance plans (offered or administered by for-profit and not-for-profit insurers). Recent analyses find that the growth in health care spending for the commercially-insured population is largely due to growth in the prices charged for commercially-insured patients, and the vast majority of that spending is on provider services.[3]

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[1] CMS, National Health Expenditure Accounts (NHEA). Data reflect spending for 2019, the latest calendar year for which it is available. Total spending in 2019 was $3.8 trillion or $11,582 per capita.

[2] Anderson GF, Hussey P, Petrosyan V. It's still the prices, stupid: why the US spends so much on health care, and a tribute to Uwe Reinhardt. Health Aff (Millwood). 2019;38(1):87–95; Commonwealth Fund, "Mirror, Mirror: Comparing Health Systems Across Countries," https://www.commonwealthfund.org/series/mirror-mirror-comparing-health-systems-across-countries; Gary Claxton et al., How Have Healthcare Prices Grown in the U.S. Over Time?, Peterson-Kaiser Health System Tracker (May 8, 2018), https://www.healthsystemtracker.org/chart-collection/how-have-healthcare-pricesgrown-in-the-u-s-over-time/#item-start; Miriam Laugesen and Sherry Glied, "Higher fees paid to US physicians drive higher spending for physician services compared to other countries," *Health Affairs* 30, no. 9 (2011): 1647–56

[3] Zack Cooper, Stuart Craig, Martin Gainer, and John Van Reenan, "The Price Ain't Right? Hospital Prices and Health Spending on the Privately Insured," *Quarterly Journal of Economics* 134, no. 1 (2019): 51–107. Health Care

Prices for commercially-insured patients are much higher than prices for publicly-insured patients,[4,5] and the gap is widening. Commercial prices were around 10 percent higher than Medicare in the late 90s, but by 2012 were 76 percent higher.[6] A recent (2020) study found that *average* commercial prices for inpatient and outpatient services were *double* Medicare reimbursement rates, while prices for professional services – e.g., physician services rendered with hospital-based care – were 60 percent larger.[7]

In the commercial marketplace, there is also substantial variation in prices *for the exact same undifferentiated service* across markets, across providers within markets, and even within providers across insurance contracts.[8] A striking depiction of this variation is presented in Figure 2, which orders a sample of providers by their average commercial price for a lower-extremity MRI and contrasts the amounts with payments for the same test by Medicare, which sets prices and provides only limited scope for variation in those prices. At the low end, many providers charge less than $1,000, still well above the Medicare price. At the high end, many providers charge over $2,000, which is more than four times the Medicare price.

Some portion of this variation reflects variation in market-level resource costs (such as wages or rent), in production efficiency, and perhaps health care quality. A significant portion of this variation, however, reflects market power and market failures.[9] The key question for this hearing is whether consolidation has strengthened market power and and/or enabled health care providers

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Cost Institute, "2018 Health Care Cost and Utilization Report," Presentation, Feb. 2020, https://healthcostinstitute.org/annual-reports/2020-02-13-18-20-19.

[4] Zack Cooper et al.," Hospital Prices Grew Substantially Faster than Physician Prices for Hospital-Based Care in 2007-14," *Health Affairs* 38, no. 2 (2019): 184–189.

[5] Cooper et al.(2019), *supra* note 3. Private insurers administer benefits for a large portion of Medicare and Medicaid-insured beneficiaries, and for these enrollees, insurers and providers must agree to the terms, including price, under which a provider is included in-network. However, for Medicare Advantage plans, CMS requires providers that participate in Traditional Medicare to accept its fee-for-service price schedule for any out-of-network care, reducing the ability of most providers to negotiate for Medicare Advantage rates that are much higher. See Laurence Baker, Kate Bundorf, Aileen Devlin, and Daniel Kessler, "Medicare Advantage Plans Pay Hospitals Less Than Traditional Medicare Pays," *Health Affairs* 35, no. 8 (2016): 1444–51; Vilsa Curto et al., "Health Care Spending and Utilization in Public and Private Medicare," *American Economic Journal: Applied Economics* 11, no 2 (2019): 302–32.

[6] Selden TM, Karaca Z, Keenan P, White C, Kronick R. The growing difference between public and private payment rates for inpatient hospital care. Health Aff (Millwood). 2015;34(12):2147–50.

[7] Chernew, Hicks, and Shaw. "Wide State-Level Variation In Commercial Health Care Prices Suggests Uneven Impact Of Price Regulation," *Health Affairs* 39, No. 5 (20201): 791-99. The authors report professional services represent 20 percent of national health expenditures.

[8] (Cooper et al. 2019).

[9] For additional discussion, see Chernew, Dafny, and Pany, "A Proposal to Cap Provider Prices and Price Growth in the Commercial Health Care Market," *Policy Proposal 2020-08*, The Hamilton Project, Brookings Institute, March 2020; see also, Cooper et al (2019) *supra* note 3, which shows that both within and across Health Referral Regions, provider market concentration explains the largest share of variation in commercial prices.

and insurers to exploit that power in health care markets. I summarize the academic research that concludes the resounding answer to the question is "yes." While every merger is different and antitrust authorities must evaluate each on its own merits, too many harmful and anticompetitive mergers are occurring under the current review and enforcement regime. At the end of this testimony, I discuss legislative and regulatory interventions that could mitigate the harm from consolidation and deter future harmful consolidation.[10]

II. Health Care Markets a Decade After the ACA: Bigger, but Probably Not Better

Over the past decade, health care markets have increased substantially in size. Per-capita health care spending in 2019 stood at $11,582, yielding a national total of $3.8 trillion, as compared to $8,383 in 2010, or a national total of $2.6 trillion.[11] At the same time, many sub-sectors of health care have become substantially consolidated. There were nearly 1,600 hospital and hospital system mergers over the 20 years from 1997 to 2017, involving thousands of hospitals. This merger and acquisition activity has increased the absolute size and geographic footprint of hospital and health care delivery systems——and with it, their market power and political heft.[12] Merger and acquisition activity in physician markets has also increased, and the share of physicians employed in practices wholly or partly owned by hospitals has increased from below 20% in the mid-2000s, to 30% in 2012 and 50% in 2018.[13] Commercial health insurance markets have grown increasingly consolidated as well. By 2019, more than 74 percent of metropolitan areas were "highly concentrated" as defined in the FTC/DOJ *Horizontal Merger Guidelines*.[14]

Given that consolidation has coincided with substantial growth in commercial prices and spending, the question of whether consolidation has *caused* these increases has attracted significant attention from researchers as well as various stakeholders. To date, the most

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[10] My discussion focuses on consolidation that (1) occurs in an already-concentrated market (which are the majority of markets nationwide for many healthcare services) or consolidation that would create a concentrated market and (2) for which there are not clearly verifiable extenuating factors that would, with high likelihood, outweigh any anticompetitive effects. See the discussion in Leemore Dafny and Thomas Lee, "The Good Merger," *NEJM* 372, no. 22 (2015): 2077–79, https://www.nejm.org/doi/full/10.1056/NEJMp1502338.

[11] CMS, "National Health Expenditure Accounts," https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata.

[12] Hospital merger count is based on data from the American Hospital Association and summarized by Gaynor in https://onepercentsteps.com/policy-briefs/addressing-hospital-concentration-and-rising-consolidation-in-the-united-states/.

[13] Carol Kane, "Updated Data on Physician Practice Arrangements: For the First Time, Fewer Physicians are Owners Than Employees," White paper, American Medical Association, 2019, https://www.ama-assn.org/system/files/2019-07/prp-fewer-owners-benchmark-survey-2018.pdf; Carol Kane and David Emmons, "New Data On Physician Practice Arrangements: Private Practice Remains Strong Despite Shifts Toward Hospital Employment," White paper, American Medical Association, 2013, https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/premium/health-policy/prp-physician-practice-arrangements_0.pdf; Michael Furukawa et al., "Consolidation Of Providers Into Health Systems Increased Substantially, 2016–18," *Health Affairs* 39, no. 8 (2020): 1321–1325, https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2020.00017.

[14] American Medical Association, "Competition in Health Insurance: 2020 Update," https://www.ama-assn.org/system/files/2020-10/competition-health-insurance-us-markets.pdf.

conclusive research derives from analyses of "structural changes" in markets—i.e., mergers and acquisitions, divestitures, and exits. I summarize the results of these studies below. However, it is important to recognize that a good deal of consolidation to date is non-structural, e.g., consolidation arising from greater growth of large firms.

Some of the large-firm growth may well be due to anticompetitive conduct. For example, some dominant hospital systems' contracts forbid insurers from using financial incentives to "steer" patients to other (typically smaller and less expensive) providers and/or may prohibit insurers from contracting with only a subset of the dominant system's providers (e.g., selecting which of the system's specialists to include in-network).[15] Such "all or nothing" contracting can enable a system to allocate services efficiently across different facilities, but it can also be a means for a system with market power to potentially expand its reach by "tying" access to its providers in more competitive markets to access to its most highly-valued providers.[16]

A. Evidence on the Effects of Health Care Mergers

A.1. *Providers*

Most research on provider mergers[17] has focused on hospitals, which account for over 30 percent of U.S. health care spending.[18] The extensive academic literature on the subject has been well-

[15] *See*, e.g., Elizabeth Mitchell, "Seizing on the Sutter Health Settlement to Create Competitive Health Care Markets Nationwide," https://www.milbank.org/2020/01/seizing-on-the-sutter-health-settlement-to-create-competitive-health-care-markets-nationwide/.

[16] That is, under an all-or-none contract, the dominant system requires insurers, as a condition of contracting with its most highly-valued hospitals and medical groups, to also contract with the system's less highly-valued providers (even of the price and quality of those providers are such that the insurer would otherwise choose not to contract with them). Although largely beyond the scope of my testimony today, the antitrust agencies can and have investigated conduct by dominant actors in the health care system that may lessen competition. For example, DOJ successfully challenged a health insurer's use of most favored nation (MFN) and "MFN+" provisions that contractually required hospitals to not negotiate lower prices—and sometime specified higher prices—to the dominant insurer's rivals. DOJ, "Justice Department Files Motion to Dismiss Antitrust Lawsuit Against Blue Cross Blue Shield of Michigan After Michigan Passes Law to Prohibit Health Insurers from Using Most Favored Nation Clauses in Provider Contracts," Press release, Mar. 25, 2013, https://www.justice.gov/opa/pr/justice-department-files-motion-dismiss-antitrust-lawsuit-against-blue-cross-blue-shield. In another action, the DOJ successfully ended a dominant hospital system's use of "anti-tiering" provisions that prevented insurers from using narrow and tiered networks to steer patients to the system's rivals. DOJ, "Atrium Health Agrees to Settle Antitrust Lawsuit and Eliminate Anticompetitive Steering Restrictions," Press release, Nov. 15, 2018, https://www.justice.gov/opa/pr/atrium-health-agrees-settle-antitrust-lawsuit-and-eliminate-anticompetitive-steering.

[17] For additional discussion, see Claudia Williams, Robert Town, and William Vogt, "How Has Hospital Consolidation Affected the Price and Quality of Hospital Care?" The Synthesis Project Policy Brief No. 9, Feb. 2006; Martin Gaynor and Robert Town. "The Impact of Hospital Consolidation—Update." The Synthesis Project Policy Brief No. 9 Revised, 2012; Martin Gaynor, "Diagnosing the Problem: Exploring the Effects of Consolidation and Anticompetitive Conduct in Health Care Markets," Statement before the Committee on the Judiciary Subcommittee on Antitrust, Commercial, and Administrative Law, U.S. House of Representatives, March 7, 2019.

[18] CMS, "The Nation's Health Dollar, Calendar Year 2019," https://www.cms.gov/files/document/nations-health-dollar-where-it-came-where-it-went.pdf.

summarized and reviewed elsewhere,[19] so I describe only the key conclusions here. Several peer-reviewed, academic economic studies have shown that commercial prices tend to increase after hospital mergers, regardless of whether they involve for-profit or nonprofit hospitals. A number of studies also directly link high hospital market concentration with high prices and price growth.[20] In addition, numerous studies fail to find systematic evidence of benefits to consumers from mergers in terms of clinical outcomes or patient experience, and many studies link more hospital competition to higher quality.[21] Simply put, due to consolidation we are paying more for our hospital care, but there is no evidence that we are getting more in return.

Research on physician mergers and consolidation is more limited, but the conclusions are the same. A study of commercial prices following a large merger of orthopedic physician groups found substantial price increases for the physician group, even though prices for other orthopedic physicians did not change.[22] Studies also show that physician prices are higher in more concentrated physician markets.[23] More evidence is likely to emerge from the FTC's recently launched "6(b)" study of "the impact of physician consolidation during this period, including physician practice mergers and hospital acquisitions of physician practices."[24] Such studies are essential to informing both enforcement and regulation, and thus warrant adequate funding. I return to this subject in the recommendations I offer at the end of this statement.

Most research on the impact of mergers focuses on "within market" or horizontal transactions, but more recent research has evaluated the effects of "cross market" hospital mergers, or

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[19] *See* sources listed, *supra* note 17.

[20] E.g., Leemore Dafny, "Estimation and Identification of Merger Effects: An Application to Hospital Mergers," *Journal of Law and Economics* 52 (2009): 523–50; Cory Capps and David Dranove, "Hospital Consolidation and Negotiated PPO Prices," Health Affairs 23, no. 2 (2004): 175–81 at 179; and Zack Cooper, Stuart Craig, Martin Gaynor, and John Van Reenen. "The price ain't right? Hospital prices and health spending on the privately insured." *Quarterly Journal of Economics* 134 (2019): 51–107.

[21] E.g., Daniel Kessler and Mark McClellan, "Is Hospital Competition Socially Wasteful," *Quarterly Journal of Economics* 115, no. 2 (2000): 577–615; Studies of quality competition in the U.K. include Zack Cooper, Stephen Gibbons, Simon Jones, and Alistair McGuire, "Does Hospital Competition Save Lives? Evidence from the English NHS Patient Choice Reforms." *The Economic Journal* 121, no. 554 (2011), 228–260., and Martin Gaynor, Rodrigo Moreno-Serra, and Carol Propper, "Death by Market Power: Reform, Competition, and Patient Outcomes in the National Health Service," *American Economic Journal: Economic Policy* 5, no. 4 (2013): 134–66. Cooper et al. studied the introduction of greater competition among hospitals into the English National Health System and find that heart attack mortality decreased the most in areas with the greatest increases in competition. Gaynor et al. study the same English NHS reforms but examine a broader set of quality and efficiency measures and find that hospital competition improves quality without lowering costs.

[22] Thomas Koch and Shawn Ulrick, "Price Effects of a Merger: Evidence From a Physicians' Market," *Economic Inquiry* 59, no. 2 (2021): 790–802, https://onlinelibrary.wiley.com/doi/abs/10.1111/ecin.12954.

[23] Abe Dunn and Adam Shapiro, "Do Physicians Possess Market Power?" *Journal of Law & Economics* 57, no.1 (2014):159-193, https://www.jstor.org/stable/10.1086/674407; Laurence Baker, Kate Bundorf, Anne Royalty, and Zachary Levin. "Physician Practice Competition and Prices Paid by Private Insurers for Office Visits," *JAMA* 312, no. 16 (2014): 1653–62, https://doi.org/10.1001/jama.2014.10921

[24] FTC, "FTC to Study the Impact of Physician Group and Healthcare Facility Mergers," Jan. 14, 2021, https://www.ftc.gov/news-events/press-releases/2021/01/ftc-study-impact-physician-group-healthcare-facility-mergers.

combinations occurring among hospitals in different, sometimes adjacent, geographic markets.[25] This research shows that acquisitions of hospitals, even by out-of-market hospital systems, often leads to substantial price increases both for acquired hospitals and for acquiring hospitals located in the same state.

Researchers have also documented that hospitals in more concentrated markets charge higher prices and are less likely to receive fixed, prospective payments—a payment methodology that creates incentives for providers to control costs. Specifically, hospitals are less likely to be paid based on patients' diagnoses and conditions (as under the traditional Medicare system), and more likely to be paid based on their list charges (giving hospitals an incentive to render more care and to increase list charges).[26] This pattern shows that hospitals with market power are better-positioned to reject cost-containing payment innovations by insurers.

Research on vertical combinations of health care providers has focused on the effects of hospital acquisition of physician practices. Several studies find these combinations result in higher prices and higher spending; for example, one study based on detailed commercial claims data finds average price increases of 14 percent.[27] However, as with hospital care, evidence of improvements in patient outcomes is elusive. One recent study finds only negligible effects of vertical integration of hospitals and physicians on a set of health outcome measures.[28] Other research likewise finds either no relationship or a positive but small relationship between vertical integration of hospitals with physicians and measures of quality.[29] And, in the nursing-home sector, a recent study found that hospitals that own skilled nursing facilities were likelier to "self-

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[25] Leemore Dafny, Kate Ho, and Robin S. Lee, "The Price Effects of Cross-Market Mergers: Theory and Evidence from the Hospital Industry," *RAND Journal of Economics* 50, no. 2 (2019): 286–325, https://doi.org/10.1111/1756-2171.12270; Matthew S. Lewis and Keven E. Pflum, "Hospital Systems and Bargaining Power: Evidence from Out-of-Market Acquisitions," *RAND Journal of Economics* 48, no. 3 (2017): 579–610, https://doi.org/10.1111/1756-2171.12186.; Matt Schmitt, "Do Hospital Mergers Reduce Costs?," *Journal of Health Economics* 52 (2017): 74–94, https://doi.org/10.1016/j.jhealeco.2017.01.007.

[26] Cooper et al. (2019), *supra* note 3.

[27] Cory Capps, David Dranove, and Christopher Ody, "The Effect of Hospital Acquisitions of Physician Practices on Prices and Spending," *Journal of Health Economics* 59 (2018): 139–152. The authors estimate hospital acquisitions of physician practices increase prices by 14% on average, with about half the increase attributable to higher unit prices and half to payment rules that reimburse services performed at or billed through a hospital at a higher rate. *See also*, Caroline Carlin, Roger Feldman, and Bryan Dowd, "The Impact of Hospital Acquisition of Physician Practices on Referral Patterns," *Health Economics* 25 (2016): 439–454; Hannah T. Neprash *et al.*, "Association of Financial Integration Between Physicians and Hospitals With Commercial Health Care Prices," *JAMA Intern Med.* 175, no. 12 (2015): 1932–1939, https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2463591; James Robinson and Kelly Miller, "Total Expenditures per Patient in Hospital-Owned and Physician-Owned Physician Organizations in California," *JAMA* 312, no. 16 (2014): 1663–1669, https://jamanetwork.com/journals/jama/fullarticle/1917439.

[28] Thomas Koch, Brett Wendling, and Nathan E. Wilson, "The Effects of Physician and Hospital Integration on Medicare Beneficiaries' Health Outcomes," *Review of Economics and Statistics*, March 2020,.

[29] Marah Short and Vivian Ho, "Weighing the Effects of Vertical Integration Versus Market Concentration on Hospital Quality," *Medical Care Research and Review* 77, no. 6 (2020): 538–48,; Rachel Machta, et al., "A Systematic Review of Vertical Integration and Quality of Care, Efficiency, and Patient-Centered Outcomes," *Health Care Management Review* 44, no. 2 (2019): 159–173.

refer" profitable patients to those facilities, but those patients did not experience any significant changes in clinical outcomes.[30]

The higher provider prices fueled by consolidation harm commercially insured plan members, both directly through higher out-of-pocket spending and higher premiums and indirectly through lower wages.[31] If these higher prices were associated with better outcomes, the financial toll might be easier to justify, but the evidence does not support this conclusion. Because health care providers compete on non-price dimensions such as clinical outcomes and patient experience, consolidation that lessens competition also can be expected to worsen quality for both commercially insured and government-insured patients.

A.2. *Insurers*

Research on consolidation in the health insurance sector is less abundant than research on the provider sector, partly due to the very limited public data on commercial insurance premiums, plan characteristics, and enrollment. However, two peer-reviewed studies examine the impact of insurer mergers on premiums, one using data for large employers and a second using data for small groups.[32] Both find evidence of premium increases in markets where the merging parties have the most pre-merger overlap. In addition, a study of the Health Insurance Marketplaces (i.e., ACA exchanges) finds that additional insurer participation, particularly when the insurer has substantial share in the individual market, yields lower premiums.[33]

A number of other studies find that larger insurers are able to negotiate greater provider discounts.[34] However, no study has found evidence that these discounts result in lower insurance premiums. In the absence of competition, there is minimal pressure on insurers to pass savings on to downstream customers.

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[30] David Cutler, Leemore Dafny, David Grabowski, Steven Lee, and Christopher Ody, "Vertical Integration of Healthcare Providers Increases Self-Referrals and Can Reduce Downstream Competition: The Case of Hospital-Owned Skilled Nursing Facilities," *NBER Working Paper* 28305, December 2020.

[31] Daniel Arnold and Christopher Whaley, "Who Pays for Health Care Costs? The Effects of Health Care Prices on Wages," Working paper, RAND Corporation, 2020, https://www.rand.org/pubs/working_papers/WRA621-2.html; Katherine Baicker and Amitabh Chandra, "The Labor Market Effects of Rising Health Insurance Premiums," *Journal of Labor Economics* 24, no. 3 (2006): 609–634, https://www.jstor.org/stable/10.1086/505049.

[32] Leemore Dafny, Mark Duggan, Subramaniam Ramanarayanan, "Paying a Premium on Your Premium? Consolidation in the US Health Insurance Industry," *American Economic Review* 102, no. 2 (2012): 1151–1185, https://www.aeaweb.org/articles?id=10.1257/aer.102.2.1161; Jose Guardado, David Emmons, Carol Kane, "The Price Effects of a Large Merger of Health Insurers: A Case Study of UnitedHealth-Sierra," Health Management, Policy and Innovation 1, no. 3 (2013): 16-35.

[33] Leemore S. Dafny, Jonathan Gruber, Christopher Ody, "More Insurers Lower Premiums: Evidence from Initial Pricing in the Health Insurance Marketplaces," *American Journal of Health Economics* 1 no. 1 (2015): 53–81.

[34] Erin Trish and Bradly Herring, "How Do Health Insurer Market Concentration and Bargaining Power with Hospitals Affect Health Insurance Premiums?" *Journal of Health Economics* 42, no. 1 (2015): 104–114; Cooper et al. (2019), *supra* note 3. *See also,* Commonwealth Fund, "Evaluating the Impact of Health Insurance Industry Consolidation: Learning from Experience," Nov. 20, 2015.

III. The Pandemic Should Not Delay Actions to Prevent Anticompetitive Consolidation

During the Covid pandemic, health care organizations have struggled with financial challenges created by decreases in revenue for services such as elective surgery, and higher costs related to personnel and measures required to keep patients and employees safe. The experience of "going it alone" has led some providers to conclude that their status quo is fraught, and they must explore consolidating into a larger organization. They point to success stories in which patients, personnel, medications, and equipment were moved among health care organizations to meet needs wherever they were greater. However, it is worth noting that such admirable cooperation occurred among distinct health care organizations, not just within them.

Any argument that the challenges associated with the pandemic should trump concerns about market consolidation is not compelling, as there has been no permanent change in the health care ecosystem that would imply a change in the dynamics associated with health care consolidation. If anything, the pandemic has exposed some of the harm linked to consolidation. Providers compensated on a fee-for-service basis have struggled financially, spurring a government bailout.[35] As noted above, researchers have shown that more dominant hospitals have successfully resisted the shift away from fee-for-service reimbursement and toward risk-sharing models; had more shifted in this direction prior to the pandemic, hospital systems would be on stronger financial footing today.

The pandemic has also exposed the limited degree of competition in the insurance sector. As medical expenses have declined, insurers' earnings are soaring. In a competitive market, insurers would try to retain fully-insured customers by refunding premium payments for much of 2020 and reducing premiums for 2021. However, there is scant evidence of refunds beyond the minima required by statute.[36] When patients/employers have few rival insurers to turn to, any market imperative for insurers to share medical cost savings with customers is limited.

Going forward, there is growing concern that the pandemic is accelerating consolidation—e.g., by hastening the movement of physicians into employment with hospitals, insurers, and private equity-owned groups. Paired with greater exit by financially-strapped health care providers, this is a recipe for even higher prices.

The possibility of a different type of "long haul" effect of Covid—higher prices due to consolidation—is substantial enough that some stakeholders have called for a merger moratorium. In May 2020, a group representing large employers, whose members include

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[35] Kaiser Family Foundation, "Distribution of CARES Act Funding Among Hospitals," May 13, 2020, https://www.kff.org/coronavirus-covid-19/issue-brief/distribution-of-cares-act-funding-among-hospitals/.

[36] Kaiser Family Foundation, "Data Note: 2021 Medical Loss Ratio Rebates," Apr. 12, 2021, https://www.kff.org/private-insurance/issue-brief/data-note-2021-medical-loss-ratio-rebates/.

Boeing, Salesforce, Tesla, and Walmart, asked Congress for a year-long ban on mergers and acquisitions among hospitals and physician groups that received government money to cope with the effects of the COVID-19 pandemic.[37]

IV. Current State of Enforcement

A. Horizontal mergers

Antitrust enforcement vis-a-vis horizontal transactions among health care providers or payers is active,[38] although as I discuss later, it does not have sufficient resources to be as active as needed. In the past few years, the DOJ, together with State plaintiffs, successfully blocked two proposed mega-mergers of large health insurers.[39] In the past decade, the FTC and DOJ have successfully challenged over a dozen hospital mergers and a number of mergers among other health care providers, including matters settled with consent decrees requiring divestitures to preserve competition and matters the parties abandoned in the face of Agency opposition.

However, as Commissioner Rebecca Slaughter, the current acting FTC Chair has noted, these efforts have "faced resistance, with two of these recent victories only coming after district court setbacks."[40] Blocking a horizontal merger, even when it appears to be an "open and shut" case to a layperson, requires extraordinary resources, including large investigation and litigation teams, as well as economic and other subject matter experts who must analyze the transaction, lay out the case for blocking the merger, and rebut arguments advanced by Defendants' attorneys and experts.[41] The higher the payoff from the merger for the merging parties—and the payoff in the case of an increase in market power can be substantial—the greater the incentive for Defendants

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[37] Rebecca Spalding, "Large employers push back on U.S. healthcare mergers during coronavirus crisis," *Reuters* May 22, 2020, https://www.reuters.com/article/us-health-coronavirus-hospital-m-a/large-employers-push-back-on-u-s-healthcare-mergers-during-coronavirus-crisis-idUSKBN22Z015.

[38] According to Dr. Nathan Wilson, Deputy Assistant Director of the FTC, around one-half of the FTC's merger challenges between 2010-2018 involved healthcare providers. Nathan Wilson, "Editor's Note: Some Clarity and More Questions in Healthcare Antitrust," *Antitrust Law Journal* 82, no. 2 (2019): 435–440.

[39] Dafny, L., "Good Riddance to Big Insurance Mergers," *New England Journal of Medicine,* 2017; 376:1804-1806.

[40] https://www.ftc.gov/system/files/documents/public_statements/1520570/slaughter_-_hospital_speech_5-14-19.pdf.

[41] To pick a recent example, consider the proposed merger of two hospital systems in the Memphis area, which the FTC filed to block in November 2020. Based on the FTC's complaint, the merger would have reduced the number of competing systems from four to three and created a system with over a 50% market share. In the face of litigation, the parties abandoned the deal—consistent with this being an open and shut case. (See FTC, "FTC Sues to Block Proposed Acquisition of Two Memphis-Area Hospitals," Press release, Nov. 13, 2020, https://www.ftc.gov/news-events/press-releases/2020/11/ftc-sues-block-proposed-acquisition-two-memphis-area-hospitals.)
Although the FTC prevailed without a trial, it took nearly a year from the merger announcement to the abandonment. Over that period, the FTC would in all likelihood have already devoted thousands of staff hours to the investigation and lawsuit and expended substantial taxpayer resources on expert witnesses.

to invest extraordinary resources to fight a merger challenge. Even if there is only a middling (and in some cases, small) chance of getting a merger through, it may well be in the parties' interest to see if they can prevail, absorbing the Agencies' (i.e., DOJ and FTC's) scarce resources in that attempt and preventing them from devoting those resources to investigate other transactions or anticompetitive practices.

The substantial resources required to challenge transactions, paired with stagnating enforcement budgets, may explain why authorities have elected not to challenge some horizontal transactions they would likely have challenged in previous eras.[42]

Because pre-merger reporting to the federal agencies is only required for transactions exceeding minimum dollar thresholds (currently $92 million),[43] the Agencies have limited visibility into smaller acquisitions, as well as some larger combinations not involving asset exchanges. Even if the agencies become aware of so-called "non-reportable" transactions, the parties may legally merge before an Agency has reviewed the transaction. Unwinding consummated transactions parties is notoriously difficult, reducing the odds of a resolution that restores competition. A recent study found that an amendment to the HSR Act in 2000, which raised the effective asset threshold for reporting from $10 million to $50 million, resulted in a large increase in mergers of rivals in that range, relative to mergers among rivals in the always-exempt range (<$10 million) or the never-exempt range (>$50 million).[44] Importantly, the number of federal investigations into transactions in the newly-exempt range fell from around 150 per year to nearly zero. Clearly, reporting thresholds matter for competition, and in health care, where many transactions are small, many are escaping detection and investigation.[45]

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[42] Using data on a wide range of industries, antitrust scholar John Kwoka documents that enforcers rarely raise concerns about changes in market structure that used to draw scrutiny—that is, mergers that yield 5 or more market participants. See Kwoka, J. "Reviving Merger Control: A Comprehensive Plan for Reforming Policy and Practice," *American Antitrust Institute*, https://www.antitrustinstitute.org/wp-content/uploads/2018/10/Kwoka-Reviving-Merger-Control-October-2018.pdf.

[43] FTC, "HSR threshold adjustments and reportability for 2021," Feb. 17, 2021, https://www.ftc.gov/news-events/blogs/competition-matters/2021/02/hsr-threshold-adjustments-reportability-2021.

[44] Thomas Wollmann, "Stealth Consolidation: Evidence from an Amendment to the Hart-Scott-Rodino Act." *American Economic Review: Insights* 1, no. 1 (2019): 77–94.

[45] Capps et al. (2017), *supra* n. 27. The *de facto* safe harbor for the vast majority of small transactions is particularly concerning in light of empirical evidence showing that some incumbents acquire innovative targets (which are likelier to be small) for the purpose of pre-empting future competition." So-called "killer acquisitions" may snuff out nascent competition and "mavericks" (firms that "play a disruptive role in the market to the benefit of consumers") in a range of sectors throughout the U.S. economy. See Colleen Cunningham, Florian Ederer, and Song Ma, "Killer Acquisitions," *Journal of Political Economy* 129, no. 3 (2021): 649–701. The authors use data on pharmaceutical mergers and find acquired drug products are less likely to be brought to market when they compete with the acquirer's existing products.

[45] US Department of Justice and Federal Trade Commission, *Horizontal Merger Guidelines*, issued Aug. 19, 2010, http://www.justice.gov/atr/public/guidelines/hmg-2010.html. .

B. Non-horizontal mergers

Both federal and state enforcement agencies have largely steered clear of challenging non-horizontal transactions in health care.[46] However, as I described earlier, there is substantial evidence that at least two common forms of non-horizontal integration among health care providers—hospital acquisitions of physician groups and cross-market mergers—can lead to significant increases in prices without commensurate benefits and, therefore, raise health care spending without any clear improvements for patients.

One reason enforcement agencies may not challenge these mergers is a belief – with a theoretical foundation but scarce empirical support – that vertical mergers are likely to be efficient. Another reason is a belief—held by some authorities and many in the private antitrust bar—that mergers that enable greater exploitation of *existing* market power (as opposed to *enhancing* market power) are not prohibited by the Clayton Act. While such combinations could be challenged as monopolistic conduct under Section 2 of the Sherman Act, my understanding is that sustaining the burden of proof for a Section 2 monopolization theory involves a very high hurdle in court for several reasons—including the fact that the federal antitrust agencies do not benefit from the presumptions that apply in merger cases where the merging parties have high combined market shares.

I will leave it to the witnesses with legal backgrounds to support or to challenge this understanding; however, as a non-attorney, it is clear to me from the evidence on consolidation and the state of enforcement that some combination of the laws, either as written or construed, and/or the ways in which they are being enforced today, are not protecting the public from the harmful effects of many transactions and business practices.

In the section below, I suggest reforms that can assist the Agencies in halting anticompetitive acquisitions and practices.

[46] The FTC is currently seeking, under a vertical theory of harm (that also involves issues of nascent competition), to block a proposed acquisition in the cancer detection space. FTC, "FTC Challenges Illumina's Proposed Acquisition of Cancer Detection Test Maker Grail," Mar. 30, 2021, https://www.ftc.gov/news-events/press-releases/2021/03/ftc-challenges-illuminas-proposed-acquisition-cancer-detection.

V. Reforms to Bolster Antitrust Enforcement and Preserve and Promote Competition in Health Care Markets

1. *Strengthen the federal enforcement agencies' ability to identify and review potentially problematic transactions and conduct in health care.*

   - Require more health care transactions to be reported. Implement additional filing requirements, specifically lowering the asset value threshold and adding revenue thresholds to cover smaller facility and provider consolidation and transactions involving low- or no-asset transfers; and require filers to provide information that can facilitate the screening process, such as the distance and driving time between the closest establishments of the merging parties.[47]

   - Increase the budgets of enforcement agencies. The volume of transactions the Agencies must review has increased dramatically even as funding has declined in real terms.[48] The Agencies require these resources to develop expertise in a range of new and changing sectors, to litigate and establish new precedents that protect competition, and to advocate for pro-competitive policies. Investing in our enforcement agencies will help to prevent anticompetitive practices and consolidation and yield a return for years to come.

   - Remove two unnecessary limitations on the authority of the FTC. The first precludes the FTC from investigating anticompetitive conduct by nonprofit organizations, and the second precludes the FTC from studying the business of insurance absent explicit Congressional authorization. These restrictions have no merit. The former results in an arbitrary and likely inefficient allocation or transfer of cases across the Agencies, and the latter impedes the FTC's efforts in a sector where the lines between provision of care and insurance are increasingly blurred.

2. *Request that the Agencies issue revised Health Care Statements (or "Health Care Guidelines").*

   - Issued in 1996, the *Statements of Antitrust Enforcement Policy in Health Care* describe how the DOJ and FTC evaluate—or once evaluated—certain types of mergers, joint

[47] For more detailed and helpful suggestions on expanding and streamlining pre-merger reporting, see Bill Baer et al, "Restoring competition in the United States: A vision for antitrust enforcement for the next administration and Congress," Nov. 19, 2020, https://equitablegrowth.org/research-paper/restoring-competition-in-the-united-states/.

[48] Testimony of Bill Baer, "Hearing on 'Proposals to Strengthen the Antitrust Laws and Restore Competition Online,'" Oct. 1, 2020, https://docs.house.gov/meetings/JU/JU05/20201001/111072/HHRG-116-JU05-Wstate-BaerW-20201001.pdf.

ventures, and contracting practices among health care entities.[49] The health care landscape has changed considerably since 1996, and the guidelines should be updated and expanded to include discussions of recent types of transactions that have been shown to harm consumers, such as "cross-market" mergers of providers in adjacent geographic markets. The revised Statements, which should be renamed "Health Care Guidelines," in keeping with Agency practice when issuing significant documents setting forth the Agencies' approach to assessing mergers, should also describe concerns about the contracting clauses imposed by dominant health care systems, including but not limited to "all or nothing" provisions and anti-steering/tiering provisions, as well as range of pharmaceutical practices that weaken competition. The revised Guidelines would provide an opportunity for the DOJ and FTC to set forth their interpretation of antitrust statutes, provide valuable guidance to the health care industry, and potentially deter anticompetitive conduct and mergers that would otherwise be costly and time-consuming for the authorities to challenge even if they are highly likely to prevail.

3. *Amend and strengthen the antitrust statutes.*

- Per Clayton Act Section 7, the agencies must demonstrate a transaction "*substantially*" lessens competition or "tends to create a monopoly" in order to block a merger. Replacing "substantially" with "meaningfully" or "materially" could reduce the burden of merger challenges, and expand the scope of such challenges. For example, with such a change authorities may be able to address the problem of smaller acquisitions, such as serial acquisitions of physician practices by hospital systems, that may have not have substantial effects individually but, collectively, lead to the same outcomes as a large merger.[50]

- Implement a legal framework—whether by amending the Clayton Act, amending Section 2 of the Sherman Act, or interpreting the agency's unfair methods of competition authority — to explicitly prohibit health care mergers that enable greater exploitation of existing market power and are likely to result in harm to consumers. Such a reform would discourage transactions that yield price increases without commensurate benefits to consumers, such as when a dominant hospital buys a suburban hospital and instantly raises its price, or when a new acquirer (such as a private equity firm) implements surprise billing to the detriment of patients.

[49] US DOJ and FTC, "Statements of Antitrust Enforcement Policy in Health Care," Aug. 1996, https://www.justice.gov/atr/page/file/1197731/download.

[50] Capps et al. (2017), *supra* n. 27.

- Ease the Agencies' legal burden for challenging certain combinations. This burden-shifting should be limited, but particularly for the largest transactions, and for those with especially high potential to prove anticompetitive, such a shift would help to deter anticompetitive mergers and conserve scarce Agency resources.

4. *Create a federal database to track health care ownership and spending, both private and public.*

- This database could form the basis for regularly scheduled reports by HHS or the enforcement agencies, and could inform public hearings on industry consolidation and its effects. It would also allow the antitrust agencies to more quickly and efficiently distinguish innocuous and potentially concerning provider transactions, which will be particularly useful if, as I recommend above, the reporting thresholds for such transactions are lowered. At a minimum, the data should be available to public agencies for use in analysis and investigations; ideally, it would be available to researchers for analysis as well, subject to all the necessary privacy and confidentiality protections.

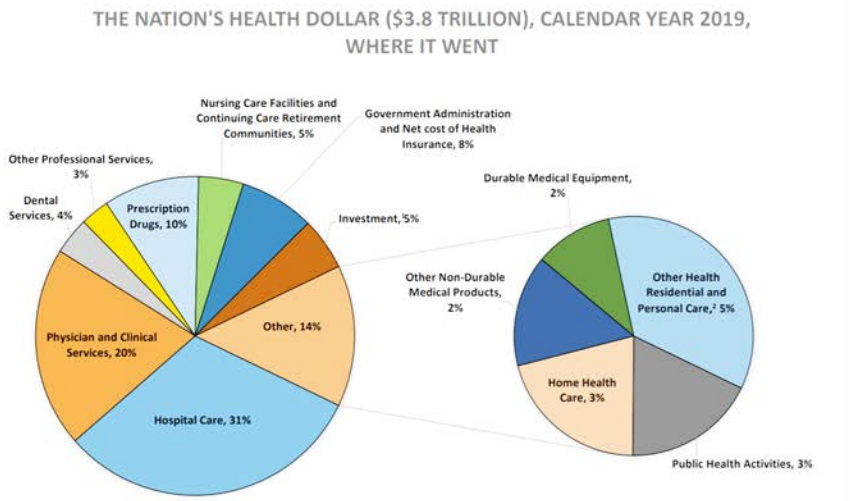
VI. Conclusion

Although the current health care system is rapidly evolving, there is no reason to believe that consolidation in our health care sectors is likely to be less harmful going forward than it has been, on average, in the past. Indeed, as the share of the population that is publicly insured increases, and as commercial insurers increasingly administer health plans for the publicly insured, there is considerable risk that market power exercised vis a vis the privately insured population through higher prices will become apparent for the publicly insured as well. And consolidation-fueled price increases are not linked to improvements in patient outcomes or satisfaction. Congress should provide funding and pass needed legislation to support and promote competition in health care markets. It is precisely during this time of change in the health care system that the risks of consolidation are highest and the rewards of vigilance will be greatest.

Figure 1. International Medical Prices for Selected Services as a Percentage of U.S. Price

Source: Chernew, Dafny, and Pany, "A Proposal to Cap Provider Prices and Price Growth in the Commercial Health Care Market," *Policy Proposal 2020-08*, The Hamilton Project, Brookings Institute, March 2020.

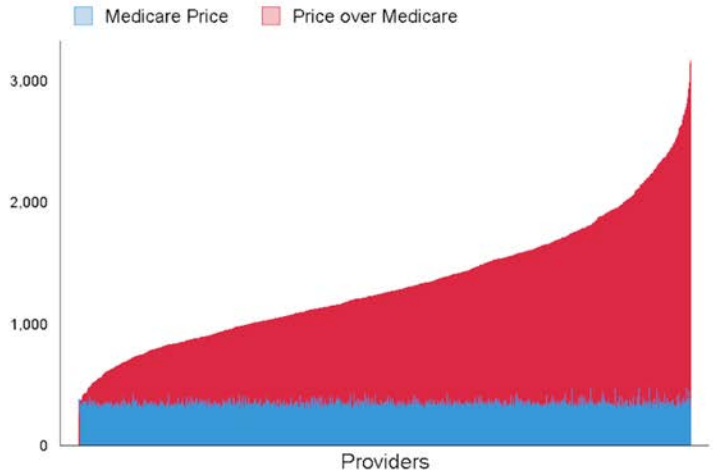
Figure 2. U.S. Health Care Spending, By Category, 2019



[1] Includes Noncommercial Research and Structures and Equipment.
[2] Includes expenditures for residential care facilities, ambulance providers, medical care delivered in non-traditional settings (such as community centers, senior citizens centers, schools, and military field stations), and expenditures for Home and Community Waiver programs under Medicaid.
Note: Sum of pieces may not equal 100% due to rounding.

SOURCE: Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group.

Figure 3. Commercial and Medicare Price for a Knee MRI



Note: Each column is an individual hospital with at least 50 episodes included in the source data. Hospitals are ordered by their average commercial price. Data is for 2007-2011.
Source: Health Care Pricing Project, @Coopper, Gaynor, and Van Reenen, https://healthcarepricingproject.org/sites/default/files/papers/pricing_variation_slides.pptx

Mr. CICILLINE. Thank you very much, Dr. Dafny.

I now recognize Professor Carrier for 5 minutes.

TESTIMONY OF MICHAEL CARRIER

Mr. CARRIER. Thank you very much.

Drug prices are too high. One main reason why is that brand companies play all sorts of games, like product hopping, pay-for-delay settlements, citizen petitions, and biosimilar disparagement. All these things harm consumers and there's no justification at all based on patents or innovation.

At the same time, there is increasing consolidation. The industry is getting more and more consolidated, and the FTC has responded only by requiring the divestiture of overlapping products. Congress can Act to make consumers' lives better and will not touch innovation in the process. The CREATES Act is a great model. Chair Cicilline, I thank you for your leadership on this important bill which has had a significant effect.

I also wanted to tie my remarks to what Senator Lee said. Senator Lee said that we wanted a "light touch reform" and "incremental targeted fixes." Every one of these pieces of legislation fits that description exactly.

My name is Michael Carrier. I'm a distinguished professor at Rutgers Law School. I've spent my career focused on the intersection of the antitrust and the IP laws. I have written 130 articles, am coauthor of the leading treatise on the topic, and really spend all my time thinking about these issues.

The first thing that Congress can do is to address product hopping. Most reformulations by drug companies are fine. Most of the time there's innovation, and there is not a pending generic. Some of these reformulations are very concerning. Some of the reformulations make no sense at all other than harming the generic. Every time that the brand company makes a tiny switch from a capsule to a tablet or just adjusts the dose a little bit, the generic cannot be substituted at the pharmacy counter and so it has to go back to the drawing board and consumers are stuck paying high prices.

Brand companies often have no good reason for what they are doing. In the Namenda case, the brand company pulled a $1.5 billion drug from the market. In the Suboxone case, it disparaged its own product. Legislation being considered, H.R. 2873, would address these issues. The courts have not figured out what to do with soft switches, which occur when the old drug remains on the market. This is the best piece of legislation to deal with the problem.

Second is pay-for-delay settlements. Brand companies have paid generics to delay entry. There's no good reason for this, but even though the Supreme Court, in *FTC* v. *Actavis*, clearly said this violates antitrust law, the settling parties have come up with all sorts of reasons why their agreement is not a pay-for-delay settlement. This piece of legislation would be very important to give the FTC power to go to court and not have to spend a decade trying to prove something that is very difficult to prove. It also would solve some problems in the courts. Not every court gets Actavis right, and so that's why the legislation is so important.

Third is citizen petitions. Citizen petitions are meant to raise legitimate concerns with the FDA. As it turns out, however, most of

them are filed by brand companies and the FDA denies most of them. So, H.R. 2883 would be very helpful in giving the FTC power to go after this sham-related conduct to make clear that a series of petitions could be a sham and to show that the penalties are significant, which would increase deterrence.

Fourth is biosimilar disparagement. In the biologics industry, which is the next big wave, there's not as close a relationship between the biologic and the biosimilar as there is between the brand and the generic. Biologic manufacturers have made all sorts of claims that the biosimilar is not identical, that maybe if you take it, something bad will happen to you. The courts have not shown that they're up to the task of getting this right. So, I would recommend a presumption that monopolists engaging in false advertising constitute monopolization.

Fifth is mergers. There has been a ton of consolidation in the industry. The FTC has responded by focusing on the divestiture of overlapping products. I believe that there is a theory of unilateral effects that is well established that would cover what is going on here. So, the first thing I'd say is that there should be a presumption against mergers between large companies. If you look at these large companies, they have significant advantages in insurance and reimbursement, marketing and detailing, and financing. There's no good reason for them to merge.

In terms of mid-size firms, even if I might not recommend a presumption, there are other factors to look at beyond the overlapping products. I'd consider factors like must-have blockbusters, rebate laws, and anticompetitive conduct. For example, the AbbVie-Allergan merger, all three of those were present, and that deserved more attention.

Finally, generic mergers deserve more attention as well. Not every generic is doing what it was supposed to do. When it starts getting a lot of its revenue from the brand side, that alters its incentives and that should be considered.

At the end of the day, the three pieces of legislation that this Committee is considering would make consumers' lives better and would not touch innovation.

Thank you very much.

[The statement of Mr. Carrier follows:]

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Having Our Cake and Eating it Too:
Five Things Congress Can Do To Address Anticompetitive Pharmaceutical Conduct and Consolidation

House Committee on the Judiciary, Subcommittee on Antitrust, Commercial and Administrative Law
Hearing on "Treating the Problem: Addressing Anticompetitive Conduct and Consolidation in Health Care Markets"
April 27, 2021

I. Introduction

A. Drug prices too high; consumers unable to afford needed medicines. Why?
   1. Brand drug companies abuse system by delaying generic entry
      a) Examples: product hopping, pay-for-delay settlements, citizen petitions, biosimilar disparagement
      b) None of this conduct can be justified by patents or innovation
         (1) Like the proverbial boy who cried wolf, the pharmaceutical industry for at least the past 60 years has claimed that every legislative proposal to restrict patents or apply antitrust would decimate innovation.[1]
   2. At the same time, the industry has undergone significant consolidation, which has increased price
      a) In response, the FTC has not blocked mergers but has only required divestitures of overlapping products

B. Congress can address these anticompetitive abuses and consolidation through legislation

II. My Background

A. I have studied pharmaceutical antitrust law as co-author of leading IP/antitrust treatise; author of more than 130 articles (65 on pharmaceutical antitrust law); drafter of 20 "amicus" briefs on behalf of hundreds of professors; and one frequently cited in media (2000+ times) and courts (including Supreme Court)

III. Product Hopping: Harm

A. Brand firms have switched drugs so generics can't be substituted and migrated patients before generic entry
   1. Examples: capsule to tablet, different dosage, single- and dual-scored tablet
   2. Product hopping combines reformulation of product with encouragement of doctors to write prescriptions for new version
      a) No innovation reason: brand does not *expand* prescription base but just *migrates* base to block generics

B. Every time brand changes drug slightly, generic cannot be substituted
   1. Substitution requires "AB rating": generic "therapeutically equivalent" to brand (same active ingredient, form, dosage, strength, safety/efficacy profile) and "bioequivalent" (absorbed into body at same rate).[2]
   2. Product hopping exploits this regulation as minor changes prevent generic from obtaining AB rating
   3. Generic then must start over: reformulate drug, get FDA approval, and fight new set of patents (litigation, automatic 30-month stay)

C. Harms from both "hard switches" (original drug pulled from market) and "soft switches" (original remains)
   1. Greater harms when brand switches before generic enters market (promotion/marketing more effective in convincing doctors to prescribe reformulated version)

D. Product hopping harms consumers
   1. Most recent (2009) empirical analysis found $28 billion worth of drugs subject to product hopping, including Advair, Allegra, Augmentin, Caduet, Clarinex, Kapidex, Lexapro, Nexium, Prozac, Risperdal.[3]
      a) For $1 billion blockbuster drug, consumers pay extra $765 million each year from delayed competition.[4]
   2. Consumers have overpaid $1.7 billion for Namenda, $200 million for Effexor, $700 million/year for TriCor, and (according to legal complaints) $11.5 billion for Nexium and $650 million annually for Suboxone.[5]

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[1] Michael A. Carrier & Genevieve Tung, *The Industry that Cries Wolf: Pharma and Innovation*, STAT (Sept. 26, 2019).

[2] FDA, *Orange Book Preface* (last visited Apr. 25, 2021).

[3] Steve Shadowen et al., *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 RUTGERS L. J. 1 (2009).

[4] FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 8 (2010) (multiple generics take 90% of sales at average 85% discount).

[5] *New York ex rel. Schneiderman v. Actavis*, 787 F.3d 638, 661 (2d Cir. 2015) (Namenda); *Explainer: Evergreening and How Big Pharma Keeps Drug Prices High*, THE CONVERSATION (Nov. 5, 2014) (Effexor); Kevin Drum, *How To Keep Healthcare Costs High*

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3. *E.g.*: Opioid-dependence-treating Suboxone was switched from tablet to sublingual (under-the-tongue) film
   a) Reckitt publicly announced removal of tablets for safety reasons (even though safer than film), waited 6 months to remove, disparaged (and raised price of) tablets, and promoted film to doctors.[6]
   b) *Made no sense*: Raising price of tablets (even though film more expensive) costly, as was warning of false safety concerns, all to receive "substantially reduced profit margins" on $700 million in annual sales![7]

E. Product hopping can harm innovation
   1. No empirical evidence has shown that innovation would be deterred by applying antitrust law
   2. Brand firms often *withhold* incremental innovations from market to use later as part of product hop:
      a) TriCor: Abbott delayed seeking new indication for original product, reserving it for reformulation, even though "data necessary to get the new indication was available much earlier."[8]
      b) Neurontin: Warner-Lambert conceded that "principal reason[] for not seeking FDA approval" for off-label uses was that it "wanted to reserve them for a later promotional campaign for its reformulated product."[9]
      c) Namenda: Forest waited until generic competition for twice-daily Namenda was imminent before introducing once-daily version (even though obtained FDA approval three years earlier!).[10]
      d) If value of "innovation" to consumers was greater than value to brand firm of delaying generic, would immediately introduce innovation to reap increased gains

IV. Product Hopping: Solution

A. Affordable Prescriptions for Patients Act of 2021 offers strong and effective approach to product hopping
   1. Gives FTC power under Section 5 to challenge anticompetitive hard and soft switches
      a) Hard switch = (1) withdraw drug or destroy inventory and impede competition + (2) sell follow-on drug
      b) Soft switch = (1) unfairly disadvantage original and impede competition + (2) sell follow-on drug
      c) Several provisions provide strong support to drug manufacturers:
         (1) Competition window limits liability to reformulations made when generic entry expected
         (2) Exclusions protect promotional marketing and cessation of marketing
         (3) Justifications allowed based on (a) taking action regardless of effect on competition and (b) safety/supply-disruption/procompetitive reasons for switch
   2. Legislation ensures courts recognize harms of soft switches when only reason for change is to harm generic
      a) *Walgreen's* court ignored price disconnect in asserting that AstraZeneca did not "eliminate[] any consumer choices" but instead "added choices," with superiority determinations "left to the marketplace."[11]
         (1) Pharmaceutical markets characterized by "price disconnect": doctor who prescribes product does not pay and consumer/insurer who pays for it does not choose
         (2) This characteristic could reduce choice when patients are switched from original drug (expiring patent, impending generics) to reformulated version (patented, no generics)
      b) *Doryx* court upheld product hop, focusing on competitor rather than consumer even though company "made . . . 'hops' primarily to 'delay generic market entry.'"[12]
      c) Congress is uniquely situated to recognize the harms of soft switches not acknowledged by courts

V. Pay-for-Delay Settlements: Harm

A. Brand firms have colluded with generic companies, paying them to delay entering the market
   1. Alone among anticompetitive pharmaceutical conduct, settling generics align with brands against consumers

B. Patients harmed from collusion, not innovation, as generics delay entry from payment, not patent
   1. FTC has calculated that pay-for-delay settlements cost consumers $3.5 billion a year.[13]
   2. Generics agree to delay entry in return for dropping patent challenge

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in One Easy Lesson, MOTHER JONES (Apr. 18, 2012) (TriCor); Complaint, *Louisiana Wholesale Drug Co. v. AstraZeneca Pharms LP*, (D.D.C. filed Feb. 28, 2007) (Nexium); Complaint, *In re: Suboxone Antitrust Litig.* (E.D. Pa. filed Apr. 13, 2015) (Suboxone).

[6] *In re Suboxone Antitrust Litigation*, 64 F. Supp. 3d 665, 674 (E.D. Pa. 2014).

[7] *Suboxone Complaint* ¶ 38.

[8] Steve Shadowen, Keith B. Leffler, & Joseph T. Lukens, *Bringing Market Discipline to Pharmaceutical Product Reformulations*, 42 IIC 698, 710 (2011) (data "used to get approval for the new indication had been developed in studies for the original product").

[9] *Id.* (noting that Warner-Lambert "was concerned" that generics "would undermine sales" of the new drug).

[10] *Namenda*, 787 F.3d at 647.

[11] *Walgreen v. AstraZeneca Pharmaceuticals*, 534 F. Supp. 2d 146, 151 (D.D.C. 2008).

[12] *Mylan Pharmaceuticals v. Warner Chilcott*, 838 F.3d 421, 431 (3d Cir. 2016).

[13] FTC, PAY-FOR-DELAY.

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a) But most (89%) of the patents at issue in settlements are secondary patents on which the brand firm is less likely to win (32%), as compared to active-ingredient (92%) patents.[14]
b) Examples of settlements on secondary patents: Actos, AndroGel, Cephalon, Effexor, K-Dur, Lidoderm, Loestrin, Niaspan, Opana, Solodyn, Wellbutrin

3. Consumers unable to afford high prices cut pills in half, choose between paying for drugs and food/rent, and do not take needed medicines

VI. Pay-for-Delay Settlements: Solution

A. H.R. 2375, the Preserve Access to Affordable Generics and Biosimilars Act, would play a critical role in stopping anticompetitive settlements
1. Legislation provides that generic receiving "anything of value" for delayed entry is presumptively illegal
a) Common-sense approach reflects Supreme Court's *Actavis* ruling, which broadly considered payment.[15]
b) Important to recognize that "anything of value" includes "an exclusive license"
(1) Settling parties have claimed that subjecting exclusive licenses to potential antitrust liability would be "extraordinary" and "call[] into question the continued viability of any patent litigation settlement."[16]
(2) To the contrary, as the Third Circuit has explained, defendants seek not "a patentee's right to grant licenses" but "a right to use valuable licensing in such a way as to induce a patent challenger's delay."[17]
c) Legislation helpfully rejects mistaken presumptions that courts have adopted that entry will not occur until patent expires and that pre-expiration entry is procompetitive
2. Legislation offers beneficial provisions for defendants:
a) Exception when payment for goods/services or procompetitive effects outweigh anticompetitive effects
b) Exclusion from liability for right to market and secure regulatory approval, payment of reasonable litigation expenses, and covenant not to sue

B. Benefit 1: Standard makes clear that pay-for-delay settlements anticompetitive and helps FTC prove cases in court
1. Payments are taking the form not of cash but of compensation hidden in increasingly obscure corners
2. Treating pay-for-delay settlements as presumptively anticompetitive will deter blatantly illegal conduct that courts do not always recognize and that bogs down the FTC for years in resource-intensive litigation
a) *E.g.*: The FTC's *Actavis* litigation, which did not even involve a trial, took *10 years* to settle.[18]

C. Benefit 2: Legislation addresses judicial errors relating to payment, "scope of patent," and risk aversion. *E.g.*:
1. *AbbVie*: Brand provided generic with drug at price "well below what is customary" but court (despite recognizing deal's "large value") concluded that it "was not a reverse payment."[19]
2. *AbbVie* and Administrative Law Judge in *Impax*: Assumed entry before patent expiration procompetitive (despite Supreme Court's overturning of scope-of-patent test).[20]
3. *Wellbutrin*: Relied on risk aversion defense (rejected by Supreme Court) to dismiss argument that payment size reflects patent weakness.[21]

D. Potential strengthening amendment 1: Make clearer that risk aversion is not legitimate procompetitive justification
1. A new subsection 27(b)(3) could provide that the fact finder shall not presume that "arguments based on the reduction of risk or promotion of certainty mean that the agreement is procompetitive"

E. Potential strengthening amendment 2: Expand H.R. 2375 to private plaintiffs (who litigate most settlement cases), which could address overly strict causation standards so that plaintiffs need not definitively prove patent invalidity (as *Wellbutrin* and *Nexium*[22] courts required)

F. Potential strengthening amendment 3: Expand H.R. 2375 to open 180-day bottleneck, which would have even stronger effect on settlements
1. *E.g.*: H.R. 1506, Fair and Immediate Release (FAIR) of Generic Drugs Act, enlarges category of "first applicants" to include generics obtaining judicial invalidity/noninfringement decision

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[14] C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 SCIENCE 1386, 1387 (2013).

[15] *FTC v. Actavis*, 570 U.S. 136 (2013).

[16] Petition for a Writ of Certiorari, *SmithKline Beecham Corp. v. King Drug Co.*, at 1, 14 (U.S. filed Feb. 19, 2016).

[17] *King Drug Co. v. SmithKline Beecham Corp.*, 791 F.3d 388, 405–06 (3d Cir. 2015).

[18] FTC, *Last Remaining Defendant Settles FTC Suit that Led to Landmark Supreme Court Ruling on Drug Company "Reverse Payments,"* Feb. 28, 2019.

[19] *FTC v. AbbVie*, 107 F. Supp. 3d 428, 436 (E.D. Pa. 2015), *aff'd*, 976 F.3d 327 (3d Cir. 2020).

[20] *In the Matter of Impax Labs.*, Dkt. No. 9373, at 144, 146 (FTC ALJ Chappell May 18, 2018).

[21] *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 165 (3d Cir. 2017). For a discussion of additional errors in settlement cases, see Michael A. Carrier, *Three Challenges for Pharmaceutical Antitrust*, 59 SANTA CLARA L. REV. 613 (2020).

[22] *In re Nexium Antitrust Litig.*, 842 F.3d 34, 63 (1st Cir. 2016). *See generally* Kevin B. Soter, *Causation in Reverse Payment Antitrust Claims*, 70 STAN. L. REV. 1295 (2018).

2. This addresses perversion of Hatch-Waxman Act by which 180-day period has morphed from incentive to invalidate patents to bottleneck blocking entry

VII. Citizen Petitions: Harm

A. Meant to raise legitimate concerns, but really used to delay generic entry, with my empirical study showing that FDA denies 92% of "505(q)" petitions (against pending generic), 98% of late-filed petitions.[23]
B. Concerning examples: Shire ViroPharma's 46 filings, Teva's multiple Copaxone petitions, Bayer's Mirena petition 1 day before patent expiration, Mylan's delayed filing of petition on EpiPen alternative.[24]
C. From 2011 to 2015, 118 petitioners filed 505(q) petitions: *108* brand firms, 4 generic firms, 4 law firms or consultants, but only *2* public interest groups and *0* individuals
D. FDA has shown "concern[] that section 505(q) may not be discouraging the submission of petitions that are intended primarily to delay the approval of competing drug products and do not raise valid scientific issues."[25]
   1. FDA "remains concerned" that the resources it is forced to incur come "at the expense of completing the other work of the Agency."[26]

VIII. Citizen Petitions: Solution

A. The Stop Stalling Access to Affordable Medications Act is helpful in giving the FTC authority to bring Section 5 claim (and obtain strong penalties) against sham petitions. Benefits:
   1. Finding that delaying conduct is sham could help courts cut through firewall of *Noerr-Pennington* immunity.[27]
   2. Helpful to include as "sham" not only individual petitions but also "series" of such petitions
   3. Beneficial to give FTC Section 5 authority and put stamp of disapproval on abusive citizen petitions
   4. Useful deterrent to impose penalty of drug revenue (while petition under review) or (if larger) $50,000 a day
B. Potential strengthening amendment 1: Add supporting detail to general "sham" conduct
   1. Because of importance of petitioning, courts set high bar before finding sham exception to *Noerr* immunity
   2. Legislation could make clear that sham conduct bears specific markers of abusive behavior
   3. Relevant factors appear in FDA draft guidance[28] on "primary purpose of delay": (a) unreasonable length of time to submit petition; (b) multiple petitions challenging conduct that reasonably could have been known at time of earlier petition; (c) petition submitted close in time to date on which application could be approved; (d) petition submitted without supporting data/information; (e) petition raising same or substantially similar issues as prior petitions that have received response; (f) petition addressing standards for which FDA provided opportunity for public input but petitioner did not comment; (g) petition requesting that other applicants meet standards more rigorous than petitioner; (h) petitioner's history
   4. These factors common in abusive petitions
      a) In my empirical studies, I did not come across sham petitions not covered by these categories
      b) The factors also appear in S. 1895, the Lower Health Care Costs Act (approved 20-3 by Senate HELP Committee in June 2019) and H.R. 2455, the Ensuring Timely Access to Generics Act of 2019
C. Potential strengthening amendment 2: Recognize difficulty of proving subjective prong
   1. The legislation reflects the caselaw's "subjective" prong in a petitioner's use of the governmental process, as opposed to the outcome, to interfere with a rival
      a) But it is difficult to know why a petition is filed, and this information is often shielded by privilege issues
      b) For that reason, the court in *FTC v. AbbVie* made clear that:
         (1) Because of the difficulty of proving state of mind, intent "is usually a matter of inference."[29]
         (2) Subjective intent could be shown by the actions of experienced attorneys filing objectively baseless suits, which makes it "reasonable to conclude that they intended the natural and probable consequences of acts they knowingly did."[30]

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[23] Michael A. Carrier & Carl J. Minniti III, *Citizen Petitions: Long, Late-Filed, and At-Last Denied*, 66 AM. U. L. REV. 305 (2016).

[24] *See id.* at 344–47; Michael A. Carrier & Carl J. Minniti III, *The Untold EpiPen Story: How Mylan Hiked Prices by Blocking Rivals*, 102 CORNELL L. REV. ONLINE 53, 64–66 (2017).

[25] FDA, REPORT TO CONGRESS: EIGHTH ANNUAL REPORT ON DELAYS IN APPROVALS OF APPLICATIONS RELATED TO CITIZEN PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION FOR FISCAL YEAR 2015, at 8 (2016).

[26] *Id.*

[27] *Prof'l Real Estate Investors v. Columbia Pictures Indus.*, 508 U.S. 49 (1993); *United Mine Workers v. Pennington*, 381 U.S. 657 (1965); *E.R.R. Presidents Conference v. Noerr Motor Freight*, 365 U.S. 127 (1961).

[28] FDA, *Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act*, 2018.

[29] *FTC v. AbbVie*, 329 F. Supp. 3d 98, 125 (E.D. Pa. 2018), *aff'd on this ground*, 976 F.3d 327 (3d Cir. 2020).

[30] *Id.* at 126.

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2. Like *AbbVie*, legislation could make clear that:
   a) Evidence of intent can be shown not only through direct evidence but also through indirect evidence
   b) Experienced actors engaging in objectively baseless conduct could satisfy subjective prong

D. Potential strengthening amendment 3: Administrative changes
1. In addition to addressing antitrust liability for sham behavior, legislation could make helpful administrative changes, such as those offered in S. 660, the Efficiency and Transparency in Petitions Act.[31]
2. Because of delayed and serial petitions, require petition to be filed within finite period (60 days) of learning of safety/efficacy issue and mandate explanation for why repetitive petitions filed
3. Because of lack of transparency, require FDA to include comprehensive list of 505(q) petitions in annual reports to Congress, including:
   a) Timing of petition in relation to patents listed in Orange Book
   b) Time FDA expended on petition
   c) Delay (if any) in generic approval caused by petition and determination of how delay calculated
4. Such provisions would be helpful because FDA does not maintain an easily searchable list of 505(q) petitions, nor does it explain what constitutes a "delayed" petition
   a) FDA claims that only one petition each year is delayed, but considers delay only if it responds after 150-day deadline for addressing 505(q) petitions.[32]
   b) FDA does not consider that there could be delay from not approving generic until it resolves petition.

IX. Biosimilar Disparagement: Harm

A. Biosimilars have been subject to disparagement claims in a way that generics have not
1. Because of their complexity, biosimilars differ more from biologics than generics differ from brand drugs
2. Biosimilars also rely on advertising campaigns rather than (as generics do) state substitution laws

B. Biosimilars are legally required to be "highly similar" to and have "no clinically meaningful differences" from biologics.[33]
1. FDA has made clear that "[m]inor differences . . . in clinically inactive components are acceptable,"[34] and even biologics themselves are "not identical batch-to-batch."[35]

C. Despite this, biologic firms have raised safety concerns with biosimilars, using four types of disparagement:
1. Fearmongering: *E.g.*, warning that a switch to a biosimilar could result in "another thalidomide" (which famously caused birth defects) or that a patient "could end up in an emergency room, or be[] hospitalized."[36]
2. Biosimilars act differently: *E.g.*, asserting that biosimilar "can behave differently in the body."[37]
3. Biosimilars not identical: *E.g.*, "no two biologic medicines are identical."[38]
4. Biosimilars not interchangeable: *E.g.*, "Even though infliximab biosimilars are very similar to REMICADE®, that doesn't mean they are interchangeable with REMICADE®."[39]

D. FDA has shown frustration with this conduct
1. Former Commissioner Scott Gottlieb "worried" about "efforts by branded companies to create confusion" about biosimilars' safety and effectiveness.[40]
   a) These messages "can potentially undermine consumer confidence in biosimilars in ways that are untrue" and "negatively impact a patient's judgment about an otherwise safe and effective product."[41]
2. FDA and FTC jointly explained that they "support competitive markets for biologics" and "have serious concerns about false or misleading statements and their negative impacts on public health and competition."[42]

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[31] For an explanation of these changes, see Michael A. Carrier, *Five Actions to Stop Citizen Petition Abuse*, 118 COLUM. L. REV. ONLINE 81 (2018).

[32] FDA, REPORT TO CONGRESS: SEVENTH ANNUAL REPORT ON DELAYS IN APPROVALS OF APPLICATIONS RELATED TO CITIZEN PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION FOR FISCAL YEAR 2014, at 9 (2015).

[33] 42 U.S.C. § 262(i)(2).

[34] FDA, *Biosimilar and Interchangeable Products*, https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products (last visited Apr. 24, 2021).

[35] Boehringer Ingelheim letter to FDA, Docket #FDA-2018-P-3281, at 3, Jan. 25, 2019.

[36] Christopher Rowland, *Marketers Are Having a Field Day*, WASH. POST, Jan. 9, 2019.

[37] *Pfizer Citizen Petition to FDA*, Aug. 22, 2018, https://www.bigmoleculewatch.com/wp-content/uploads/sites/2/2018/08/Citizen_Petition_from_Pfizer.pdf (referring to Amgen YouTube video).

[38] *Id.*

[39] Janssen Biotech, Inc., *Finely Tuned Patient Brochure*, Dec. 2017 (cited in *Pfizer Citizen Petition*, at 8).

[40] Rowland, *Marketers Are Having a Field Day*.

[41] *Id.*

E. Most courts apply approaches not likely to recognize harm to biosimilars and patients from disparagement
   1. Judicial approach 1: No liability for disparagement-based antitrust claims.[43]
   2. Judicial approach 2: Presumption that exclusionary effects of disparagement de minimis, rebutted only by making difficult showing that alleged anticompetitive conduct is (1) clearly false, (2) clearly material, (3) clearly likely to induce reasonable reliance, (4) made to buyers without knowledge of the subject matter, (5) continued for prolonged periods, and (6) not readily susceptible to neutralization or other offsets by rivals.[44]
   3. Judicial approach 3: Case-by-case approach to determine antitrust liability.[45]
   4. Most courts apply first or second approach, making it nearly impossible to find antitrust liability even for monopolists that disparage rivals and harm consumers

X. Biosimilar Disparagement: Solution

A. Legislation could provide presumption that false advertising by monopolists constitutes monopolization.[46]
   1. As mentioned above, most courts excessively defer to advertising-related conduct
   2. The most fundamental critique against applying antitrust to false advertising conduct—that it does not require marketwide effects—is addressed by the defendant's control over the market
   3. Before presumption applies, plaintiff must show defendant has monopoly power
      a) Biologics likely to have such power, as judged by charging of high prices without suffering losses

B. Presumption applies if plaintiff shows that defendant engaged in false advertising
   1. Liability for false advertising requires that defendant's conduct is literally false or misleading, is material, actually deceived (or was likely to deceive) consumers, and caused (or was likely to cause) harm to plaintiff.[47]
   2. False advertising's requirements assist antitrust by focusing on bad conduct, showing its relevance, and demonstrating harm
   3. A monopolist's materially false advertising makes it more difficult to compete on merits, can be repurposed to harm any rival, and is hard to credibly rebut without souring consumers on factual claims more generally
   4. Presumption also is appropriate given the near certainty of anticompetitive effects: in small field, at least one competitor is harmed, with safety-based claims against biosimilars likely to harm all competitors

C. Defendant can rebut presumption by showing ineffectiveness of false or deceptive statement
   1. Monopolist could show that, despite likelihood of deception from literally false or misleading claim, harm from deception did not materialize
      a) Rebuttal not likely for biologic firms, as consumers are not able to do own testing and rely on results

D. Framework for attempted monopolists
   1. Because attempted monopolists do not control the market, I do not propose a rebuttable presumption of an antitrust violation
   2. But in determining whether the defendant engaged in exclusionary conduct, legislation could focus on four key factors: (a) targeting a new entrant; (b) actual harm from the false or misleading advertising; (3) the degree of materiality; and (d) interactions with other anticompetitive conduct.

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[42] Joint Statement of the Food & Drug Administration and the Federal Trade Commission Regarding a Collaboration to Advance Competition in the Biologic Marketplace, at 3, Feb. 3, 2020.

[43] Retractable Tech. v. Becton Dickinson & Co., 842 F.3d 883, 895 (5th Cir. 2016); Sanderson v. Culligan Int'l Co., 415 F.3d 620, 624 (7th Cir. 2005).

[44] Nat'l Ass'n of Pharm. Mfrs. v. Ayerst Labs., 850 F.2d 904, 916 (2d Cir. 1988); Am. Council of Certified Podiatric Physicians & Surgeons v. Am. Bd. of Podiatric Surgery, 323 F.3d 366, 370 (6th Cir. 2003); Am. Prof'l Testing Serv., v. Harcourt Brace Jovanovich Legal & Prof'l Publ'ns, 108 F.3d 1147, 1152 (9th Cir. 1997); Lenox MacLaren Surgical Corp. v. Medtronic, 762 F.3d 1114, 1127–28 (10th Cir. 2014); Duty Free Am.'s v. Estee Lauder, 797 F.3d 1248, 1268–69 (11th Cir. 2015).

[45] W. Penn. Allegheny Health Sys. v. UPMC, 627 F.3d 85, 108–09 (3d Cir. 2010); Caribbean Broad. Sys. v. Cable & Wireless PLC, 148 F.3d 1080, 1087 (D.C. Cir. 1998); Int'l Travel Arrangers v. W. Airlines, 623 F.2d 1255, 1268 (8th Cir. 1980).

[46] For a more complete elaboration of this framework, see Michael A. Carrier & Rebecca Tushnet, *An Antitrust Framework for False Advertising*, 106 IOWA LAW REVIEW __ (forthcoming 2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3593914.

[47] *Id.* [draft at 131].

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XI. Pharmaceutical Consolidation: Harm

A. In recent years, the pharmaceutical industry has become more consolidated, which has contributed to higher prices.[48]

B. The consolidation is not driven by innovation
   1. If innovation and individual drugs' competitive advantage determined success, we would see turnover among leading firms, reflecting success in R&D
   2. In contrast, the industry is marked by the dominance of the same large firms over time, with the top 20 firms (by global pharmaceutical sales) nearly identical (other than acquisitions) between 2009 and 2019.[49]
   3. Large firms' share of New Active Substances submitted to FDA declined from 30% in 2009 to 20% in 2018, with small firms' share increasing to 70%.[50]
   4. The industry's consolidation shows expansion "through M&A" rather than "organic growth and innovation."[51]
      a) At the same time, "the pace of merger activity" has "become disconnected from FTC enforcement."[52]

C. The FTC has continued its longstanding approach of addressing potentially anticompetitive mergers by requiring the divestiture of overlapping products in specific markets
   1. Between 1994 and 2020, the FTC "challenged 67 drug mergers worth over $900 billion, moved to block only one, and settled virtually all of the remainder subject to divestitures."[53]
      a) Result of narrow focus on specific markets? "[T]he swapping of assets within a relatively small group of large and increasingly powerful firms."[54]
   2. Commissioner Chopra has lamented that "[t]he FTC's strategy of focusing on whether pharmaceutical companies have any overlaps in their drug product lineup is narrow, flawed, and ineffective."[55]
   3. Then-Commissioner (current Acting Chair) Slaughter has demonstrated "concern[]" that the "analytical approach [based on drug overlaps] is too narrow" and called for an approach looking "more broadly" at whether a merger "is likely to exacerbate anticompetitive conduct . . . or to hinder innovation."[56]

XII. Pharmaceutical Consolidation: Solution

A. Theories of merger enforcement
   1. Traditional theory of competitive harm is based on coordinated effects: in reducing number of firms in market, merger would make it easier for remaining firms to collude.[57]
   2. But the agencies also have recognized a role for unilateral effects, as "[t]he elimination of competition between two firms" resulting from the merger "may alone constitute a substantial lessening of competition."[58]

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[48] *E.g.*, Alice A. Bonaime & Ye (Emma) Wang, *Mergers, Product Prices, and Innovation: Evidence from the Pharmaceutical Industry* (June 2020), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3445753; Chintan V. Dave, Aaron S. Kesselheim, Erin R. Fox, Peihua Qiu, & Abraham Hartzema, *High Generic Drug Prices and Market Competition: A Retrospective Cohort Study*, 167 ANN. INTERN. MED. 145 (2017).

[49] See Patricia M. Danzon & Michael A. Carrier, *The Neglected Concern of Firm Size in Pharmaceutical Mergers*, 84 ANTITRUST LAW JOURNAL [draft at 5, Table 1] (forthcoming 2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3787161 (8 of top 10 in 2019 were in top 10 in 2009, with remaining 2 in top 15).

[50] IQVIA INSTITUTE, THE GLOBAL USE OF MEDICINE IN 2019 AND OUTLOOK TO 2023, at 36 (Jan. 2019).

[51] AMERICAN ANTITRUST INSTITUTE, FROM COMPETITION TO CONSPIRACY: ASSESSING THE FEDERAL TRADE COMMISSION'S MERGER POLICY IN THE PHARMACEUTICAL SECTOR 12, Sept. 3, 2020.

[52] *Id.*

[53] *Id.* at 10.

[54] *Id.* at 3.

[55] Dissenting Statement of Commissioner Rohit Chopra, *In the Matter of AbbVie, Inc. / Allergan plc*, Comm. File No. 1910169, at 3, May 5, 2020.

[56] Dissenting Statement of Commissioner Rebecca Kelly Slaughter, *In the Matter of Bristol-Myers Squibb and Celgene*, Comm. File No. 191-0061, at 1, Nov. 15, 2019.

[57] DOJ & FTC, HORIZONTAL MERGER GUIDELINES ¶ 7.1 (2010).

[58] *Id.* ¶ 6.

a) In particular, by "eliminating competition," a merger "gives the merged firm incentives different from those of the merging firms."[59]
b) The FTC has used the concept of bargaining leverage in settings as varied as hospitals, pharmacy chains and insurers, and broadband.[60]

3. Congress can address pharmaceutical consolidation by applying this leverage analysis to four settings:

B. Solution 1: Adopt Presumption Against Mergers Between Large Firms[61]

1. Large firms (roughly top 10[62]) possess advantages in insurance and reimbursement, marketing, and financing
   a) Insurance and reimbursement advantages as company with large portfolio has more leverage in negotiating with PBMs through bundled rebates
   b) Detailing, marketing, and sales benefits from, for example, combining multiple drugs on same visit to doctor's office
      (1) Firms also gain from economies of scope in marketing drugs across multiple therapeutic areas to large, multi-specialty doctor groups
   c) Financing advantages as firms with large portfolios use retained earnings from sales to fund marketing and acquisitions, providing a lower cost of capital than is available to smaller firms relying on external sources
2. Combination of large firms' enduring and unique advantages, typically without any countervailing efficiencies, supports presumption that merger of two large firms harms competition
   a) Empirical data provides no evidence that mergers between large firms improve R&D productivity through economies of scale or scope.[63]
   b) In fact, some studies show *negative* impact on R&D, patents, and the number of new molecular entities after large firms merge.[64]
   c) Any efficiency savings are not likely to be passed on to consumers through lower prices because of insurance and patients' lack of information about alternatives
   d) In rare case, firms could rebut presumption by showing synergies from cross-national complementarity of assets or better utilization of excess manufacturing capacity without risk of increased market power

C. Solution 2: Consider Multiple Factors for Mid-size Firms

1. For mid-size firms (roughly 11-20[65]), the agencies should apply heightened scrutiny
   a) These firms compete with the largest firms in marketing and as potential acquirors of smaller firms
   b) Ownership of a "must-have" blockbuster product favors aggressive enforcement
2. Example: AbbVie/Allergan, combining large (AbbVie) and mid-size (Allergan) firms
   a) Merger threatened harm because of presence of must-have blockbuster products
      (1) AbbVie's Humira and Allergan's Botox are blockbuster drugs that PBMs must include on formularies
   b) Relatedly, merger raises concern of rebate walls, which occur when manufacturers provide rebates or discounts on condition that payors purchase bundled collection of drugs
      (1) In theory, "rebates" sound good but in reality, they can be used to stifle competition, preventing patients from accessing quality, lower-cost medicines
      (2) *E.g.*: Pfizer sued J&J for threatening not to pay rebates unless insurers limited coverage of Pfizer's Inflectra; as a result, 90% of accounts did not purchase Inflectra, resulting in 4% market share

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[59] FTC & DOJ, COMMENTARY ON THE HORIZONTAL MERGER GUIDELINES 25 (2006).

[60] *ProMedica Health System, Inc. v. FTC*, 749 F.3d 559 (6th Cir. 2014) (hospitals); FTC, *Price Increases May Result from Combination of the Two Full-service Hospitals in Slidell, Louisiana*, Sept. 13, 2006, http://www.ftc.gov/opa/2003/04/lahospmerger.htm (same); *FTC v. OSF Healthcare System*, 852 F. Supp. 2d 1069 (N.D. Ill. 2012) (same); FTC, MERGER GUIDELINE COMMENTARY, at 35–36 (retail drug store chains); U.S. Dept. of Justice, *Revised Competitive Impact Statement in U.S. v. Aetna Inc. and The Prudential Ins. Co.* (N.D. Tex., filed Aug. 3, 1999), https://www.justice.gov/atr/case-document/file/483491/download (health insurance); Cecilia Kang & Emily Steel, *Regulators Approve Charter Communications Deal for Time Warner Cable*, N.Y. TIMES, at B1, Apr. 25, 2016, https://www.nytimes.com/2016/04/26/technology/charter-time-warner-cable-bright-house-cable-deal.html (broadband).

[61] For additional detail, see Danzon & Carrier, *Neglected Concern of Firm Size*.

[62] Based on 2019 global sales, the top 10 firms are Pfizer, Roche, Novartis, Johnson & Johnson, Merck, Sanofi, AbbVie, GlaxoSmithKline, Takeda, and Bristol Myers Squibb. *See id.* at 5 (Table 1).

[63] *See, e.g.*, Patricia M. Danzon, Sean Nicholson, & Andrew J. Epstein, *Mergers and Acquisitions in the Pharmaceutical and Biotech Industry*, 28 MANAGERIAL & DECISION ECON. 307 (2007).

[64] Justs Haucap, Alexander Rasch, & Joel Stiebale, *How Mergers Affect Innovation: Theory and Evidence*, 63 INT'L J. INDUS. ORG. 283 (2019); Carmine Ornaghi, *Mergers and Innovation in Big Pharma*, 27 INT'L J. INDUS. ORG. 70 (2009); Bernard Munos, *Lessons from 60 Years of Pharmaceutical Innovation*, 8 NATURE REVIEWS DRUG DISCOVERY 959 (2009).

[65] Based on 2019 global sales, firms 11 through 20 are AstraZeneca, Amgen, Gilead, Eli Lilly, Bayer, Novo Nordisk, Allergan, Boehringer-Ingelheim, Celgene, and Biogen. *See* Danzon & Carrier, *Neglected Concern of Firm Size*, at 5 (Table 1).

(3) Consumer groups worried that "combining AbbVie's blockbuster drugs with Allergan's is likely to exacerbate . . . anticompetitive conduct" because of merged firm's "increased ability to bundle rebates across its enlarged drug portfolio in order to keep competing branded drugs, generics, and biosimilars off of PBMs' and insurers' preferred position on their drug formularies."[66]

3. Also raising concern was the firms' history of potentially anticompetitive behavior
   a) AbbVie: ongoing cases on pay-for-delay settlements, sham conduct, and patent thickets
      (1) The Third Circuit reversed the dismissal of the FTC's complaint alleging that AbbVie paid Teva to delay entering the market with a generic version of a testosterone gel by providing Teva with an authorized generic version of a cholesterol drug with expected sales of more than $175 million over four years.[67]
      (2) The court upheld the refusal to dismiss the FTC's claim that AbbVie engaged in objectively baseless litigation because "no reasonable litigant" in its position "would believe it had a chance of winning."[68]
      (3) A court dismissed a lawsuit[69] challenging AbbVie's "thicket" of more than 100 patents covering rheumatoid-arthritis-treating Humira, but the case is on appeal and the opinion has been criticized.[70]
   b) Allergan: citizen petitions and sovereign immunity
      (1) Filed repetitive citizen petitions to delay generic competition on dry-eye-disease-treating Restasis; FDA denied second by stating that Allergan "should not be surprised" by its response and denied third by lamenting that petition "repeats many of the assertions" central to petitions already addressed.[71]
      (2) In a maneuver that failed[72] and garnered widespread criticism,[73] sought to avoid "inter partes review" at Patent Office by transferring patents to a Native American tribe to exploit tribal immunity

D. Solution 3: Address Incentives in "Killer Acquisitions" and Innovation Markets Settings

1. "Killer acquisitions" worrisome, with empirical study showing a 23% reduced likelihood that a drug would be developed after being acquired by an incumbent with an overlapping drug.[74]
   a) *E.g.*: Questcor had monopoly on infant-seizure-treating ACTH; acquired rights to competing Synachten, then repeatedly raised price, which increased 85,000% from 2001 ($40/vial) to 2017 ($34,000/vial).[75]
2. Drug mergers are structured to avoid Hart-Scott-Rodino Act's (HSR's) pre-merger notification requirements
   a) Empirical analysis found "clear bunching of deals right below the review threshold," but only for "deals in which the target has projects that overlap with the acquirer.[76]
      (1) Below-threshold acquisitions resulted in lower product launch rate (1.8% vs. 9.1%) and higher discontinuation rate (94.6% vs. 83.3%).[77]
3. Congress could consider HSR adjustments in pharmaceutical industry
   a) Could lower thresholds by a certain percentage for size-of-person and size-of-transaction tests
   b) Size of reduction would depend on tradeoff between greater chance of finding anticompetitive deals and increased burden of heightened reporting requirements
   c) Congress could solicit guidance from agencies on threshold adjustments to balance these objectives
4. Related concept is "innovation markets" (markets for research and development)
   a) The concern is that a merger between the two firms most advanced in R&D results in a heightened incentive to suppress one of the research paths
   b) Antitrust agencies have challenged mergers in innovation markets, like (1) Glaxo and Wellcome, (2) Upjohn and Pharmacia, (3) GlaxoWellcome and SmithKline Beecham, and (4) Baxter and Immuno.[78]

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[66] Letter from Families USA et al. to The Honorable Joseph J. Simons, at 5, Sept. 12, 2019.

[67] *FTC v. AbbVie*, 976 F.3d 327, 357 (3d Cir. 2020).

[68] *Id.* at 366.

[69] *In re Humira (Adalimumab) Antitrust Litig.*, 465 F. Supp. 3d 811 (N.D. Ill. 2020).

[70] HERBERT HOVENKAMP, MARK D. JANIS, MARK A. LEMLEY, CHRISTOPHER R. LESLIE, & MICHAEL A. CARRIER, IP AND ANTITRUST § 15.03[A][2][c], at 15–42.4 to 15-42.4–4 (Supp. 2020).

[71] Citizen Petition Denial Response Letter from FDA CDER to Allergan and Physical Pharmaceutica, Feb. 10, 2016; Citizen Petition Denial Response Letter from FDA CDER to Allergan, Jan. 2, 2018.

[72] Saint Regis Mohawk Tribe v. Mylan Pharm. Inc., 896 F.3d 1322, 1325 (Fed. Cir. 2018).

[73] Meg Tirrell, *Allergan Responds to Mounting Criticism of Mohawk Patent Deal*, CNBC, Oct. 3, 2017.

[74] Colleen Cunningham, Florian Ederer, & Song Ma, *Killer Acquisitions*, 129 J. POLIT. ECON. 649, 652 (2021).

[75] FTC, *Mallinckrodt Will Pay $100 Million to Settle FTC, State Charges It Illegally Maintained its Monopoly of Specialty Drug Used to Treat Infants*, Jan. 18, 2017.

[76] Cunningham, Ederer, & Ma, *Killer Acquisitions*, at 685.

[77] *Id.* at 686.

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c) A framework for innovation markets could examine (1) concentration among firms reasonably likely to reach the market, (2) anticompetitive theories of innovation suppression, and rebuttals based on (3) rivals' entry, (4) efficiencies, and (5) a "Schumpeterian" need for size.[79]

E. Solution 4: Encourage More Nuanced Analysis of Generic Mergers

1. In recent years, the generics industry has been changing, with certain companies earning a significant amount of revenue from patented brand drugs
2. My co-authored empirical analysis of the industry found that, as compared to "pure" generics, "mixed" generics do not as robustly promote competition: they are less likely to challenge patents, more likely to abandon those challenges, and less likely to win them.[80]
   a) The mixed generic firms (in decreasing order of generic share) are Endo, Fresenius, Horizon, Teva, Shire, Valeant, Allergan, Novartis-Sandoz, and Pfizer
   b) The pure generic firms (in decreasing order of generic share) are Aurobindo, Amneal, West Ward, Alvogen, Perrigo, Dr. Reddy's, Prasco, Apotex, Mallinckrodt, Mylan, and Lupin.[81]
3. The agencies should consider the nature of "generic" companies that merge, welcoming mergers that create purer generics and exercising more scrutiny of those diluting generics by mixing them with brand sales
   a) When a mixed firm merges with a pure generic, the expected effects on "acting like a generic" may depend on the shares of the mixed firm and the relative size of the two firms
   b) Pure generics can act like "mavericks" that "play[] a disruptive role in the market to the benefit of customers."[82]
4. Congress can require the agencies, when evaluating mergers, to consider a generic firm's nature as a mixed or pure firm and its incentives to pursue the initially intended function of promoting competition

XIII. Conclusion

A. Anticompetitive behavior costs consumers billions in unnecessary payments and untold suffering when patients go without food or rent, split pills in half, or don't take needed medicines

B. Legislation on product hopping, pay-for-delay settlements, citizen petitions, biosimilar disparagement, and pharmaceutical consolidation would make patients' lives better without harming innovation

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[78] Michael A. Carrier, *Two Puzzles Resolved: Of the Schumpeter-Arrow Stalemate and Pharmaceutical Innovation Markets*, 93 IOWA L. REV. 393 (2008).

[79] *Id.* at 415–29.

[80] Michael A. Carrier, Mark A. Lemley, & Shawn Miller, *Playing Both Sides? Branded Sales, Generic Drugs, and Antitrust Policy*, 71 HASTINGS LAW JOURNAL 307 (2020).

[81] *Id.* at 353 (Table A.1).

[82] DOJ & FTC, HORIZONTAL MERGER GUIDELINES § 2.1.5 (2010).

Mr. CICILLINE. Thank you, Professor Carrier.
I now recognize Professor Feldman for 5 minutes.

TESTIMONY OF ROBIN FELDMAN

Ms. FELDMAN. Mr. Chair and esteemed Members of the Committee, I'm honored to be here today to address an issue that is causing real pain for patients and for those who are trying to help them.

Open and vigorous competition is the backbone of U.S. markets, but we're not seeing that in the pharmaceutical industry. We know pharma markets aren't working because we see monopoly pricing extend well beyond the statutory grant of exclusivity. That hurts patients who can't access affordable medicines and it burdens taxpayers.

Quite simply, pharmaceutical companies are repeatedly gaming the system to protect and extend their monopolies. Companies are doing this through schemes to block generic entry, including product hopping, pay for delay, and citizen petition abuse. Companies string these games out one after another to maintain monopoly pricing. This Committee has an historic opportunity to address the problem.

In describing this anticompetitive gaming, I would like to focus on a few key issues. First, many of the games, including product hopping, involve making some modification to an existing drug. The company then pushes the market to the new version, which is protected by shiny new patents. One can see this, for example, in the market for treating opioid use disorder when a company switched from tablets to melt-a-ways just before the patents expired.

Now, these modification patents are often quite weak, and when generics fully challenge them in court, the generic wins three-quarters of the time. The challenge takes years, and in the meantime, there's no competition and prices stay high.

Most important, when a company makes a modification to a drug, like changing a tablet from 20–40 milligrams, the R&D is far less than for the drug's initial discovery. A company should be able to earn its reward in the market for the modification. It's really the massive investment in the initial discovery for which government should intervene in the market, put its thumb on the scale, and give the company years of patent protection.

These gaming opportunities also mean that much of the system is focused on repurposing old drugs rather than discovering new ones. In fact, 78 percent of the drugs associated with new patents aren't new drugs coming on the market; they are drugs we already have.

Now, against this backdrop of repeated anticompetitive gaming, the pharma industry also has become increasingly consolidated. Pharma now outsources most of its R&D, generally by buying startup after startup. All this reduces the chance of disruption and competition in the industry.

Antitrust law just hasn't kept up, either with the monopoly gaming or with the waves of mergers and buy-ups. Instead, courts and agencies tend to focus on a single behavior or a single startup purchase. That misses a lot. For example, if a dominant firm buys 100

companies, the likelihood that any one purchase harms competition is low. The likelihood that the pattern of acquisitions harms competition is much greater. The same is true with the pattern of behavior.

Much of this monopoly gaming has blossomed just in the last 15 years. It's not age old, and it's not inevitable. I am tremendously encouraged to see bipartisan efforts to address these critical needs and to help improve access to affordable prescription drugs for patients.

Thank you.

[The statement of Ms. Feldman follows:]

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Written Testimony of Professor Robin Feldman,
University of California Hastings College of the Law
Before the
U.S. House of Representatives, Committee on the Judiciary
Subcommittee on Antitrust, Commercial & Antitrust Law

Hearing on Treating the Problem:
Addressing Anticompetitive Conduct and Consolidation in Health Care Markets
April 29, 2021

Open and vigorous competition is the backbone of U.S. markets, but we are not seeing that in pharmaceutical markets.[1] Rather, drug companies are engaging in regulatory games, stringing these out, one after another, while competition languishes on the sidelines.

We know pharmaceutical markets are not working because we can see monopoly pricing extend beyond the statutory grant of exclusivity, to the detriment of patients and taxpayers. And we can see the harms of monopoly pricing when, for example, diabetic patients are forced to skip or ration their life-saving insulin.[2] Although discovered almost a century ago, this drug still costs Medicare patients an average of more than $800 out-of-pocket each year.[3]

In general, Americans pay an average of 4 times more for prescription drugs in comparison to other industrialized nations.[4] For certain drugs, the price can be more than 60 times greater, even

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[1] Portions of these comments are derived from the following works of mine, which contain additional, in-depth explorations of the issues: Robin Feldman & Evan Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, 53 HARV. J. LEGIS. 500 (2016); ROBIN FELDMAN & EVAN FRONDORF, DRUG WARS: HOW BIG PHARMA RAISES PRICES AND KEEPS GENERICS OFF THE MARKET (Cambridge University Press, 2017); Robin Feldman, Evan Frondorf, Andrew K. Cordova & Connie Wang, *Empirical Evidence of Drug Pricing Games—A Citizen's Pathway Gone Astray*, 20 STAN. TECH. L. REV. 39 (2017); Robin Feldman, *May Your Drug Price Be Evergreen,* 5 OXFORD J.L. & BIOSCI. 590 (2018); Robin Feldman, *Drug Companies Keep Merging. Why That's Bad for Consumers*, WASH. POST (Apr. 6, 2021), https://www.washingtonpost.com/outlook/2021/04/06/drug-companies-keep-merging-why-thats-bad-consumers-innovation/; Mark A. Lemley & Robin Feldman, *Atomistic Antitrust*, UC Hastings Research Paper Forthcoming, available at SSRN: https://ssrn.com/abstract=3793809 or http://dx.doi.org/10.2139/ssrn.3793809.

[2] *See* COLO. DEPT. OF LAW, PRESCRIPTION DRUG PRICING REPORT 2 (2020) (40% of Coloradans using insulin reported having to skip or ration doses at least once a year).

[3] *Id.* at 38.

[4] STAFF OF H.R. WAYS & MEANS COMM., 116TH CONG., A PAINFUL PILL TO SWALLOW: U.S. VS. INTERNATIONAL PRESCRIPTION DRUG PRICES 3 (2019).

after rebates.[5] It is tough to tell patients in Chicago to pay hundreds of dollars for a drug when their cousin in Toronto pays $30.

Although expensive specialty drugs are causing their fair share of pain, the out-of-pocket costs for the majority of top-selling prescription drugs have increased by more than 50% over the last decade, and many have more-than-doubled in price.[6] At some point, these price increases are unsustainable. After all, every budget—even the government's—has a breaking point. But how did we get here in the first place, and how do we fix it?

Quite simply, competition is the key to a prescription drug market that is innovative and accessible. To this end, the federal government has created a crucial system of incentives—in the form of patents and other exclusivities—that encourage drug innovation, research, and development. In theory, we should see a cycle of innovation and reward, followed by generic companies entering the market, bringing down prices to competitive levels. That is the bargain between drug-makers and society. This design, however, is a far cry from what is actually happening.

Instead, pharmaceutical companies are gaming the system to protect and extend their monopolies. Companies do this through anticompetitive schemes to block generic entry, including product hopping, pay-for-delay, and citizen petition abuse. This committee has an historic opportunity to alleviate the problem by enacting legislation that will help improve access to affordable prescription drugs for patients.

The temptation for companies to engage in anticompetitive gaming is quite strong. As a drug patent nears expiration and generic competition looms on the horizon, a brand-name company can face the loss of hundreds of millions of dollars in revenue. With so much at stake, pharmaceutical companies have entered into pay-for-delay agreements with generic drug-makers.[7] It is an ingenious approach in which the brand-name drug company shares a portion of its monopoly profits with the generic in exchange for the generic agreeing to stay out of the market for a specified period of time. It's a win-win for both the generic and the brand company, unfortunately, at the expense of everyone else.

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[5] *Id.*

[6] Nathan E. Wineinger et al., *Trends in Prices of Popular Brand-Name Prescription Drugs in the United States*, 2 JAMA NET. OPEN (2019), doi: 10.1001/jamanetworkopen.2019.4791.

[7] *See generally* FELDMAN & FRONDORF, DRUG Wars, *supra* note 1, at 34; *see also* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553 (2006); C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629 (2009); Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 TEX. L. REV. 685 (2009); Steve D. Shadowen, Keith B. Leffler & Joseph T. Lukens, *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 RUTGERS L.J. 1 (2009); Matthew Avery & Mary Nguyen, *The Roadblock for Generic Drugs: Declaratory Judgment Jurisdiction for Later Generic Challengers*, 15 N.C. J.L. & TECH. 1 (2013); Jessie Cheng, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry*, 108 COLUM. L. REV. 1471 (2008).

The 2013 Supreme Court decision in *Actavis*[8] paved the way for antitrust scrutiny of pay-for-delay. In response, companies simply have made these agreements more complex and convoluted. Today, there are numerous indications of complex value transfers in exchange for generic drugs staying off the market.[9] When competitors shake hands and agree that the less-expensive drug should stay off the market, it is bad for consumers.

Pay-for-delay is only one of the anticompetitive strategies in the vast arsenal that pharma companies launch against lower-priced competitors. Some of these games blatantly serve to delay the entry of competition. For example, The Food and Drug Administration's citizen petition process was created in the 1970s as a mechanism for ordinary citizens to raise concerns about food, drugs, and FDA regulations. That process, however, has clearly gone astray. In many cases, the concerned citizen is actually a large drug company raising frivolous or questionable claims. In some years, out of all citizen petitions filed at the FDA—including ones concerning tobacco, food, dietary supplements, and medical devices—one in five involves a pharma company attempting to block a competitor.[10] Nearly 40% of these petitions are filed a year or less before the FDA approves a generic, suggesting that many of these are last-ditch efforts to maintain higher prices as long as possible.[11] Although the FDA denies 90% of these petitions,[12] the process takes time. These abusive filings force the FDA to spend its limited resources reviewing petitions, rather than approving safe and effective medications.

Product-hopping is another strategic game deployed to block competitors.[13] Product-hopping involves modifying a drug, often just before the patents expire. The company then pushes doctors and health plans to favor the new version or removes the old one from the market altogether. If successful, there is no market for the old drug—just a market for the new one, protected by shiny new patents.

These additional patents may cover changes to a drug's dosage, formulation, or delivery system, such as whether it comes in pill or capsule form. Although the initial patent on a drug might cover the basic chemical or biologic molecule, the fifth patent might cover a change that has a negligible benefit to the patient.

In fact, much of the patenting activity these days relates to extending protection for existing medications. Specifically, 78% of the drugs associated with new patents are not new drugs coming on the market, but existing ones.[14]

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[8] Fed. Trade Comm'n v. Actavis, Inc., 133 S. Ct. 2223, 2227 (2013).

[9] *See generally* Laura Karas, Gerald F. Anderson, Robin Feldman, *Pharmaceutical "Pay-for-Delay" Reexamined: A Dwindling Practice or a Persistent Problem?*, 71 HASTINGS L.J. 959 (2020); Robin C. Feldman & Prianka Misra, *The Fatal Attraction of Pay-for-Delay*, 18 CHI.-KENT J. INTELL. PROP. 249, 253-254 (2019).

[10] Feldman et al., *Citizen's Pathway*, *supra* note 1, at 44.

[11] *See id.*

[12] *See* Michael A. Carrier & Carl Minniti, *Citizen Petitions: Long, Late-Filed, and At-Last Denied*, 66 AM. U. L. REV. 305, 332-33, 333 (table 4) (2016) (finding that between 2011 and 2015, the FDA denied 92% of section 505(q) citizen petitions, the type most often employed to oppose generic entry).

[13] *See generally* FELDMAN & FRONDORF, DRUG Wars, *supra* note 1, at 69.

[14] Feldman, *May Your Drug Price*, *supra* note 1, at 590.

These "secondary" patents are often quite weak. And when generics fully challenge such patents, the generic wins in court about three-quarters of the time.[15] A patent challenge may take years, however, during which competition is thwarted, and prices stay high. This is especially true for brand drugs fortified with dozens or even hundreds of secondary patents.

Science sometimes moves in small increments and sometimes in large leaps. The question isn't whether increments are important. The question is whether market incentives are sufficient or whether government should intervene in the market. When a company makes a secondary change to a drug—such as adjusting a drug's dosage—the R&D investment is generally far less than required for the drug's initial innovation. If that change in valuable to patients, a company should be able to earn its reward in the market for the modification. It is the massive investment in new research for which government needs to put its thumb on the scale and give the company a significant number of years of protection.

Against this backdrop of strategic behaviors, the pharmaceutical industry has become increasingly consolidated in recent decades, which lessens the chance of disruption and competition. Between 1995 and 2015, the 60 leading pharmaceutical companies merged to only 10.[16] Moreover, in 2017, just four companies produced more than 50% of all generic drugs.[17]

Consolidation has not been good for innovation. Rather, due to stagnating research results,[18] large pharma now outsources R&D, generally by buying startup after startup. In the process, innovation has shifted into lucrative, so-called "orphan drugs." Thus, although more new molecules are emerging, they help fewer people, and the price is extraordinary.

Consolidation also can enable drug-makers to directly quell competition. In what are known as "killer acquisitions," pharmaceutical companies acquire innovative companies solely to stop a potential future competitor.[19]

The consolidated industry structure raises other concerns. A small group of powerful drug manufacturers are responsible for shuttling new drugs through late-stage regulatory processes, leaving startup innovators with little choice other than acquisition or partnership with an entrenched firm.[20] The public regulatory process for drug development is rooted in concerns for patient safety. However, when large pharmaceutical companies serve as a secondary gatekeeper to FDA approval, they have every financial incentive to focus on maintaining their market position, not safeguarding the public interest.

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[15] *See* C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 SCIENCE 1386, 1387 (2013) (showing that 89% of patents in settled litigation disputes are secondary patents, which courts usually (68% of the time) find invalid or not infringed).

[16] OPEN MARKETS INSTITUTE, HIGH DRUG PRICES & MONOPOLY, https://www.openmarketsinstitute.org/learn/drug-prices-monopoly (last visited Apr. 27, 2021).

[17] Robert Coopman, *Generics Industry's Rise*, CHAIN DRUG REV. (Sept. 25, 2017).

[18] *See* Kenneth I. Kaitin, *Deconstructing the Drug Development Process: The New Face of Innovation*, 87 CLIN. PHARMACOL. THER. 356, 356 (2010) https://pubmed.ncbi.nlm.nih.gov/20130565/.

[19] *See* Colleen Cunningham, Florian Ederer & Song Ma, *Killer Acquisitions*, 129 J. POL. ECON. 649, 649 (2021).

[20] *See* Barak Richman, Will Mitchell, Elena Vidal, Kevin Schulman, *Pharmaceutical M&A Activity: Effects on Prices, Innovation, and Competition*, 48 LOY. U. CHI. L.J. 787, 787 (2017).

To compound the problem, antitrust law has not kept up, either with the behaviors that repeatedly block competition or with the waves of mergers and buy-ups. Instead, courts and agencies tend to focus on a single behavior or a single startup purchase, often missing the forest for the trees.[21] This atomistic focus is misplaced. Companies and markets don't focus on one particular act to the exclusion of all else. Business strategy emphasizes holistic, integrated planning; market outcomes aren't determined by a single act, but by the result of multiple acts in the overall context of the market.

Consider a dominant firm that buys 100 companies. The likelihood that any one purchase harms competition may be low. However, the likelihood that the pattern of acquisitions harms competition is much greater.[22]

Similarly, a drug company may take a number of actions to block competition. In the context of pharmaceutical regulation, those actions work together to prevent competition that would otherwise have occurred, not because of a genuine effort to persuade the government or the courts but because of the combined effect of multiple obstacles to generic competition.[23]

Antitrust law often misses these perspectives. For example, in deciding whether pharma company actions before courts and agencies can be considered antitrust violations, some courts have concluded that each action in a series must be evaluated separately.[24] Such approaches are misguided. One would miss the intricate harmonies of a symphony if the notes were considered separately. And so it is with antitrust. By adopting an overly atomistic approach, modern antitrust law frequently misses the power of actions in concert.

This committee has the opportunity to address anticompetitive behavior in the pharmaceutical arena, and I would like to highlight three actions that are important for reaching this goal. First, I respectfully suggest the committee approve pending bills related to citizen petition abuse, pay-for-delay, and product hopping. These are essential steps for improving access to affordable prescription drugs for patients. Second, various legislative actions can be taken to encourage a comprehensive, rather than an atomistic, application of antitrust law. [25] This would encourage courts and agencies to consider the effects of behaviors as a whole.

Third, I recommend what I call a robust "Second Look" policy. Most law is backward-looking, asking whether a defendant breached a contract, committed a tort, infringed a patent, etc. Merger analysis, however, is designed to prevent future harm, requiring a court or agency to predict what would happen with and without the merger.

The law struggles with this predictive task. Thus, we should rely, not only on the crystal ball predictions of a merger's effects, but also on an examination of what actually happens to competition in the future. Economic models are great, but the marketplace is where the rubber

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[21] *See generally* Lemley & Feldman, *Atomistic Antitrust*, *supra* note 1.

[22] *See id.*

[23] *See id.* at 3; *see also* Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 TEX. L. REV. 685 (2009).

[24] *See id.* at 19-21 (discussing disagreement among the federal circuits).

[25] *See id.* at 63-78 (discussing prospective solutions to the limiting focus of antitrust law).

hits the road. With this in mind, competition agencies should establish a robust system of post-merger review to ensure that predictions related to the competitive effects of pharmaceutical mergers and acquisitions were accurate.

Much of this monopoly gaming has blossomed just in the last 15 years. It is not age-old, and it is not inevitable. I am tremendously encouraged to see bipartisan efforts to address these critical issues affecting patient access to affordable drugs.

Mr. CICILLINE. Thank you, Professor Feldman.

I now recognize Mr. Abbott for 5 minutes.

TESTIMONY OF ALDEN ABBOTT

Mr. ABBOTT. Thank you, Chair Cicilline, Ranking Member Buck, distinguished Members of the Subcommittee. Thanks for this opportunity to testify.

As Chair Cicilline noted, I'm a former general counsel in the Federal Trade Commission. I served in other roles there as well. I also formerly served in the Antitrust Division of the Department of Justice.

In my statement today I will focus on four points.

(1) Additional funding for the Federal antitrust agencies;
(2) granting the FTC's statutory authority over nonprofit entities;
(3) what status antitrust statutory changes are appropriate;
(4) major legal reforms unrelated to antitrust.

First, additional funding. Federal antitrust enforcement is a bipartisan endeavor, and the FTC Commissioner unanimously supports substantially increased funding for FTC enforcement. As already noted, in real terms, resources have diminished over the last decade for such enforcement at the FTC.

I expect that the Biden Administration will recommend additional funding for the Justice Department's Antitrust Division as well.

Acting FTC Chair Slaughter recently testified before the Senate Commerce Committee that FTC employment has remained flat despite a growing workload, with merger filing doubling in recent years. She noted that FTC resource constraints lead to difficult tradeoffs that may adversely affect the pursuit of some meritorious investigations. I can attest to the accuracy of her observation based on my personal experience as FTC general counsel.

The problem of resource constraints is particularly acute in the case of healthcare merger review, given the increasing consolidation of healthcare institutions in recent years. Antitrust enforcers will need additional resources to ensure that this trend does not yield mergers that undermine the competitive process and harm consumers.

Second, FTC authority over nonprofits. Many healthcare entities, particularly hospitals, are organized as nonprofits. FTC and Antitrust Division Clayton Act merger enforcement applies both to for-profit and not-for-profit enterprises. The FTC Act has not reached nonprofit corporations. Then FTC Chair Simons testified in 2019 that this limitation, which makes no logical sense, has prevented the FTC from examining problematic unilateral conduct by hospitals.

In short, it's high time the FTC be given statutory authority over nonprofits.

Third, legislative change. While a few marginal adjustments to the antitrust statutes appear appropriate, I believe the mainstream consensus consumer welfare approach in the major statute should be retained. I believe there's a risk that far-reaching extensive statutory changes could generate costly welfare reducing uncertainty in antitrust enforcement.

However, as noted already by a couple of speakers, targeted statutory amendments narrowly tailored to address specific competitive healthcare sector abuses may be appropriate in the right circumstances. For that reason, I testified in favor of the CREATES Act.

Several distinguished scholars, including my fellow Witnesses, have advanced a number of thoughtful, additional targeted legislative proposals to address competitive problems affecting healthcare.

I will not comment today on the merits of specific proposals, but I would respectfully suggest that before legislating, Congress seriously weigh whether the benefits of eliminating targeted harmful conduct will likely be outweighed by the cost of condemning and deterring specific instances of such conduct that could have benefited consumers.

Fourth, nonantitrust issues. Major improvements to the competitive condition of the healthcare sector require far more than enhanced antitrust enforcements—and enhanced antitrust enforcement. Serious competitive distortions are posed by a host of State and Federal statutory provisions that bedeviled the healthcare sector, including as merely one example, State certificate of need laws that restrict competitive entry.

The Federal antitrust agencies have over the years done an outstanding job in calling for statutory and legislative reforms to improve healthcare competition under Republican and Democratic Administrations. Enhancing competition in healthcare markets, whether through enforcement or legislative and regulatory reform, has been and should remain a nonpartisan endeavor.

Thank you. I look forward to your questions.

[The statement of Mr. Abbott follows:]

MERCATUS CENTER
George Mason University

TESTIMONY

LACK OF RESOURCES AND LACK OF AUTHORITY OVER NONPROFIT ORGANIZATIONS ARE THE BIGGEST HINDRANCES TO ANTITRUST ENFORCEMENT IN HEALTHCARE

Alden F. Abbott
Senior Research Fellow, Mercatus Center at George Mason University

Treating the Problem: Addressing Anticompetitive Conduct and Consolidation in Health Care Markets
US House Committee on the Judiciary, Subcommittee on Antitrust, Commercial, and Administrative Law

April 29, 2021

Chairman Cicilline, Ranking Member Buck, and distinguished members of the Subcommittee on Antitrust, Commercial, and Administrative Law:

My name is Alden Abbott, and I am a senior research fellow at the Mercatus Center at George Mason University. My research focuses primarily on antitrust and competition policy. I formerly served as general counsel of the Federal Trade Commission (FTC). I have served in the US Department of Justice's Antitrust Division as well. I welcome the opportunity to give testimony that highlights key considerations in addressing anticompetitive conduct and consolidation in healthcare markets.

In this testimony, I will focus on four key points:

1. Additional funding for the federal antitrust agencies will substantially enhance their ability to deal effectively with antitrust challenges posed by healthcare competition.
2. The Federal Trade Commission Act should be modified so as to give the FTC authority over nonprofit entities.
3. Though existing antitrust statutes and agency guidance are fully adequate to address healthcare antitrust issues, narrowly targeted legislation to deal with specific abuses may be warranted.
4. Major legal reforms unrelated to antitrust, including state laws such as certificate-of-need laws, are key to substantially improving the effectiveness of healthcare competition.

ADDITIONAL FUNDING FOR THE ANTITRUST AGENCIES WILL SUBSTANTIALLY ENHANCE THE EFFECTIVENESS OF FEDERAL ANTITRUST ENFORCEMENT IN THE HEALTHCARE SECTOR

Federal antitrust enforcement is a bipartisan endeavor, and the commissioners who lead the FTC unanimously support substantially increased funding for the FTC's enforcement endeavors. Biden Administration requests for increased Antitrust Division resources may be forthcoming as well.

For more information or to meet with the scholar, contact
Mercatus Outreach, 703-993-4930, mercatusoutreach@mercatus.gmu.edu
Mercatus Center at George Mason University, 3434 Washington Blvd., 4th Floor, Arlington, Virginia 22201

Although government agencies invariably have a strong incentive to advocate for increased appropriations, such requests are fully warranted in the case of the FTC and the Antitrust Division.

Appropriate federal antitrust and consumer protection enforcement is good for the American economy. It promotes enhanced competition and consumer welfare. Regrettably, however, the effectiveness of federal enforcement in achieving these benefits is threatened by insufficient resources. As FTC Acting Chair Rebecca Kelly Slaughter explained in her April 20 testimony before the US Senate Committee on Commerce, Science, and Transportation,[1] FTC employment has remained flat despite a growing workload, with merger filings doubling in recent years. Lauren Feiner reports on that testimony:

> "The absence of resources means that our enforcement decisions are harder," [Slaughter] said. "If we think that we have a real case, a real law violation in front of us, but a settlement on the table that is maybe OK but doesn't get the job done, we have to make difficult decisions about whether it's worth spending a lot of taxpayer dollars to go sue the companies who are going to come in with many, many law firms worth of attorneys and expensive economic experts, versus taking that settlement."[2]

I can attest to the accuracy of Slaughter's observation, based on my experience as FTC general counsel in the Trump Administration. During my tenure, the FTC did indeed have to contend with resource limitations that adversely affected merger enforcement decision-making.

The problem of resource constraints is particularly acute in the case of healthcare merger reviews, given the increasing consolidation of healthcare institutions. As one noted healthcare scholar stated in 2019, "The Affordable Care Act did not start the consolidation rapidly occurring with hospitals/health systems and medical groups, but it most definitely accelerated the movement to combine. In the last five years, the number and size of consolidations have been at an all-time high."[3]

Moreover, according to health policy analyst Brian Miller and coauthors, "experts have expressed concern regarding a new merger wave due to pandemic-induced financial distress driven by the temporary cessation of profitable elective care and decreased hospital use."[4] Antitrust enforcers will need additional resources to ensure that this trend does not yield mergers that undermine the competitive process and harm consumers.

AMENDING THE FEDERAL TRADE COMMISSION ACT TO GIVE THE FTC AUTHORITY OVER NONPROFIT ENTITIES

Many healthcare entities (particularly hospitals) are organized as nonprofit corporations. This fact does not present problems for FTC and Antitrust Division merger enforcement under section 7 of the Clayton Act, which applies both to for-profit and not-for-profit enterprises. The Sherman Antitrust Act of 1890, enforced by the Antitrust Division (but not the FTC), also applies to nonprofits. Unfortunately, however, FTC nonmerger antitrust enforcement is stymied by the fact that it does not reach nonprofit

1. Lauren Feiner, "FTC Commissioners Agree They Should Act to Protect Consumer Privacy If Congress Doesn't," CNBC, April 20, 2021.
2. Feiner, "FTC Commissioners Agree."
3. Lawrence E. Singer, "Considering the ACA's Impact on Hospital and Physician Consolidation," *Journal of Law, Medicine & Ethics* 46, no. 4 (2019): 913–17.
4. Brian J. Miller et al., "Reversing Hospital Consolidation: The Promise of Physician-Owned Hospitals," *Health Affairs*, April 12, 2021; Lovisa Gustafsson and David Blumenthal, "The Pandemic Will Fuel Consolidation in U.S. Health Care," *Harvard Business Review*, March 9, 2021.

corporations.[5] This limitation makes no sense. It places major if not insurmountable obstacles before the FTC's ability to investigate and, where necessary, take enforcement action against a wide range of monopolizing or otherwise anticompetitive conduct in the healthcare sector.

Elimination of the nonprofit jurisdictional limitation has received bipartisan support by FTC commissioners, who have emphasized the constraint it places on the FTC's law enforcement capabilities. In September 2019, testifying before the US Senate Committee on the Judiciary, Subcommittee on Competition Policy, Antitrust, and Consumer Rights, then-FTC Chair Joseph Simons stated, "We're very interested in looking at unilateral conduct by hospitals, that are problematic under the antitrust laws[.]... But, generally when we do that, we find that they're nonprofits, and we don't have jurisdiction over them. That's another reason why we've been asking the Congress to eliminate our exemption for nonprofits."[6]

The FTC staff has profound expertise in healthcare markets, developed over decades.[7] It is high time it be given statutory authority over nonprofit entities to enable it to apply this expertise fully to all aspects of healthcare antitrust enforcement.

EXISTING ANTITRUST STATUTES AND AGENCY GUIDANCE ARE FULLY ADEQUATE TO ADDRESS HEALTH CARE ANTITRUST ISSUES, BUT NARROWLY TARGETED LEGISLATION TO DEAL WITH SPECIFIC ABUSES MAY BE WARRANTED

At this time, there are a variety of legislative proposals for far-reaching change in federal antitrust law. Respectfully, I do not believe that major statutory change in the antitrust field would be helpful. As I have argued recently,[8] although a few marginal adjustments to the antitrust statutes appear appropriate, such as elimination of the nonprofit exception to FTC jurisdiction, the mainstream consensus consumer-welfare approach should be retained. Antitrust statutory amendments affecting such areas as burdens of proof, presumptions, merger and monopolization standards, and blanket limits on mergers applicable to certain categories of firms (among other possible changes being advanced) would transform enforcement norms and judicial analysis, generating enormous private-sector uncertainty. This uncertainty would tend to deter innovation, harming consumers and the American economy. The claims by some that broad-based sweeping changes are needed owing to reduced competition in the American economy and ineffective antitrust enforcement have been rebutted by sound economic analysis[9]—at the very least, those claims have not been proven.

During my years as an executive in the FTC's Bureau of Competition and as FTC general counsel, I became quite familiar with FTC antitrust development and policy research applicable to healthcare. In

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5. Specifically, the FTC may enforce section 5 of the Federal Trade Commission Act (which forbids "unfair methods of competition") against "persons, partnerships, or corporations." The Federal Trade Commission Act defines the term "corporation" as an entity "organized to carry on business for its own profit or that of its members," thereby placing a major obstacle in the path of FTC enforcement against nonprofits. To be sure, the FTC has asserted the power to act when nonprofit status has in effect been a sham device to shield actual for-profit activities. See In re Ohio Christian College, 80 F.T.C. 815, 1972 FTC LEXIS 223 (F.T.C. July 29, 1970). And a federal court recognized the FTC's authority over a nonprofit that acted in concert, in profit-making activities, with a for-profit entity. See FTC v. AmeriDebt, Inc., 343 F. Supp. 2d 451 (D. Md. 2004). Nevertheless, the FTC is, at best, severely hampered when it seeks to bring an enforcement action under section 5.

6. Steven Porter, "Nonprofit Hospitals and Antitrust Enforcement: Should FTC Have Jurisdiction?," *HealthLeaders*, September 17, 2019.

7. For links describing the full measure of FTC competition-related research and enforcement initiatives over time, see Federal Trade Commission, "Health Care Competition," accessed April 26, 2021, https://www.ftc.gov/news-events/media-resources/mergers-competition/health-care-competition.

8. Alden F. Abbott, "US Antitrust Laws: A Primer" (Mercatus Policy Brief, Mercatus Center at George Mason University, Arlington, VA, March 2021).

9. White House, *Economic Report of the President*, February 2020, 199–226.

my opinion, the FTC staff possesses the legal tools (with the exception of the nonprofit limitation, discussed earlier) to fully investigate and take action against anticompetitive behavior in this sector. What's more, the FTC has had an excellent enforcement track record, including in hospital mergers. It currently is addressing a broad range of healthcare-related activity. Existing agency guidance, including the 2020 *Vertical Merger Guidelines*,[10] provide ample support for appropriate, evidence-based, economically sound enforcement. New general legislation is not needed.

Nevertheless, I recognize that targeted statutory amendments, narrowly tailored to address specific competitive healthcare sector problems, may be appropriate in certain circumstances. A good example is the newly minted CREATES Act, which deals with regulatory abuses that had allowed branded pharmaceutical companies to forestall competition from both generic drug and biosimilar producers.[11] I testified in favor of the CREATES Act in 2017 before this subcommittee and in 2016 before the Subcommittee on Competition Policy, Antitrust, and Consumer Rights.[12] There is an extensive literature on how regulated entities may manipulate the regulatory process to undermine competition,[13] and the abuses dealt with by the CREATES Act present a prime example of such conduct.

Several scholars recently have advanced a number of additional legislative proposals to deal with perceived competitive problems afflicting healthcare. Professor Michael Carrier notably has called for legislation providing that pharmaceutical "pay for delay" settlements are presumptively illegal; authorizing the FTC to challenge pharmaceutical "product hopping"; allowing the FTC to challenge certain "patent thickets" (a particular issue in the area of biologic drugs); and limiting sham citizen petitions filed by brand-name drug producers with the FDA.[14]

I will not comment in this testimony on the merits of these or other targeted healthcare-related proposals, which deserve serious scrutiny. I would, however, add a word of caution. Antitrust enforcement focuses on the specific facts of a case to determine whether conduct in the particular instance at hand is likely to undermine competition and reduce consumer welfare. But proposals that broadly seek to condemn a certain practice risk rendering illegal (and deterring businesses from pursuing) specific beneficial manifestations of that practice. Accordingly, before legislating, Congress should seriously weigh whether in attacking a particular practice, the benefits of eliminating targeted harmful conduct would likely be outweighed by the costs of condemning and deterring specific instances of such conduct that could have benefited consumers, including through innovation.[15]

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10. US Department of Justice and Federal Trade Commission, *Vertical Merger Guidelines*, June 30, 2020.
11. The CREATES Act, which was enacted in December 2019, establishes a private right of action that allows developers to sue brand companies that refuse to sell them product samples needed to support their applications. Food and Drug Administration, "Access to Product Samples: The CREATES Act," current as of March 13, 2020, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/access-product-samples-creates-act.
12. Antitrust Concerns and the FDA Approval Process, hearing before the Subcomm. on Regulatory Reform, Commercial and Antitrust Law of the H. Comm. on the Judiciary, 115th Cong. (2017) (statement of Alden F. Abbott, Deputy Director and Senior Legal Fellow, Heritage Foundation); The CREATES Act: Ending Regulatory Abuse, Protecting Consumers, and Ensuring Drug Price Competition, hearing before the Subcomm. on Antitrust, Competition Policy, and Consumer Rights of the S. Comm. on the Judiciary, 114th Cong. (2016) (statement of Alden F. Abbott, Deputy Director and Senior Legal Fellow, Heritage Foundation).
13. Amihai Glazer, "Regulatory Policy," in *The Elgar Companion to Public Choice*, 2nd ed., ed. William F. Shughart II, Laura Razzolini, and Michael Reksulak (Cheltenham, UK: Edward Elgar, 2013).
14. Michael A. Carrier, "Helping Consumers Afford Prescription Drugs: An Antitrust Agenda for the New Congress," *HealthAffairs*, February 1, 2021.
15. Innovative activity may generate enormous welfare benefits, and thus particular care should be taken to avoid legal prohibitions that may reduce innovation.

MAJOR LEGAL REFORMS UNRELATED TO ANTITRUST ARE KEY TO IMPROVING THE EFFECTIVENESS OF HEALTHCARE COMPETITION

Whereas this hearing centers on antitrust, in some sense the antitrust treatment of healthcare-related transactions affects only the tip of the proverbial healthcare policy iceberg. Major improvements to the competitive condition of the healthcare sector require far more than enhanced antitrust enforcement.

Serious competitive distortions are posed by a host of state and federal statutory actions that bedevil the healthcare sector, including, as merely one example, economically unjustified state restrictions on entry into healthcare provision, so-called certificate-of-need laws.[16] More generally, as FTC Commissioner Christine Wilson has stated,

> The health care system is so fundamentally broken that antitrust cannot fix all that ails it. I believe many of these problems come down to consumers' ability and incentive to choose among different products and services. Because insurers pick up much of the tab, one set of consumers – patients – have very little incentive to compare the prices of various health care providers. Even if they were inclined to comparison shop, it's not clear they could, given the opacity of most prices. And the ability to comparison shop based on quality – in other words, patient outcomes – is even more limited, given the dearth of data available to patients.[17]

Although addressing non-antitrust-related healthcare reform is beyond the scope of this hearing,[18] it is noteworthy that the federal antitrust agencies have over the years done an outstanding job in calling for statutory and legislative reforms to improve healthcare competition under both Republican and Democratic administrations.[19] Enhancing competition in healthcare markets, whether through enforcement or legislative and regulatory reform, has been and should remain a nonpartisan endeavor.

CONCLUSION

Appropriate antitrust enforcement in healthcare strengthens competition and directly benefits American consumers. Given existing agency resource constraints and burgeoning antitrust-related issues affecting healthcare, congressional allocation of additional resources to support the FTC and Antitrust Division is fully warranted. Congressional elimination of the statutory limitation on FTC actions against nonprofits likewise is appropriate. There is no need, however, to amend the federal antitrust statutes to better address healthcare—existing antitrust enforcement standards are fully adequate to the task. Narrowly targeted statutory fixes to deal with specific competition abuses in the healthcare sector may, however, be warranted. Finally, substantive reforms unrelated to antitrust are urgently needed to improve the effectiveness of healthcare competition.

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16. As Mercatus Center scholars have explained, "Certificate-of-need (CON) laws require healthcare providers to seek permission from state regulators before they offer new services, expand facilities, or invest in technology. Researchers find that these laws tend to restrict access to healthcare, make services more expensive, and undermine the quality of care." Matthew D. Mitchell, Anne Philpot, and Jessica McBirney, "CON Laws in 2020: About the Update," Mercatus Center, February 19, 2021, https://www.mercatus.org/publications/healthcare/con-laws-2020-about-update.
17. Christine S. Wilson, "The FTC's Ongoing Efforts to Promote Competition and Choice in Our Health Care System" (remarks, The Price of Good Health – 2020 and Beyond, Council for Affordable Health Coverage, Washington, DC, January 16, 2020) 12. Wilson's remarks cite academic scholarship that focuses on some of these deficiencies.
18. Mercatus Center scholars have been and remain at the forefront of exploring market-oriented procompetitive healthcare policy reform. For links to Mercatus healthcare scholarship, see "Healthcare," Mercatus Center at George Mason University, accessed April 26, 2021, https://www.mercatus.org/tags/healthcare.
19. Maureen Ohlhausen, "Beyond Law Enforcement: The FTC's Role in Promoting Health Care Competition and Innovation," *Health Affairs Blog*, January 26, 2015; US Department of Justice, "Healthcare Competition Advocacy," accessed April 26, 2021, https://www.justice.gov/atr/health-care-competition-advocacy.

Mr. CICILLINE. Thank you, Mr. Abbott.

We will now—again, thank you to our Witnesses for their opening statements. We'll now proceed under the 5-minute rule for questions. I will begin by recognizing myself for 5 minutes.

Professor Feldman, in a recent op-ed you note that between 1995 and 2015, the 60 leading pharmaceutical companies merged to only 10. As you note, this has resulted in a handful of manufacturers sourcing the vast majority of prescription drugs. So, my question is, why has there been so much consolidation in this industry? What are the effects of such extreme consolidation? To what extent do killer acquisitions pose a problem in the pharmaceutical markets?

Ms. FELDMAN. Thank you. The closer we can get to a free market, the better we're going to do for competition and for lowering drug prices. The competition agencies in the United States have essentially taken the view that they can manage mergers by allowing for divestiture of pipeline products or other types of changes. It simply hasn't been effective. We need a far greater response to mergers and buy-ups at startup after startup. We also need a second look, where we look back at the mergers that have happened to see whether competition has actually improved or lessened, and then try to fix it.

Mr. CICILLINE. Thank you, Professor Feldman.

Dr. Dafny, in your written testimony, you recommend implementing a legal framework, and I quote, "to explicitly prohibit healthcare mergers that enable greater exploitation of existing market power and are likely to result in harm to consumers." What are some examples of mergers in the healthcare sector that are harmful to consumers but nonetheless go unchecked under current law? Secondly, do you think it would be helpful to shift the burden to merging parties to show that their merger would not result in higher prices or lower quality of care?

Dr. DAFNY. Chair Cicilline, I thank you very much for asking this question. Examples of harm that are occurring that are not currently being investigated or are not publicly or seriously so, when hospitals are buying up other hospitals, not in the exact same area but nearby areas, that show a dominant hospital in a town has a great reputation, high prices will buy up a community hospital in the suburbs and then instantly be able to roll that hospital on to its contract, raising prices, which all gets passed down to us. That's one example.

Another example, hospital acquires a physician practice. Physician practice, everything's the same, puts up a sign, everything's the same for the patient, okay, which is what counts right here. Puts up a sign, says, you will now be also paying hospital facility fees for this service; increases prices.

These transactions are proceeding unchallenged because either the statutes don't allow or the interpretations of those statues don't allow challenges to them on competition grounds.

You second asked about shifting the burden. This is a good example where one could require the parties that are proposing such an acquisition to demonstrate why their transaction is not going to be harmful, as opposed to requiring the plaintiffs, the government, to

demonstrate why it is going to be harmful to the standards that are currently required in the competition statutes.

Mr. CICILLINE. I take it you think that would be a good idea?

Dr. DAFNY. I do.

Mr. CICILLINE. Okay. Great.

Professor Carrier, my last question, you explain in your testimony that product hopping causes patients to overpay by potentially billions of dollars annually for their prescription drugs. Can you explain why this product hopping is so harmful and how the Affordable Prescriptions for Patients Act legislation, which I introduced with Ranking Member Buck and Senators Cornyn and Blumenthal, would combat this abusive practice? Respond to the defense that pharmaceutical companies have expressed that preventing product hopping will somehow stifle innovation and block new treatments from coming to the market.

Mr. CARRIER. Sure. Product hopping is concerning because it evades the regulatory regime. Drug product substitution laws are designed to bring affordable generics to the market. When a brand company makes a tiny change just to avoid substitution, everybody suffers. The legislation would be very helpful in making clear that these soft switches, in which the old product is left on the market, that courts are not understanding is a problem. The legislation would be incredibly helpful for that.

In terms of innovation, I'd say that, first, the legislation is quite targeted. There's a competition window that allows for challenges only in a short period of time. There are exclusions, and there are justifications. Also, this is limited to the FTC under section 5. The FTC almost never brings a case. At most it will be once every year or two.

Then, finally, in terms of innovation, this is not the first time that the pharmaceutical industry has made this argument. I wrote an op-ed that showed that, going back to 1961, every single time there's patent or antitrust legislation in this body, they say it's going to be the end the world. Now, there's a new variation based on COVID, but it's still the same thing. This is sort of like the boy who cried wolf.

Mr. CICILLINE. Thank you, Professor.

I now recognize the Ranking Member of the Subcommittee, Mr. Buck, for 5 minutes.

Mr. BUCK. I thank the Chair. I would ask the Chair, I'd like to go last with my questions. If the Chair could recognize Congressman Issa, I would very much appreciate it.

Mr. CICILLINE. Happily. I recognize Mr. Issa for 5 minutes.

Mr. ISSA. Thank you. I want to thank the Ranking Member for letting me go out of order.

The fact is I support this legislation in principle. I know that, as we go through the process, many companies can give us examples where they may want to have a nuance change but let me go through a couple of quick questions that may go the other direction. We'll start with Professor Carrier.

Many of the changes that we're trying to thwart with this legislation are predictable and repeatable. If we cannot get, if you will, some of these commonsense reforms through, is there any reason

that this body couldn't, for example, give a right of anyone not having a patent to put up barriers to, if you will, the obvious?

You mentioned or it was mentioned in the earlier testimony that, for example, changing the dosage or the method of delivery, time release, each of these nuances that are currently going on at the end of a product life, and the opioids are famous for them, these are, in fact, patentable because we allow them to be patentable, and we don't bar them based on obvious. Yet, something—if you will, medicines continue to basically add these features that are predictable and repeatable, wouldn't. You say that it is certainly within our purview to, as a matter of law, define those as obvious if we can't get some sort of middle ground with pharma and their pattern of abuse?

Mr. CARRIER. You're absolutely right that the patent system is incredibly important. We need to make sure that we give the patent system the deference it deserves. At the same time, however, not every patent is valid. A lot of these patents are not on the active ingredient. The concerns with product hopping is that it is an evasion of the regulatory regime.

I talked about the drug product substitution laws. The Hatch-Waxman Act, also included a whole bunch of provisions to increase generic competition. So, I view this as purely bipartisan legislation that is narrowly targeted, that will not affect innovation, and that will make consumers lives better.

Mr. ISSA. I want to do one more follow-up. In most areas of patent law, we all are used to the common statement that a patent, by definition, on its face, with the disclosure, has to be sufficient for someone of ordinary skill in the art to, in fact, duplicate the product.

Please explain for the record why that does not occur in biologics today, and why the entire pattern of abuse where you're at the end of a patent life at the point in which a biosimilar would like to produce something and doesn't have, in some cases, even the medicine, but they don't have the ability to do it. Because, if I'm correct as a layperson, we have not forced the disclosure at the front end to meet that test that if someone of ordinary skill in the art can't on the face of the disclosure know how to duplicate the product.

Mr. CARRIER. You're absolutely right. What's going on with the biologics industry is not just patent protection, not just patent secrets, but there's also trade secret protection. So, even if, exactly as you mentioned, the patent system is designed to enable inventions, when a lot of the process of creating biologics is hidden under lock and key, it's hard for the biosimilar to figure that out. We have the patent system that's designed to serve a purpose. You don't usually have trade secrecy layered on top of that. That's what's going on here, and it's an additional reason why we're not seeing enough biosimilar entry.

Mr. ISSA. So, let me ask it as a final question. Certainly, I appreciate trade secrets, and manufacturing nuances are abundant in the electronics industry that I came from many years ago. In return for the bargain of providing a patent, the assumption would be that, again, someone of ordinary skill in the art with the information that, by definition, someone of ordinary skill in the art has, can duplicate the product.

Should we be looking at an outright recognition that the trade secrets cannot, in fact, be allowed to create a barrier if you want the patent? For example, putting it in simple terms, Coca-Cola can't have a secret formula and patent the formula. Just a quick answer if you would, please.

Mr. CICILLINE. Yeah. The time of the gentleman has expired, but the Witness can answer briefly.

Mr. CARRIER. Sure. You're right. In most areas, and inventor needs to choose between patent and trade secret protection; in contract with biologics, one builds on top of the other. This is worth attention.

Mr. CICILLINE. The gentleman yields back.

Mr. ISSA. Thank you. I thank the Chair for the indulgence.

Mr. CICILLINE. Thank you. I now recognize the gentleman from New York, Mr. Jones, for 5 minutes.

Mr. JONES. Thank you, Mr. Chair and to the Ranking Member, for your strong leadership. This has been a pleasantly bipartisan hearing thus far. I look forward to joining Mr. Issa in reforming our Nation's patent laws.

I also want to thank the esteemed Witnesses on both of our panels today for joining us this afternoon. I am excited to be part of this vital effort to ensure that everyone in the United States of America can afford the prescriptions that they need.

I also, of course, want to thank the sponsors of the three important bills before us today, for their leadership. Thanks to you, we have the opportunity to help patients and families across the United States, and I am so committed to working with you.

Today, pharmaceutical companies are confronting the American people with a terrible choice: Miss rent payments and skip meals to pay for their prescriptions or go without the lifesaving medications that they need. I know the toll that takes firsthand, because when I was growing up, my family didn't always know if we could afford the healthcare that we needed. There is simply no reason, indeed no excuse, for leaving patients and their families struggling to get by just so that pharmaceutical profits can continue to soar.

Professor Carrier, in your testimony today, you have illuminated a source of the crisis of high drug prices that we have not yet heard enough about, and that is the consolidated power of the biggest pharmaceutical firms. As pharmaceutical companies have expanded through mergers, they have raised drug prices higher and higher. I've been hearing that same message from a range of leading experts from the American Economic Liberties Project to my courageous colleagues like Katie Porter and, of course, our distinguished Chair, David Cicilline.

To help clarify the stakes for everyone, could you share an example of a pharmaceutical merger that shows how these mergers can harm patients, families, and our communities?

Mr. CARRIER. Sure. Thank you for your attention to mergers, which are a really important issue. I would focus on the AbbVie-Allergan merger, where this received a lot of attention. At the end of the day, the FTC solution just came down to forcing the divestiture of a few overlapping products.

When you think about the harm, however, it comes from more than just particular markets. So, in this case, both companies had

blockbuster products in AbbVie's Humira and Allergan's Botox. When you get all these must-have products in one company, they have a lot of power to provide rebates to PBMs. That makes it harder for consumers who need to have these medications.

At the same time, you have these rebates that make it tougher for any other competitor that can't compete with that broad range of products. You have some companies that are in antitrust hot water. For example, Abbvie has been accused of pay-for-delay settlements, and with Allergan, there have been concerns with tribal immunity and citizen petition challenges. There is a lot that's going on that's not captured by the current approach. I think that this harms consumers and, therefore, a new approach should be considered.

Mr. JONES. Last month, acting FTC Chair Rebecca Kelly Slaughter declared that, quote, "Given the high volume of pharmaceutical mergers, skyrocketing drug prices, and ongoing concerns about anticompetitive conduct in the industry, it is imperative that the FTC rethink its approach toward pharmaceutical merger review."

In your testimony, you called for imposing a presumption against mergers between large pharmaceutical companies. Can you explain your proposal further and tell us more about why a presumption against these mergers is so important to ensuring that everyone can afford the drug they need?

Mr. CARRIER. Absolutely. Patricia Danzon at Wharton and I have an article forthcoming in the Antitrust Law Journal where we look at pharmaceutical mergers and the key element of size. Size makes a really big difference. Basically, we conclude that there's no good reason for two large companies to merge. They have entrenched advantages in things like financing, marketing and sales, insurance, and reimbursement. You put that all together, and it makes it almost impossible for anyone else to compete. Plus, there's no good innovation reason for two large firms to merge.

So, that's why we suggest a presumption against the merger of two large firms. With mid-size firms, I might not go all the way to a presumption, but I still would apply those factors. So, the size of the firm really needs to be considered.

Mr. JONES. Thank you so much.

Professor Dafny, let me ask you as well, how would it help patients if we made certain kinds of healthcare mergers presumptively unlawful?

Dr. DAFNY. I thank you for the question. If we took a set of healthcare mergers that are known typically to be damaging to consumers and insisted that the acquiring parties demonstrate that they are not going to damage consumers, that would save substantial regulatory resources.

Mr. JONES. Thank you so much.

Thank you, Mr. Chair. I yield back.

Mr. CICILLINE. The gentleman yields back.

I now recognize the gentleman from Louisiana, Mr. Johnson, for 5 minutes.

Mr. JOHNSON of Louisiana. Thank you, Mr. Chair. Thanks to all my colleagues. It is rare, as has been noted, for us to have bipartisan things to work on these days in Judiciary. So, this is a refreshing hearing that we've had so far.

Mr. CICILLINE. Mr. Johnson, I won't take this time away from you, but not rare on the Antitrust Subcommittee.

Mr. JOHNSON of Louisiana. Oh, yes. I salute you for that, sir, and Ken Buck as well.

Listen, this is a big problem, a big issue, and there's a lot to deal with. So, it's not even really fair to give these Witnesses just 5 minutes apiece and letting us ask some questions. Let me drill down into something that is of great concern to a lot of people, and that is the certificates of need issue. Let me ask Mr. Abbott, if he will, maybe describe what that is, and then talk a little bit about the anticompetitive effects of certificates of need.

Mr. ABBOTT. Thank you for that question, Congressman. A certificate of need basically is a State law provision which states that any additional investments, say in a hospital, a healthcare facility, depending upon how it's defined, must be justified. Often you will have a panel that will decide if a particular investment is justified and is cost effective. The theory, if you find out about it, about certificates of need, is that a concern about scarce resources, overinvestment in certain resources, cost saving in short.

The reality is, and the FTC and the Justice Department over the last 20 years have done many studies of certificates of need. They've shown that, in reality, certificates of need cause barriers to entry. It is a way, for example, that a powerful incumbent hospital might argue that, oh, well, you don't really need new beds, you don't really need new entry because our supply of hospital facilities is sufficient. That can prevent badly needed entry.

Also, the existing certificate of need law prevented the FTC from doing anything about a merger to monopoly in the State of Georgia in the Phoebe Putney case. On the case, the Supreme Court, the relief to sort of before change in hands of assets required to get relief. Yet, certain divestitures were effectively blocked by a certificate of need law in the State of Georgia.

This has been totally bipartisan, both Republican and Democratic Administrations, the FTC, and Justice Department have regularly submitted letters saying, we have found certificates of need to be anticompetitive and we recommend against them. They don't really do much into save resources at all. Their main effect really is to limit competition, which we've already heard can raise prices and reduce quality.

Mr. JOHNSON of Louisiana. Very good. So, if we [inaudible] particular service, just in layman's terms, how would that improve the healthcare experience for the average consumer over time? I mean, the presumption is it would unleash more competition. Right? I mean, is that oversimplifying it?

Mr. ABBOTT. Yes, Congressman. Indeed, it would. It would allow new entry in markets. It would allow the market to decide about how many beds are needed, what new facilities can be brought forth, say it's an imaging facility, and it would prevent particularly rural or regional monopolies from entrenching their market power.

As I mentioned, that was a problem in Georgia. So, I think that's a particular issue. I don't have the specific numbers in front of me, would be glad to provide them to you. As I say, I think there has been a lot of research. The research that I am aware of unequivo-

cally has shown that this tends to be anticompetitive and drive up prices.

Mr. JOHNSON of Louisiana. I appreciate that. If it will not be too much effort, if you could supply that to us after the hearing [inaudible] because we need real ammunition and evidence for making these changes and that would be a big help.

I'm having technical glitches, Mr. Chair, so I yield back. Thank you.

Mr. CICILLINE. The gentleman yields back.

Mr. Raskin, if you turn on your camera, you are next. If not, we'll move to Ms. Jayapal.

Mr. RASKIN. Yes. Thank you, Mr. Chair. I didn't realize I was coming up. Thank you so much.

A number of our colleagues have remarked upon the pleasant bipartisanship of this hearing. I wonder if we'd take a moment to reflect on what that means historically. I know that socialism has become part of the political dialogue in America today. I wonder if we could examine the way in which antitrust enforcement really became an answer to socialists who were saying that we needed to take over the big businesses because they were so out of control. The progressive response—progressives meaning both Republicans like Teddy Roosevelt and Democrats like Franklin D. Roosevelt—was to say, let's break up the big businesses to make sure that there's real competition.

I'm wondering, Professor Feldman, perhaps if you would reflect for a moment on the development of antitrust law as a response to other efforts to deal with the problem of monopoly power in the country.

I think you're muted.

Ms. FELDMAN. Thank you. Markets need to be fair, open, and efficient if we are going to have the type of free market economy that you envision there. The antitrust laws are an essential partner for making sure we can do that. Unfortunately, antitrust laws haven't kept up with the sophistication that has happened in the healthcare field along the way and with the games that have developed. If we want antitrust to be an effective tool and to guarantee the free market that we all would like, we're going to have to update it.

Mr. RASKIN. On that point, it does seem as if within the antitrust field we're always playing catch-up with the various innovations by businesses or would-be monopolists to take advantage of their power. I suppose that's built into the system too.

Is there any way that we can create an antitrust system that is more readily and nimbly responsive to the kinds of things that people have been talking about today, the kinds of schemes that are derived to take advantage of market power?

Ms. FELDMAN. It's always more difficult for government to stay ahead, particularly for a body like Congress that is deliberative. I believe one has to pass legislation that has two parts. One is examples of specific, targeted behaviors that are inappropriate, and another is sufficient language that gives the agencies the space they need to respond as new games develop.

Mr. RASKIN. Okay. Thank you.

Professor Dafny, let me ask you this question, what have we learned from many decades of antitrust legal enforcement as to what the most effective ways are to make government more rapidly and readily enabled to deal with the kinds of schemes that you're talking about?

Dr. DAFNY. Thank you for the question, Representative Raskin. So, to just elaborate on the previous query, there needs to be an incentive not to play games. When those incentives to play games exist, when incentives to merge for the purpose of raising price because we are willing to pay whatever price is charged or the increase in price, when those incentives exist, that's when people play games. That's when mergers happen.

How do you prevent them? Research shows, you know, that a lot of mergers that have been able to go through under the current enforcement regime have caused substantial price increases. So, if we strengthen enforcers' hands by increasing the reportability of transactions, because there's evidence that they are not typically challenged below the threshold, if we reduce the burden of proof in certain transactions, and if we explicitly make unlawful certain practices that are gaming, I think we'll end up with better outcome.

Mr. RASKIN. All right.

So, Mr. Chair, I just want the record to demonstrate that both parties here are looking for effective public action to guarantee real market competition. No party, either Republican or Democrat, seems to be looking for a government takeover of the healthcare sector or any other business sector. This is very much within the tradition and mainstream of American progressive, legal, and policy action.

I yield back to you.

Mr. CICILLINE. The gentleman yields back.

I now recognize the gentleman from Florida, Mr. Steube, for 5 minutes.

Mr. STEUBE. Thank you, Mr. Chair.

My questions are for Mr. Abbott. Beyond certificate of needs, Mr. Johnson asked you about that, can you further discuss State policies that might be labeled as, quote, "anticompetitive," or are these purely State issues, or is there a role for Congress to play?

Mr. ABBOTT. Well, thanks for that question, Congressman. Certainly, there are occupation licensing restrictions that unnecessarily restrict competition certainly in healthcare. A good example is restrictions on a nurse practitioner practice. We see that there are some—many boards, health-related boards in States that have limited competition without any good justification. For example, on a North Carolina dental board case, which FTC won before the Supreme Court, this was a case where you had a dental regulatory board dominated by dentists that, in effect, passed the regulation, effectively preventing clinics providing whitening services without the involvement of a dentist. Obviously drove prices up.

South Carolina, there were dental board restrictions, again examined by the FTC, that prevented services being offered by dental hygienists to poor people in rural areas without the presence of a dentist. That tended to raise costs and limit valuable dental services.

In general, occupational licensing is a big problem. I think this, again, is bipartisan. The Obama Administration recommended major occupational licensing legal reforms in summer of 2016, and it certainly might be—I know Senator Lee, I think, supported legislation that would allow people in the Armed Forces that had a spouse who would not need to get licensing elsewhere.

Given the interstate nature of movement of many American professionals is an argument. You could have nationwide licensing of positions or at least lowering your barriers for States that unnecessarily delay new licensing of positions in particular States.

I won't get—it's a rather complicated topic, but the certificate of public advantage by which a State may give an antitrust immunity for businesses that want to merge or consolidate, that also may have helped consolidations. The argument there was that this was to promote better outcomes and efficiencies. Again, I think some economists say there's little evidence of that.

So, in short, there are a number of restrictions, State restrictions, some of which could be preempted, if Congress wanted to do that.

Mr. STEUBE. It's my understanding that the Trump Administration HHS issued a final rule on Medicare part F. Can you talk about the current status of that rule, and whether it would help with the issues that we're discussing today, in particular, realigning incentives in healthcare?

Mr. ABBOTT. I apologize, Congressman, I'm really not an expert on details of that rule. I'm glad to get back to you and provide a response for the record.

Mr. STEUBE. That's fine. I can move on to my next question.

You address ObamaCare or the Affordable Care Act in your testimony and note that it accelerated the consolidation of hospitals, health systems, and medical groups. Could you explain on why this has been detrimental, particularly to consumers and patients?

Mr. ABBOTT. Right. Well, there's certainly some research by a number of economists that suggest that the incentives—it did create incentives for consolidation and that those incentives could—tended to, in an increased concentration indeed and also the set of reimbursement rules. Again, I'm not a full expert on that. I just know I've seen literature suggesting that that was the case. Again, I'm glad to provide more details. It's a complicated topic. I'm more of a pure antitrust person, but I've certainly seen that literature from a number of economists whom I view as reputable.

Mr. STEUBE. Well, let me take it a little broader. What are the dangers of broad-sweeping antitrust laws to address very narrow healthcare issues? How can the problems discussed today be addressed in an appropriately narrow way?

Mr. ABBOTT. Well, I think the danger with broad laws, for instance, generally reversing presumptions and mergers or presumptions against mergers of a certain size or changing the language of section 2 of the Sherman Act, some of the proposals out there apply to all industries. Healthcare is unusual precisely because they have a combination of extensive State and Federal regulation. A lot of payments going, as you see, through Medicare and Medicaid involving government involvement. You've got State licensing restrictions, you've got Federal FDA restrictions, HHS restrictions. This

combination of—you had Hatch-Waxman Act, which created incentives for gaming.

This combination of laws enacted even with the best of intentions created opportunities for regulations and laws to strategically be used to harm entry or deny competition.

Mr. CICILLINE. The time of the gentleman has expired, so I just ask the Witness to wrap up your answer, please.

Mr. ABBOTT. Yes, sir. Yes, Mr. Chair. So, that basically is it.

Mr. CICILLINE. I thank the gentleman. The gentleman yields back.

I now recognize the distinguished gentleman from New York and the author of the Stop Stalling Access to Affordable Medications Act, Mr. Jeffries, for 5 minutes.

Mr. JEFFRIES. I thank the distinguished Chair for your great leadership. I also thank Ranking Member Buck for his leadership, particularly as it relates to this issue of citizen petition abuse.

Professor Carrier, the FDA has a citizen petition process that was meant to provide for an opportunity to raise legitimate concerns about the health and safety of a new prescription drug or device that's under review by the agency. Is that right?

Mr. CARRIER. That's correct.

Mr. JEFFRIES. This process does seem to make sense in theory, consistent with its intent. Is there reason to believe that it has been increasingly abused in an anticompetitive manner by brand name drug companies as part of an effort to delay the entry of generics onto the market?

Mr. CARRIER. Absolutely. I've conducted two empirical studies of all citizen petitions filed between 2001–2015. My most recent one found that of the 505(q) petitions, which are petitions against a pending generic, the FDA denies 92 percent. That figure rose to 98 percent, 49 out of 50, when they were filed at the last minute. So, this certainly is an abuse.

Mr. JEFFRIES. So, the overwhelming majority of petitions filed actually are found to be frivolous or at least lacking merit. Is that correct?

Mr. CARRIER. Exactly, yes.

Mr. JEFFRIES. Now, this would be one thing if this were citizens actually using a legitimate process that was put into place. Could you tell us what your study has found in terms of who actually is filing these petitions?

Mr. CARRIER. The brand firms are the ones that are filing these petitions. Ninety-two percent of these 505(q) petitions were filed by brand firms. There are almost none that are filed by individual citizens.

Mr. JEFFRIES. So, the brand firms are actually filing these petitions, subsequently found to be almost always meritorious, and that results in the delay of lower cost generic drugs being brought to the market. Is that right?

Mr. CARRIER. Yes. Because as frivolous as a citizen petition is, the FDA has never summarily denied one on its face. The FDA has that power, but it has never used it, because it has to review these long petitions, with lots of scientific language. The FDA can't resolve these immediately and that delays generic entry.

Mr. JEFFRIES. So, how does this stalling tactic adversely impact the consumer?

Mr. CARRIER. Every day that a consumer does not have access to an affordable, generic medicine is a bad day for that consumer. Citizen petitions are used, along with other conduct, like product hopping and pay-for-delay settlements, to make it harder for consumers to afford the medications that they need.

Mr. JEFFRIES. So, generic drugs generally cost 80–85 percent less than the brand-name drugs on average. Is that right?

Mr. CARRIER. Yes.

Mr. JEFFRIES. So, this will be part of the reason why adversely delaying the arrival of generic drugs onto the market clearly has a significant financial impact on the consumer?

Mr. CARRIER. Absolutely. Every day of delayed generic entry harms the consumer.

Mr. JEFFRIES. Now, is there any explanation that has been offered by the brand-name companies as to the justification to engage in this type of frivolous practice?

Mr. CARRIER. Well, they claim that they are raising safety concerns. When courts look at this, they often find that it's a sham. Sometimes there's no good reason for what they're doing. Oftentimes, companies hide behind the First amendment and petitioning immunity. At the end of the day, when they're asking the generic to do something they don't do themselves, or they knew about an issue and waited years to raise it, that raises some real questions about what they're doing.

Mr. JEFFRIES. Thank you for your work. Thank you for your testimony. In the past, this Committee has unanimously moved forward legislation to address this egregious practice with the support of the Chair of the Subcommittee as well as the Chair of the Full Committee. We have reintroduced legislation to address this. It is being championed on the other side of the aisle by Ranking Member Buck. We look forward to addressing this egregious practice again. Thank you for your testimony.

Mr. CARRIER. Thank you.

Mr. CICILLINE. The gentleman yields back.

I now recognize the gentleman from North Carolina, Mr. Bishop, for 5 minutes.

Mr. BISHOP. Thank you, Mr. Chair.

I too am glad for the bipartisan approach here and the uniform commitment to improving competition healthcare market. I think that—when I was a State legislator for 5 years, I was a consistently pro-CON repeal. I favor, I think the three bills that have been discussed today are no-brainers.

I want to take up something that Mr. Steube mentioned, I and I thought I was sort of prepared for this hearing, and then saw some materials that suggested there's something to it.

In 2014, Scott Gottlieb talked about a flurry of takeover transactions in the healthcare space set in motion by the Affordable Care Act. The *Wall Street Journal* described in the next year 2015, 5 years after the Affordable Care Act helped set off a healthcare merger frenzy, the pace of consolidation is accelerating.

I even understand, looking at some other material here that the architects of the Affordable Care Act were condensed, the consoli-

dation in healthcare relief to decrease healthcare spending by eliminating duplications, standardizing treatment protocols, and incentivizing better utilization. So, that is to say not only did the law encourage consolidation throughout the healthcare space as a matter of result; it was intended to do so on the theory that that would result in lower cost in price.

So, maybe, Professor Feldman, I certainly have liked what you had to say about markets. I wonder is that true of the ACA? If it is, are we not engaged in sort of a Sisyphean or futile task to try to advance competition in the healthcare space if the primary design of the healthcare system through ACA is designed to promote consolidation?

Mr. CICILLINE. Professor, I believe you might be on mute.

Ms. FELDMAN. My apologies. I am having a little bit of an equipment problem here. So, I have sometimes been asked whether it might be better to just give up competition in the healthcare space, whether you're talking about hospitals or pharmaceuticals because it's too difficult, it's too complicated, it's already layered with too many regulations. Personally, I don't believe that. I believe that even if it is not perfect, the closer we can get to competition, and the more we can make the changes that will encourage that competition, the better off our patients will be.

So, I understand there are pressures throughout the system, but I think we have extraordinary opportunities to try to Act in the patient's interest.

Mr. BISHOP. Do you have a view as to whether the ACA does promote consolidation or not.

Ms. FELDMAN. It's an interesting question, sir. I would love to take the time to think about that and come back to you with a thoughtful response.

Mr. BISHOP. Okay.

Let me go to Dr. Dafny then and see if you have a few of that question. Dr. Dafny.

Dr. DAFNY. Certainly. Well, it's been 10 years since the ACA was passed. We have seen enormous consolidation during that period. There's no evidence that it's causal. Right? So, we don't have a counterfactual State of the world of what would have happened, and there was a lot of activity before.

What I will say is that the Act promoted coordination of multiple providers, and that some people have invoked it as a reason for a merger: If I am going to be responsible for the whole episode of care, then I ought to own all the components of the delivery system. The problem is that a lot of those transactions have not been about the whole episode of care: That is, the physician, the hospital, the rehab clinic, and home health. It's been a lot about buying up the same of what you do and more horizontal consolidation.

Mr. BISHOP. Is it possible, Dr. Dafny, that if you promote consolidation, let's say, among the healthcare plans, and then you are robustly enforcing antitrust law as against hospital systems or pharmaceutical company that you might produce distortions that would be problematic?

Dr. DAFNY. I believe you just asked, would it be better—problematic to consolidate the health insurers while keeping the provider sector competitive. My answer would be that yes, that would con-

cern me. There is evidence that when insurers are larger, they tend to negotiate lower prices, but there's no evidence they pass those on down to consumers. Think about it. What's the incentive if you don't have very many rivals as an insurer, why would you pass on savings?

Mr. BISHOP. Yeah. I am inclined to yield, if I have any time left, to the gentleman from Maryland to address this because he might be more even on the point. I find that to be a fascinating issue that we are—because I believe in competition in the healthcare space. Glad we interested in it on a bipartisan basis; confused if ACA was designed in part to impair it. I yield back because my time is out.

Mr. CICILLINE. The gentleman yields back.

I now recognize the gentlelady from Washington, Ms. Jayapal for 5 minutes.

Ms. JAYAPAL. Thank you, Mr. Chair, for a very important hearing. I think we all understand that when components of consolidation in healthcare promised us better quality of care, the reality that we got is that patients had been forced to pay exorbitantly high medical costs in exchange for worse care. We see a system that's plagued with unregulated mergers, hospital closures, skyrocketing healthcare costs only exacerbated by COVID–19.

At a time in which healthcare services are needed the most, medical institutions serving low-income communities, communities of color, rural communities, have fared worse than wealthier institutions, despite serving patients who have suffered a disproportionate rate of COVID–19 infections and deaths. So, I think the issue of consolidation is actually deeply tied to the issues of health inequity for so many communities.

Dr. Dafny, in your article, "Health Care Needs Real Competition," you mentioned that, quote, "The U.S. Healthcare System is inefficient, unreliable, and crushingly expensive." Has the lack of fair competition contributed to these issues, and if so, how?

Dr. DAFNY. I thank you for the question Representative Jayapal. Absolutely. Unequivocally, the source of our higher spending is not the health of our population, not that we use more services but that we pay higher prices for them. Now, there's some difference in the intensity of the service and the technology. You could debate a little bit the level. The growth in prices, the explosion in commercial prices that has coincided with what Representative Bishop was observing, the increasing consolidation of the healthcare sector, that's unmistakable. Then later on academic research that looks really at what happened when there is a discrete change in consolidation, and there is significant evidence across a range of sectors, both providers and insurers, that increasing the market power enable higher prices and is the driver.

Ms. JAYAPAL. Just for people who are listening, how does hospital consolidation affect their quality of care, patient choice, patient experience, even what effects does it have on small businesses?

Dr. DAFNY. Right. A couple of ways. First, it affects spending. Right? Because it's going to pass through higher out-of-pocket spending. When you have increases your deductible, burdens the employers because they have higher premiums.

Second, reduction in your options. A reduction in—there's evidence of a reduction in patient experience, and no evidence of improvements in clinical outcomes or other process measures.

Ms. JAYAPAL. In your testimony, you also noted the role of nonprofit hospitals. Nonprofit hospitals are often considered charitable institutions. In 2019, 66 percent of all hospital and health system mergers and acquisitions involved nonprofit entities.

In the upcoming documentary, "InHospitable," directed by Sandra Alvarez, the fact that nonprofit hospitals behave like for-profit hospitals is discussed. Can you talk a little bit about how nonprofit and for-profit hospitals engage in similar behaviors to maximize profits, if you think that's true? Or if you don't, explain why that's not the case.

Dr. DAFNY. Not-for-profits and for-profits in healthcare are in the same industry. Even if not-for-profits are not seeking to return those profits to shareholders, they need to break even, and they also have other sources where they put those profits. Sometimes salary, but often just the program that they deem to be valuable, which might not be what your taxpayer wants to pay for.

Certainly, the research has not found that not-for-profits are increasing prices less after mergers and that—so I would put that out there.

What we should not have is a difference in terms of enforcement vis-à-vis the not-for-profits. The fact that the FTC is not permitted to challenge anticompetitive conduct by not-for-profits is nonsense.

Ms. JAYAPAL. So, did you get cut off or what?

Dr. DAFNY. Nope. I'm brief.

Ms. JAYAPAL. Oh, okay. Great. So, I mean, I guess you're getting at this. I wanted to ask you if these large consolidated nonprofit systems do require antitrust scrutiny due to their tax-exempt status. Can you say a little bit more about that?

Dr. DAFNY. Well, two items. First, is they absolutely require antitrust scrutiny. The authorities have brought a number of cases, challenges, and have succeeded in many of them.

The second is that there are other statutes that State attorneys general can enforce to try to ensure the not-for-profits are fulfilling the community benefit standard.

Ms. JAYAPAL. So, very quickly, just on private equity firms, because my time is out, how can antitrust laws and regulations be strengthened for better oversight to prevent harmful nonhorizontal mergers in healthcare?

Dr. DAFNY. More reporting and, when appropriate, shifting the burden: Have the party demonstrate why the transaction is not harmful.

Ms. JAYAPAL. Thank you so much, Dr. Dafny.

I yield back, Mr. Chair.

Mr. CICILLINE. The gentlewoman yields back.

I now recognize the gentlewoman from Minnesota, Ms. Fischbach, for 5 minutes.

Ms. FISCHBACH. There we go. I got it unmuted. Thank you so much, Mr. Chair. I just wanted to ask a little bit about to Mr. Abbott about the Federal role in State restrictions. I know that Congressman Steube asked a little bit about the certificates of need,

but maybe he can talk a little bit more about the Federal role in the State restrictions as related to the healthcare competition.

Mr. ABBOTT. Well, thank you very much, Congresswoman, for that question. The Federal role, I think, part of it is competition advocacy, but not always successful. As I think I indicated, the FTC and Justice Department have advocated a repeal of CON laws because they—and I am just—on a bipartisan basis.

Now, to the extent that CON laws are viewed as having a harmful effect on interstate commerce in principle and because they harm the competitive process, you could have an argument for Federal preemption if the Federal government wanted to do that. Similarly, with COPA laws. The Federal government has chosen not to do that. Certainly, part of the problem—and of course, these laws have some defenders—is that they were in a way special interests. Incumbents can take advantage of them to forestall competition.

Occupational licensing should be a no-brainer, in my view, but it's not. There has been some litigation against State occupational licensing restrictions on constitutional grounds by the Institute of Justice, for example. There is no really good reason that I'm aware of why artificial restrictions on nurse practitioners, on other medical providers, limitations on not science or based on activities, as I say, of dental hygienists should be maintained. Again, this gets sensitive because it goes to the nature of State licensing, which is historically a State function.

So, I think the Federal government certainly should look at those excessive conditions and, particularly, how State regulation interacts with Federal law and undermines the concern about consolidation, certainly, that may have some effect on consolidation as well because it denies—CON laws, for example, may preclude a new entry.

Ms. FISCHBACH. Thank you. I will just say, I know that a couple of people have mentioned that consolidation. I guess it hasn't been mentioned, I don't think, that regarding the fact—I represent a rural district, and so consolidation really does affect those rural districts and rural healthcare in general.

Mr. Abbott, maybe just briefly, I only have another minute or so. Maybe you could talk a little bit about how the regulation compliance costs and all the regulatory costs that those healthcare providers experience whether it's hospitals, pharmaceuticals, or—but how do those create barriers to entry and make competition harder?

Mr. ABBOTT. Right. Well, competition, you're asking in addition to the restrictions I already mentioned? Additional restrictions?

Ms. FISCHBACH. Yeah, and well, kind of that regulation, and we just have—I wanted to keep it short because I only have a minute or so, but just if there was anything on that regulation, those regulatory issues.

Mr. ABBOTT. Right. I think regulatory—I think major reforms for occupational licensing I have already mentioned. When I was asked earlier, Congresswoman, about—this is on State regulation. It's Federal regulation about Obamacare. One article I would mention by Christopher Pope of the Heritage Foundation. I'll describe some of the ways in which accountable care organizations and—tended to promote, like it or not, consolidation by disbursing capitated pay-

ments for integrated organizations, to provide all-inclusive packages to Medicare employees, and encouraging vertical integration, and also some horizontal integration.

I would be glad to provide additional information on how Federal and State regulations may have diminished competition. It's a very complicated topic. Lots of my colleagues at the Mercatus Center, have written about that.

Ms. FISCHBACH. Well, thank you very much, Mr. Abbott.

Mr. CICILLINE. The time of the gentleman has expired.

The gentlewoman now yields back.

I now recognize the distinguished gentleman from the State of Florida, Mr. Deutch, for 5 minutes.

Mr. DEUTCH. Thank you, Chair Cicilline. Thank you for your leadership of this Subcommittee and thank you for using that leadership to focus on affordable healthcare for the American people. It's clear to me that the sticker shock Americans are seeing when they fill a prescription or discharge from the hospital isn't a product of supply and demand.

Healthcare markets are broken. In the prescription drug market, gaming and abusing the patent system robs us of innovative new therapies. We have a responsibility to stop this profiteering that is leaving too many Americans either broke or sick or both.

This is urgent, and I acknowledge that for me and, Mr. Chair, for you, and for so many of us on this Subcommittee, we agree completely with the President when he said last night that we should give Medicare the power to negotiate directly on behalf of the beneficiaries to get fair drug prices.

This hearing is focused on the things that all of us, I believe, agree on—things that Judiciary Committee approved last Congress. So, we need to keep up the momentum to get these bills done this year.

With that, Professor Carrier, I wanted to ask you, amid the COVID–19 health emergency, the opioid overdose epidemic is surging. According to provisional data from the CDC, over 81,000 drug overdose deaths occurred in the United States in the 12 months ending in May 2020, the highest number of overdose deaths ever recorded in a 12-month period. One of the best tools to help people find recovery and save their lives is medication-assisted treatment.

Now, you mentioned that one of the drugs used to treat opioid-use disorders is Suboxone. Can you explain the story of what the drug company did when the patent was about to expire?

Mr. CARRIER. Absolutely. So, thank you for the question.

Suboxone is a poster child for all this anticompetitive conduct being used together. So, first, we begin with product hopping. Initially, the medicine could be taken in tablet form. Then the company said, you know what, we're going to switch it to a film form. When it did that, even though the patients preferred the tablets because they were easier to take—the film was irritating, it would blow in the wind, children would ingest it, so it was actually less safe—nonetheless, what the manufacturer, Reckitt, said was that the tablet was the one that wasn't safe.

The film is what the kids are putting in their mouths, but Reckitt is saying the tablet is not safe. So, it switches the market. It gives up all those sales from the tablet that everybody likes, and

then it goes to stage 2. Stage 2 is the citizen petition. Reckitt files a petition with the FDA, asking the agency to withdraw the tablets. Now, these are the tablets that it had been selling for years, and it never said there was a safety problem. The court said that this is a joke. This is objectively baseless because you dismissed the safety concern less than 1 month before when you told the FDA that the product was, quote, "successful and needed no further changes." This was so concerning that the FDA referred this to the FTC for an antitrust investigation.

So, there you have a product hop together with a citizen petition, disparaging your own product that you have been selling for years, and then together with that, you have a REMS program that delayed generic competition. Again, the CREATES Act is designed to deal with the REMS program. It's gotten a whole lot better.

In that one example—and again, this is real harm and people are really suffering—you have a drug company putting together at least three significant types of anticompetitive conduct.

Mr. DEUTCH. Can you just tell us what was the annual sales for Suboxone?

Mr. CARRIER. I do not know off the top of my head the annual sales.

Mr. DEUTCH. My understanding is it's close to $700 million. When you say that it makes no sense when pharmaceutical companies use these product hopping strategies, what does that mean? Help us understand that.

Mr. CARRIER. In antitrust law, there is a very, very conservative test called the no economic sense test, which says: Defendant, monopolist, if you have any reason at all for doing what you're doing other than harming a rival, then it's fine. So, it's more deferential than the rule of reason. Under the rule of reason, courts balance anticompetitive against pro-competitive effects. The no economic sense test is as conservative as you could get. By the way, again, most reformulations are fine; 80 percent take place outside what's called the generic window when we expect generic competition to happen. So, we're just talking about a really small handful. Those small handful are completely anticompetitive. They undercut the regulatory regime, and there's no excuse at all for it.

So, when I say there is no economic sense, there is literally no reason that Suboxone would badmouth its own product, would sell tablets for years, and then say: "Oh, FDA take this off the market because it's unsafe."

That makes no sense at all other than harming generic competition.

Mr. DEUTCH. That's why we're here today, Mr. Chair. Thanks so much for calling this hearing, and I thank the Witnesses.

Mr. CICILLINE. The gentleman yields back. I now recognize the gentlewoman from Indiana, Ms. Spartz, for 5 minutes.

Ms. SPARTZ. Thank you, Mr. Chair and Members of the Committee.

I appreciate this discussion. Actually, as someone who worked on major healthcare reform in the State of Indiana and also worked in Fortune 500 world, I can tell you we have a huge monopoly problem in healthcare markets, enormous amount of horizontal, vertical integration, dominance of health systems, aggressive

vertical mergers, hostile takeovers, ton of anticompetitive clauses, CRN, all or nothing, gag clauses, TRN. It's really problematic. It's really in the whole healthcare. We're talking about prescription drugs. It's only 10 percent of healthcare. Over half of healthcare is actually hospital and professional services. We have to have that discussion too.

If you look at when it started, it actually started after World War II due to government interventions, when they start doing wage and price controls. Then we continued doing them more and more until the Affordable Care Act did actually very conscious effort to consolidate more, and it really took it to the next level. Then so we created, as Friedman said, political entrepreneurship due to partially socialized medical care when now this, people, politicians compete for votes by offering government services, special interest groups are fighting with each other in political arena. It was protectionist, and they want to shield themselves from market competition and kind of shift the cost like hot potatoes. So, this consolidation in government interventions led to rise of oligopolies in every market, but healthcare market is really bad.

So, we're looking at some of these bills. I think these are good initiatives. They're really a top-down, not bottom-up approach. We're not looking at the causes but treating symptoms and consequences of bad policies. If you look at sham citizen petition, why we're not talking about FDA? If we are looking, since settled, why our agency have friendly settlements much as they do include some of the stakeholders, and actually Senator Grassley and I are working on some bill. We just filed a bill. Hopefully, this Committee can support it. If we're looking at product hopping, why don't we look at patent law? Our America Invents Act created a lot of advantages for larger stakeholders in our intellectual property laws.

So, my question is—I will maybe ask Mr. Abbott—are there any approaches that we can do in the bottom-up that actually will be way more effective than constantly just kind of picking losers and winners and have more government interventions where we will see how it's going to be effective? I am supportive of doing something. I am actually not against this bill, but I think it's a piecemeal approach, and it's not going to help. Do you have any other ideas, Mr. Abbott, what we can do?

Mr. ABBOTT. Well, thank you, Congresswoman, for that question. It certainly, as I say, may seem simplistic, but I think that regulatory reform and competition advocacy are very, very important, including on issues affecting potential reform to the ACA. Now, there were efforts from Federal Trade Commission in the last Administration to work with HHS to see what they could within the regulatory system do to—and I was not intimately involved at all, but some of my colleagues and the FTC were involved in policy office, working with HHS to try to see if they could reduce the regulatory costs and disincentive—and the incentive really, as you suggested, to potential consolidation.

Again, if we view this as a bipartisan matter, there are a lot of regulatory improvements that could be had. I would certainly think that FTC has 70 Ph.D. economists. Many of them have spent a lot of time thinking about the healthcare system. I would hope that they could perhaps be given a greater role in policy advocacy, work-

ing with the Executive Branch, and also openly filing advocacy letters with the State. Obviously, it's a new Administration. We'll have to decide how it wants to allocate its resources. I think that is perfectly consistent with the policy also of trying to be very aggressive and going after anticompetitive transactions, which Acting Chair Slaughter had said. I think they could go hand in hand.

Ms. SPARTZ. I yield back. Thank you.

Mr. CICILLINE. The gentlewoman yields back.

I now recognize the gentlewoman from Pennsylvania, Ms. Dean, for 5 minutes.

Ms. DEAN. Thank you, Mr. Chair.

Man, oh, man, I am impressed with these two panels. Thank you for assembling all these terrific testifiers, Senators, Members of the House, and all these experts.

I want to follow up on something that many have touched on but, most recently, Representative Deutch.

Professor Feldman, I am looking at—and I am going to study more closely your article entitled, "May Your Drug Price Be Ever Green," published in the Journal of Law and Biosciences. It was in December of 2018. I want to examine the problem of orphan drug pricing and the protection of orphan drug—of the Organ Drug Act and how it has been really misapplied to the detriment of the marketplace, to the detriment of patients very often.

I have introduced legislation, the Fairness in Orphan Drug Exclusivity Act, which would carefully and narrowly close a current loophole in the Orphan Drug Act.

The second criteria of the Orphan Drug Act allow a manufacturer to qualify for organ drug designation if there are more than 200,000 patients affected, but if the manufacturer has no reasonable expectation to recoup costs.

Unfortunately, a company approved under this criterion, as we have seen and you have talked about, can grandfather themselves into an orphan drug designation if a newly approved product has the same active ingredient regardless if the company now has the ability to recoup costs.

I was looking at just even the beginning of your article in which you analyzed more than 60,000 drug data points from 2005–2015, and you said that the results show a startling departure from the classical conceptualization of intellectual property protection for pharmaceuticals. Rather than creating new medicines, pharmaceutical companies are largely recycling and repurposing old ones. Specifically, 78 percent of the drugs associated with new patents were not new drugs.

Would you just comment on this use, this narrow use of orphan drug exclusivity, what it's doing to the marketplace, and would a closing of that loophole, the misuse of the very Act that is supposed to bring drugs to market for patients who otherwise have, you know, rare disease or the company has no ability to recoup costs, is now being misused, protecting companies to make billions of dollars?

Ms. FELDMAN. Thank you for the question. The Orphan Drug Act was intended for when companies could not possibly recoup their costs, but, instead, we're seeing big-dollar returns. So, for example, in 2015, out of the 10 drugs with the highest annual sales revenue,

7 were orphan drugs. To paraphrase an old opera, today everyone claims to be an orphan.

Closing that loophole that you talked about would go a long way for helping people who are suffering from opioid-use disorder and other patients who are struggling to reach affordable medications.

Ms. DEAN. I really appreciate that. The area of opioid overdose and death is one that is near and dear to my heart. As Representative Deutch pointed out, in this pandemic, the number of deaths from opioid overdose is dramatically up. It is possible that number in the 12 months of the pandemic will reach 100,000 people in this country dead. So, we need manufacturers and pharmaceutical companies who want to be a part of the solution, not a part of just the profits.

So, if you would broaden it out, what does this lack of competition, this protection of marketplace and lack of competition do more broadly?

Ms. FELDMAN. The problem is access to affordable medications for our patients. When we allow drug companies to extend their monopoly pricing long past the time of the original patent grant, to pile on protections one after another, we prevent patients from getting access to that medication. That's extraordinarily important for our healthcare in this country.

Ms. DEAN. Something that you talked about was slicing up, you called it the salami slicing.

Ms. FELDMAN. Salami slicing.

Ms. DEAN. Thank you. Can you describe that phenomenon and how that's getting in the way of access to medication at affordable prices?

Ms. FELDMAN. The Orphan Drug Act is intended to apply to drugs that reach only small populations. So, companies slice and dice up their populations and then apply for serial orphan drug designations. We have to differentiate between marketing and innovation. Here, companies haven't created something new; they just figured out how to adapt it to a new market, how to sell it differently. We don't give patents for marketing.

Ms. DEAN. Well, I really appreciate your work and the work of all the esteemed testifiers.

I also want to compliment the entire subcommittee. It is a bright moment of bipartisanship where we're recognizing Democrats, Republicans, that this is an issue that's really important. That's why I have enjoyed Republican support on my bill, a bill that would close the loophole by requiring a company when applying for the new product to demonstrate their ability or inability to recoup development costs, preserving the incentives to develop products to treat rare diseases. We don't want to have any impact on the ability to incentivize R&D about around rare diseases. We do need to close the loophole.

With that, Mr. Chair, I thank you, and I yield back.

Mr. CICILLINE. That is why we welcomed with open arms your wonderful addition to our Subcommittee. Thank you for those kind words.

I now recognize the gentleman from Wisconsin, Mr. Fitzgerald, for 5 minutes.

Mr. FITZGERALD. Thank you, Mr. Chair.

Senator Cornyn in the first hearing kind of alluded to this. I just wanted to underscore it once again, which is the amazing speed that we have seen from the pharmaceutical companies when it comes to COVID and the development of the vaccines. I worried sometimes we kind of lose sight of that.

I do support the bill, and I think it is something that's overdue. I just want to proceed with caution, I guess, and make sure that we do this right.

The first thing I would say for Mr. Abbott is, what we did experience, many different facets of life changed during COVID, and one of them was that occupational licensing laws were waived as a result of COVID. What I am wondering is, if there is any examples out there of laws that policymakers, that we should look at before we reinstate them? Because it might be an opportunity—maybe it's not. It might be an opportunity to kind of revisit some of these licensing laws and make some changes there both at the Federal and State level.

Mr. ABBOTT. Thank you, Congressman.

I certainly—I think you're right about licensing laws. Obviously, there are certain minimum safety standards that are required in medicine. There are many, many licensing laws that prevented, as I say, interstate movement. For example, why couldn't there be some sort of interstate compact or, better yet, some sort of national standard for medical licensing? That could allow for easier entry and movement and easier service of rural clinics that—there is the issue about, that was raised about rural hospitals. Certainly, closure is a problem there. The antitrust agencies do recognize that small hospitals can generally merge, free from antitrust scrutiny, except in most extraordinary cases. That doesn't deal with the problem of closures and some loss of revenues due to the COVID crisis.

I mentioned already certificate of need laws. I think one—some leading economists suggest that any subsidies through the ACA should probably—if you could, be redirected more towards patients, not providers, better allow patients to shop around. In fact, nationwide provision of insurance looking at State—regulatory State commissions that unnecessarily limit insurance policies, that has been called for a sort of sensible reform given the interstate nature of that, among other things.

Mr. FITZGERALD. Very good.

Just one quick question for Dr. Feldman as well. Over the last couple of weeks, I have met with a number of grocery stores in my district. Some are single store operators, and then there's some that are local chains. I would say State chains of grocery stores. I didn't meet with kind of the big box ones that we're familiar with.

In that environment, what they were all trying to relay to me was that there were supply chains that changed and were kind of segregated out as a result of COVID. It shined a white-hot spotlight on their industry and was fascinating, kind of getting their feedback. They were worried that some of the antitrust in that area is just—it was created in the 1930s. It has outlived its usefulness. I am wondering, in the discussion we had here today, I mean, you can go too far too. I am just wondering if you have any comment on that.

Ms. FELDMAN. Thank you, sir. It is important that antitrust keep pace with changes over time in many different ways. I was struck by that question and with your earlier comment about the COVID–19 vaccines. Keeping all the experiences that we've had in mind so far, the COVID vaccines are a spectacular example of science in action, but also of government-industry participation. After all, government funding here and at academic institutions across the world helped bring this great innovation forward. It's a good reminder that patents are not the only important way that governments can promote competition. It's important for us to have government funding, and to increase government funding for basic research but also to provide incentives for all students from elementary school to graduate school, to enter science careers. Our future depends on those types of initiatives, not just the patent system.

Mr. CICILLINE. The time of the gentleman has expired.

Mr. FITZGERALD. Mr. Chair, I yield back.

I now recognized the distinguished Ranking Member of the Antitrust Subcommittee, Mr. Buck, for 5 minutes.

Mr. BUCK. Thank you, Mr. Chair. I take it I'm on right now?

Mr. CICILLINE. Yes, you are, Mr. Buck.

Mr. BUCK. Thank you. Professor Dafny, I want to direct these questions to you, and it really is a follow-up on questions that Congresswoman Jayapal asked. I have noticed in the nonprofit area of hospitals, that the salaries for top executives are, in my view, excessive. When I think of a nonprofit, I think of United Way. I think of gun rights groups, gun control groups. I think of environmental groups, I think of private property rights groups. They rely, for the most part, on fundraising for their revenue stream, sometimes on government grants, sometimes on other programs, but oftentimes on fundraising. When there are issues—and there have been I think with United Way a few years back where there was an allegation of excessive salary or benefits or expenses, and I know there was recently with a gun rights group also—the funding source sort of dries up. The fundraising is more difficult, if you will. That's not the case with hospitals. For the most part, hospitals—I know of some hospital benefit events. For the most part, hospitals receive revenue from the services that they provide.

I am wondering if there is a way for the Antitrust Subcommittee to look into this area as one of the rising costs in resulting costs for healthcare in this country.

I have to tell you, when the CEO of Apple or the CEO of Microsoft or the CEO of other companies make a lot of money, I'm okay. They have a board of directors. They have a profit incentive, and there is some downward pressure on their high salaries. I don't know that there is in this area, and I just want to get your thoughts. As a small government conservative, I don't want a regulatory agency overseeing salaries for hospitals or other healthcare entities. As a taxpayer advocate, I also don't want to see a lot of taxpayer money going to pay costs when these folks are making so much money. Any thoughts on that?

Dr. DAFNY. Just briefly. Thank you for the question, Representative Buck. I am not familiar with what's with any statutes that might restrict the compensation. I would add the compensation for executives at nonprofit insurers are quite, quite high. I would say

that, just as is the case with regular for-profit businesses, it's about the boards. If the boards—they have compensation committees as well—are benchmarking against other similar CEOs and they approve the salary, then that's kind of what the market price is for someone with that skill.

I would say that the enterprises are very large in the billions of dollars. So, personally, my concern was more with what the total amount that is being charged is ending up and less with the specific compensation of the executives that belong. I would say that they ought to be touchable by a State enforcement of community benefit profit loss.

Mr. BUCK. So, often boards of directors are appointed by, or at least recruited by, the former boards of directors or the high-ranking executives. So, often—

Dr. DAFNY. A rise in governance problem, right?

Mr. BUCK. Yeah, and so, often in these areas, the high-ranking executives are treated like the shareholders in a for-profit company. The excess revenue is distributed to those at the top of the organization, and it's very concerning. You raised insurance, nonprofit insurers, and I am not trying to pick on the hospitals, but it just seems like there has to be some mechanism to try to keep those salaries in check so that we have a more responsible expenditure of Federal funds.

I would love to talk to you offline about this.

Frankly, Mr. Chair, I would love to have a dialogue with you, also, on this issue, because I think it really goes to the cost of healthcare—part of the cost of healthcare in America. I yield back.

Mr. CICILLINE. Absolutely, Mr. Buck, and I look forward to our ongoing discussion on that really critical issue.

At this time, I will seek unanimous consent to add a number of letters and statements regarding the Committee's work to address anticompetitive conduct in healthcare markets to the record.A statement from Kristen McGovern, the Executive Director of the Partnership to Empower Physician-Led Care;a statement for the record from George Slover and Sumit Sharma from Consumer Reports;a statement for the record from the Purchaser Business Group on Health; anda statement for the record from Marni Jameson Carey, Executive Director of the Association of Independent Doctors.

Without objection.

[The information follows:]

MR. CICILLINE FOR THE RECORD

PEPC
PARTNERSHIP TO EMPOWER PHYSICIAN-LED CARE

STATEMENT FOR THE RECORD

"Treating the Problem: Addressing Anticompetitive Conduct and Consolidation in Health Care Markets"

U.S. House Committee on the Judiciary, Subcommittee on Antitrust, Commercial, and Administrative Law
April 29, 2021

The Partnership to Empower Physician-Led Care (PEPC) is a membership organization dedicated to supporting value-based care to reduce costs, improve quality, empower patients and physicians, and increase access to care for millions of Americans through a competitive health care provider market. We believe that it is impossible to achieve truly value-based care without a robust independent practice community. Our members include Aledade, American Academy of Family Physicians (AAFP), California Medical Association, Florida Medical Association, and Medical Group Management Association (MGMA). We also have individual and small medical group supporters across the country, many of whom are independent physicians or practices and wish to remain so.

We believe that physicians – especially independent physician practices – are the lynchpin of our nation's health care system. They have repeatedly demonstrated their superior ability to generate positive results in value-based care arrangements, both in improved health outcomes and reduced costs. In our vision of the future, this important piece of the health care system not only survives, but thrives as a result of policies that place independent physicians on a level playing field with other providers and opportunities to test new models with components that reflect their unique circumstances.

Increasing consolidation in the provider market creates greater urgency to ensure that value-based care is a path to sustainability for practices and physicians who are independent and wish to remain so. Because many value-based care models are built on a foundation of federal policies that apply to providers regardless of their practice setting and mode of reimbursement, we are dedicated to advancing policies that create a level playing field. We believe that the primary care physician-patient relationship is most powerful when there is patient choice and provider competition within local markets. We support legislative and regulatory action that creates parity across practice settings; aligns incentives to enable a range of providers to move toward value-based care; and prohibits anti-competitive behavior such as information blocking.

We submit the following as evidence of the detrimental impact of provider consolidation and value-based care as a path to sustainability if physician-led groups are appropriately leveraged:

1. **Provider Consolidation Leads to Higher Costs Without Measurable Improvements in Quality.**

    - A March 2020 report by the Medicare Payment Advisory Commission (MedPAC) found that in most markets by 2017, a single hospital system accounted for over 50% of inpatient admissions. Incentives for physicians to join larger practices include higher commercial prices and increased efficiencies. In 2018, nearly 57% of physicians worked in small physician practices (10 or fewer physicians). Additionally, recent studies highlighted in the report found that provider consolidation with hospital/health systems led to an increase in commercial

prices from 3% to 14%, however efficiencies aren't increasing with higher total spending as was originally assumed given the potential for improved coordination via consolidated practices. This report also highlighted the following findings on quality as a result of hospital-physician integration:
    - Patients were more likely to choose a high-cost, low quality hospital when their provider was employed by the hospital.
    - Physicians whose practices were acquired by hospitals were more likely to bill for more services in the hospital setting and fewer in the office setting.
    - Hospital acquisitions of a physician practice had little effect on improved outcomes on a range of issues, such as mortality, acute circulatory conditions, and diabetes complications (Koch et al. 2019).
    - Vertical integration had a limited effect on quality metrics reported by CMS (Short and Ho 2019).
- A 2018 Health Affairs study on consolidation trends in California found that the percentage of physicians in practices owned by a hospital increased from 25% in 2010 to over 40% in 2016, and that increases in vertical integration led to a 12% increase in Marketplace premiums, 9% increase in specialist prices, and 5% increase in primary care prices between 2013 and 2016.
- A recent brief by the Committee for a Responsible Federal Budget outlined how increased consolidation in the health care market has led to less competition, an imbalance in negotiating power, and higher prices. For example, research has shown that provider consolidation has not led to improved quality or a reduction in costs, and many physician-hospital consolidation moves are motivated by enhanced bargaining power by reducing competition.
- According to another Health Affairs study, consolidation can also lead to higher prices being passed on to consumers, employers, or the government via higher premiums or cost-sharing; more concentrated hospital markets were associated with higher premium growth in California and New York. The number of providers working in practices of 11 or more increased from 20% in 1983 to 39% by 2014, giving providers more market power to negotiate higher reimbursement rates.
- Another study found that for 15 common high-cost procedures, private PPOs paid physicians 8-26% more in counties with the highest average consolidation for physician groups, compared to counties with the lowest average.
- A 2014 study found that vertical consolidation increased hospital prices paid by private insurers by 2-3% for each one-standard deviation increase in the market share of hospitals that owned physician practices (from 2001 to 2007).
- An article published in the New York Times highlighted how as competition decreases in health care markets, rates of mortality and major health setbacks increase, in addition to increased prices. Martin Gaynor, an economist and expert on competition, said that "evidence from three decades of hospital mergers does not support the claim that consolidation improves quality," especially when the government constrains prices like with Medicare and hospitals instead must compete on quality. The article also highlights another study that found when cardiology markets are more concentrated, Medicare beneficiaries who had been treated for hypertension were more likely to have a heart attack, visit the ED, be readmitted to the hospital, or die.
- A Kaiser Family Foundation brief examining health care consolidation looked at a number of studies, including one examining Medicare beneficiary patterns of health care utilization, which found that "patients are more likely to choose a high-cost, low-quality hospital when

their physician is owned by that hospital." The brief also noted that quality of care does not improve and sometimes gets worse following both vertical and horizontal consolidation. For vertical consolidation, one study of 15 integrated delivery networks found no evidence of better clinical quality or safety scores compared to competitors outside the networks, and another study found that hospital-based provider groups had higher per beneficiary Medicare spending and higher readmission rates compared to smaller groups.

2. **Without Further Action by Congress and/or the Administration, Provider Consolidation Is Expected to Continue and Accelerate As a Result of the COVID Pandemic.**

- According to a Bloomberg Law article, the first two years of 2021 saw 71 health care transactions involving over a dozen physician specialties, including 16 primary care deals. As many independent physician practices have been financially strained as a result of the ongoing COVID-19 pandemic, this trend is expected to continue.
- A Kaufman Hall review of 2020 mergers and acquisitions found that COVID-19 served as a catalyst for health care consolidation. Although a lower number of hospital and health system transactions occurred as a result of the pandemic, the number announced still remained in a historical range over the last decade, with 79 transactions taking place in 2020 (compared to 92 in 2019).
- According to an Axios article, hospitals, insurance companies, and private equity firms will see opportunity for M&A deals with physician practices who experienced financial hardships during the pandemic.
- According to the Kaiser Family Foundation, some hospital and physician practices may find it difficult to operate independently depending on the severity and duration of revenue loss as a result of the pandemic. Financial assistance provided by the government via CARES Act and the Paycheck Protection Program, for example, may not be sufficient to prevent an increase in consolidation in the coming months. The majority of aid via these sources were not targeted at health care providers that may be most vulnerable to financial hardships from the pandemic, and additional aid may not prevent health care markets from becoming more concentrated given this was a trend occurring prior to the pandemic.
- A recent September 2020 report from Bain & Company found that nearly 70% of independent physician practices were amenable to a merger or acquisition, largely due to the strained finances and drop in procedure volumes experienced during the pandemic. This finding was consistent across specialties – including primary care physicians (69%) and office-based practices (67%). In 2019, 30% of physicians who owned practices reported they would sell their practice in the next two years.
- A series of quarterly reports from Moody's Investors Service highlighted how mergers and acquisitions (M&A) in the health care sector are expected to increase throughout the remainder of 2021. Hospitals and health systems will likely target geographic expansion and revenue diversification in M&A activity, while smaller hospitals and independent practices will continue to feel the financial strain from COVID-19. The reports suggest that independent physicians will be more open to considering affiliations with larger health systems that can offer them financial incentives.

3. **There is an Urgent Need for Congress and the Administration to Ensure that Value-Based Care Models Are Fully Leveraged as an Option to Keep Provider Markets Competitive.**

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- ***Physician-Led Models Have Generated Superior Results Compared to Other Models. For Example:***
  - Comprehensive Primary Care+ is an example of a model where physicians and physician practices demonstrated their ability to reduce emergency room and acute care visits through advanced primary care medical homes. Independent practices outperformed system-owned practices by 15% in PY2017 and 18% in PY2019, even though both practice types improved their performance on overall utilization.
  - Physician-led ACOs are also creating a better experience for patients while lowering costs across the entire system. Medicare Shared Savings Program (MSSP) results from 2019 show that, across the health care system, ACOs led by physicians, often called "low revenue," typically create more than twice the Medicare savings per beneficiary than hospital-led ACOs, often known as "high revenue." According to CMS data, in 2019, physician-led MSSP ACOs had gross per-beneficiary savings of $458 compared to $169 per beneficiary for hospital-led MSSP ACOs. In the new Pathways to Success program, physician-led ACOs had per-beneficiary savings of $429 while hospital-led ACOs had per-beneficiary savings of $258.
  - The CMS Innovation Center's test of Track 1+ and ACO Investment Model (AIM) test showed that physician-led groups demonstrate better results than groups led by other types of providers. Across all three performance years of AIM, the first cohort of AIM ACOs reduced both spending and utilization relative to comparison beneficiaries. These AIM ACOs saved $39 per beneficiary per month by 2018 and generated $119.7 million in net Medicare savings. Additionally, in 2018, 63% of Track 1+ ACOs earned shared savings, compared to 32% of Track 1 ACOs and 56% of Track 3 ACOs.

- ***Congress and/or the Administration Could Take the Following Action:***
  - Expand Medicare site neutral payment policies to additional services/procedures proven to increase in cost after a practice's acquisition without an increase in quality.
  - Enforce information blocking regulations to ensure that patient information is not used as a strategic asset to retain patients.
  - Implement recent CMS regulations establishing a new Medicare/Medicaid Condition of Participation requiring event notifications to be shared with a patient's provider of record when they go to the ER, or are admitted or discharged from the hospital, in a manner that requires hospitals to send notifications to a practice's roster of patients.
  - Build new physician-led model options based on successful underlying chassis (e.g., CPC+, MSSP, etc.) to encourage providers to enter into value-based care models with predictable implementation and proven results.
  - Ensure options for providers to join entry-level value-based care models with a glidepath to greater amounts of risk and/or more sophisticated requirements while also clearly communicating the bridge or "off ramp" to another model at the end of the model test.
  - Revise regulations and/or pass legislation directing the Secretary to remove an ACO's own beneficiaries from an ACO's benchmark, thus putting rural and urban ACOs on even footing with respect to their ability to be rewarded for care improvements and cost reductions.

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Thank you for reviewing our statement on the detrimental impact of provider consolidation on provider competition and value-based care as a path to sustainability for independent physician practices. We hope you will consider this evidence and recommendations as Congress looks to take legislative and regulatory action to address the increasing trend of consolidation in the provider market.

Please do not hesitate to reach out to me if the Partnership to Empower Physician-Led Care can be a resource to you. I can be reached at kristen@physiciansforvalue.org.

Sincerely,

Kristen McGovern
Executive Director

Consumer Reports™

April 29, 2021

The Honorable David N. Cicilline
Chairman
Subcommittee on Antitrust,
Commercial and Administrative Law
Committee on the Judiciary
U.S. House of Representatives
Washington, DC 20515

The Honorable Ken Buck
Ranking Member
Subcommittee on Antitrust,
Commercial and Administrative Law
Committee on the Judiciary
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Cicilline and Ranking Member Buck:

Consumer Reports is pleased that the Subcommittee is continuing its bipartisan efforts to examine and address competition problems in our economy.

Throughout our 80+ year history, Consumer Reports has emphasized the fundamental importance of competition for ensuring a marketplace that works for consumers, by empowering them with the leverage of choice, the ability to go elsewhere for a better deal, which means businesses have to be responsive to consumers' interests. This is no less true in the health care sector. It is critical in the lives of Americans, and it needs to function effectively to provide high quality products and services at affordable prices.

In recent decades, the heath care sector has experienced significant consolidation, in hospitals, medical practices, health insurance, and prescription drugs. There has been vertical integration between hospitals and medical practices, and between health insurers, pharmacies, and clinics. We raised concerns in this Subcommittee regarding the potential for the 2018 merger of CVS and Aetna to restrict consumer choices.[1]

This Subcommittee's bipartisan leadership in promoting competition in the health care marketplace has made a tremendous difference.

Last year, your efforts achieved a signal success – eliminating the antitrust exemption the health insurance industry had obtained in the McCarran-Ferguson Act of 1945, and had been using since then to shield itself from the forces of competition under the antitrust laws. We had been advocating for this pro-consumer change for decades,[2] and were pleased to see it finally achieved.

[1] https://advocacy.consumerreports.org/wp-content/uploads/2018/02/CU-House-Judiciary-testimony-CVS-Aetna-2-27-18-FINAL.pdf.
[2] https://advocacy.consumerreports.org/press_release/congress-acts-to-restore-competition-to-health-insurance-by-removing-75-year-old-antitrust-exemption/.

The year before, your efforts led to enactment of the CREATES Act, removing two anti-competitive roadblocks imposed by brand name drug manufacturers against competition by more affordable generic alternatives. They were blocking access to samples that generics need for testing, and were blocking participation by generics in FDA-required protocols for safe distribution and use. Both these tactics took unfair advantage of FDA requirements designed to ensure that medications are safe and effective – exploiting a legitimate FDA safeguard to block competition.

The CREATES Act was one of a number of bills the Subcommittee advanced in the last Congress to stop harmful anticompetitive practices by brand-name drug makers that are costing consumers billions of dollars, by delaying or blocking generic entry into the marketplace, so that the brand-name drug maker can unjustly prolong its monopoly profits. We understand three bills that were approved by the Judiciary Committee with strong bipartisan support have been reintroduced:

- H.R. 2883, the "Stop Stalling Access to Affordable Medications Act." This bill would prohibit the abusive use of so-called "citizen petitions" by brand-name drug makers to raise spurious concerns that stall progress on developing generic alternatives. This petition process was established to provide citizens to have an opportunity to bring concerns to the FDA's attention in a timely fashion. But the procedure has been commandeered by brand-name drug makers to raise dubious concerns, often numerous times, that require the FDA to suspend while it investigates and responds. One brand-name drug company reportedly filed 43 such petitions against a single generic applicant.[3]

- H.R. 2891, the "Preserve Access to Affordable Generics and Biosimilars Act." This bill would prohibit anti-competitive "pay for delay" schemes, in which brand-name prescription drug makers effectively pay off manufacturers of more affordable generic and biosimilar alternatives to stay out of the way – perversely gaming a system designed to *promote* expedited entry of generics and biosimilars. After a sustained decade-long effort, the Federal Trade Commission obtained a Supreme Court ruling that pay-for-delay deals are subject to the antitrust laws and can be found unlawful.[4] But drug makers have continued to resist that ruling, and to look for ways to evade it. Having to bring a new full-fledged antitrust challenge each time is costly and time-consuming.

- H.R. 2873, the "Affordable Prescriptions for Patients Through Promoting Competition Act." This bill would strengthen and clarify the authority of the Federal Trade Commission to stop the anticompetitive use of "product hopping." Product hopping is the practice of making a minor, inconsequential change in a drug in order to artificially prolong the brand-name drug maker's patent-protected monopoly profits, while at the same time discontinuing the just-as-effective version that generics are on the verge of replicating at a lower price.

[3] https://www.ftc.gov/news-events/press-releases/2017/02/ftc-charges-shire-viropharma-inc-abused-government-processes.
[4] FTC v Actavis, Inc., 570 U.S. 136 (2013).

Consumer Reports has long supported and informed consumers about constructive efforts to bring down the high prices consumers pay for prescription drugs – in our advocacy work, as well as in our journalism. See our August 2016 article, "Is There a Cure for High Drug Prices?"[5]; our April 2018 article, "How to Pay Less for Your Meds"[6]; and our November 2019 article, "The Shocking Rise of Prescription Drug Prices."[7] These articles, reporting on the results of nationally representative telephone surveys we conducted, confirmed that escalating prescription drug costs have forced many consumers to choose between cutting back on needed medications or on other basic necessities.

These three bills would all significantly advance efforts to improve competition in the development and sale of medications, so that consumers who need them will be able to obtain them and afford them. We are very encouraged that all three bills have carried strong bipartisan support.

Sincerely,

George P. Slover
Senior Policy Counsel
Consumer Reports

cc: Members, Subcommittee on Antitrust, Commercial, and Administrative Law

[5] https://www.consumerreports.org/drugs/cure-for-high-drug-prices.
[6] https://www.consumerreports.org/drug-prices/how-to-pay-less-for-your-meds.
[7] https://www.consumerreports.org/drug-prices/the-shocking-rise-of-prescription-drug-prices/.

Purchaser Business Group on Health

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Statement of the Purchaser Business Group on Health
for the
House Committee on the Judiciary
Subcommittee on Antitrust, Commercial and Administrative Law

"Treating the Problem: Addressing Anticompetitive Conduct and Consolidation in Health Care Markets"

Statement for the Record
April 29, 2021

The Purchaser Business Group on Health (PBGH) appreciates the opportunity to submit for the record our comments on the problem of anticompetitive conduct and consolidation in health care markets. PBGH is a nonprofit coalition representing nearly 40 private employers and public entities across the U.S. that collectively spend $100 billion annually purchasing health care services for more than 15 million Americans and their families. Our members work with us to identify needed system reforms to achieve and pay for optimal quality and outcomes and affordable care. We applaud the Subcommittee for its attention to the problem of anticompetitive conduct and consolidation, which was extensively documented in the Subcommittee's hearing on March 7, 2019.

Employers and employees have continued to suffer under the burden of high and ever-increasing health insurance premiums, which crowd out business investment, job growth and wages. Many experts have pointed to anticompetitive conduct and industry consolidation as a driver of high health care costs. Over the past 10 years, PBGH and its members have directly observed the impact of anti-competitive practices, increased market power and high prices in California, as evidenced by the recent settlement with the Sutter Health System. Many PBGH members based in California are members of the class action lawsuit against Sutter.

PBGH strongly believes that healthy competition among hospitals and integrated health systems is essential to providing lower costs, improved quality and better value. Unfortunately, there is inadequate competition in many markets, and government must step in to ensure that health care markets function appropriately in the public interest. Furthermore, employer

purchasers and consumers seldom have the information they need to make informed choices, which is essential for a functioning market. Specifically, we support:

- **Prohibitions on anti-competitive contracting practices**, such as anti-tiering and all-or-nothing clauses, and egregious use of out-of-network pricing to create greater leverage in price negotiations. Many of these were included in the Lower Health Care Costs Act passed by the Senate Health, Education, Labor and Pensions (HELP) Committee on a bipartisan vote in 2019.
- **Stronger antitrust enforcement and increased oversight of mergers and acquisitions**, including increased resources for federal agencies and a change in the "burden of proof" for demonstrating public benefit. In addition, the scope of antitrust oversight should be expanded to include acquisitions of health providers by health insurance plans and private equity firms, as well as cross-market mergers.
- **Full transparency on prices and quality,** including standardized measures of quality (especially patient-reported outcomes), patient experience, appropriateness, total cost of care and equity for all providers.

Drug costs are another significant contributor to high health care costs for employers and employees. The COVID-19 pandemic and ensuing public health and economic crisis also underscore the need to make prescription drugs more affordable and to spend resources more wisely. Built on the tenets of **transparency, competition,** and **value**, PBGH supports public policies that drive down the cost of drugs while preserving *true innovation* as part of a value-based health care system.

Transparency

Many drug manufacturers invest a great deal of money in research and development. But those costs and other factors that form the basis for establishing prices are extremely opaque. Increasing transparency at every level of the supply chain will provide consumers, purchasers and other stakeholders the information needed to ensure that effective treatments are obtained at a fair and reasonable cost.

Competition

The drug marketplace is characterized by counterproductive incentives, inefficiencies and anti-competitive practices that obstruct healthy price competition. Many newer drugs benefit from government-sanctioned monopolies through patent and market-exclusivity laws. Leveling the playing field by requiring fair business practices would encourage competition and drive down the cost of prescription drugs.

Value

Employers and employees pay more than ever for prescription drugs. But often the price is not aligned with the value of the product. The business models of some prescribing physicians and intermediaries, such as pharmacy benefit managers (PBMs), often are misaligned with the interests of employers and patients, resulting in higher costs. We must stop rewarding payment structures and incentives that result in higher costs, and we must ensure that drugs are priced according to their value as a therapeutic agent.

Specifically, PBGH supports policies to **strengthen competition and enhance transparency.** Policymakers can take steps to indirectly reduce the cost of drugs by banning anticompetitive practices by drug makers and other actors, and enhancing price transparency. To that end, we urge policymakers to:

- **Eliminate "patent evergreening" and other "patent thickets"** to ensure that branded products will face competition from generic drugs and biosimilars in line with the intent of current laws.
- **Prevent first-to-file generic drug applicants from blocking**, beyond a 180-day exclusivity period, the entrance of subsequent generic drugs to the market.
- **Reduce citizens petition abuse** by giving the FDA additional guidance on denying petitions submitted for the purpose of delaying generic approval.
- Require drug manufacturers to **publicly report and explain price increases that exceed certain thresholds.**
- Require branded biologic companies to **publicly list drug patents** they can reasonably defend.
- Require health care providers and pharmacies to **include National Drug Codes (NDC) in claims** for commercial health plans. NDC codes are currently required for claims to public payers (Medicare and Medicaid) and provide greater transparency on prices to purchasers.
- Require complete transparency by pharmacy benefit managers and the **pass through of all rebates and related fees and payments to plan sponsors**.
- **Address spread pricing** by pharmacy benefit managers, health plans, providers, and other intermediaries. Purchasers should be given the option to accept or reject spread pricing. This policy should apply to drugs administered directly by providers and sold in the pharmacy setting.

In addition, PBGH supports policies that **maintain employers' ability to manage drug costs.** Other stakeholders have proposed policies that would limit the ability of employers and purchasers to manage their drug costs, including

banning step therapy and generic substitution. These policies would further drive up health costs for purchasers and families and have no basis in clinical efficacy. PBGH will strongly oppose policies that strip employers and purchasers of their already-limited ability to manage their drug costs.

In closing, PBGH appreciates the opportunity to offer our perspective on the serious problems of industry consolidation and anti-competitive practices that have driven up prices to unsustainable levels. We would be happy to work with the Subcommittee by providing additional information and insights regarding the depth of the problem and potential solutions.

April 29, 2021

The Honorable Jerry Nadler
Chairman, House Judiciary Committee
U.S. House of Representatives
2132 Rayburn HOB 1504
Washington, DC 20515

The Honorable Jim Jordan
Ranking Member, House Judiciary Committee
U.S. House of Representatives
2056 Rayburn HOB
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The Honorable David Cicilline
Chairman, Subcommittee on Antitrust, Commercial and Administrative Law
U.S. House of Representatives
2233 Rayburn HOB
Washington, DC 20515

The Honorable Ken Buck
Ranking Member, Subcommittee on Antitrust, Commercial and Administrative Law
U.S. House of Representatives
2455 Rayburn HOB
Washington, DC 20515

RE: Statement from independent doctors for the hearing on "Treating the Problem: Addressing Anticompetitive Conduct and Consolidation in Health Care Markets."

Dear Rep. Nadler, Jordan, Cicilline, and Buck:

The growing number of health-care consolidations is a worrisome trend for which Americans are paying a heavy price. Hospital mergers — whether among hospitals or between hospitals and independent medical practices — are not only a leading driver behind our nation's rising health-care costs, but they are also destroying competition, which reduces quality.

The Association of Independent Doctors[1] is a national, nonprofit trade association with members in 44 states. We work to educate lawmakers, employers, patients and taxpayers about why preserving our nation's independent doctors is so essential to lowering costs, improving access, and restoring the doctor-patient relationship.

One way to achieve that goal is to remove the current financial incentives that drive health-care consolidations.

To that end, AID has pursued the following mission since we were established in 2013:

- We strive to achieve systemwide price transparency, which would introduce competition into our price-opaque health-care system, and deter consolidation.
- We aim to achieve site-neutral payments, so the same medical service costs the same regardless of whether that service is performed in an independent doctor's office, or a hospital outpatient setting, which again, would reduce hospitals' financial incentives for buying medical groups.
- We work to stop the consolidation in health care, specifically the employment of physicians by hospitals, and private equity groups, which drives up costs.
- Finally, we work to expose and end the abuse of the tax-exempt status by nonprofit hospitals.

As the executive director of AID, and on behalf of our members, I would like to thank the Subcommittee for addressing the problem of health-care consolidation, and offer some suggested remedies.

Consolidation is on the rise.

Despite the pandemic, the fourth quarter of 2020 showed a marked increase[2] in health-care mergers and acquisitions. Healthcare Financial Management Association noted 177 transactions[3] in health care in the last quarter of 2020, a 21 percent increase over the same period in 2019. Total transactions numbered 642 for the year; 10 more than in 2019.

Most worrisome to us is the nationwide trend of hospitals buying up medical practices. Between July 2016 and January 2018, hospitals acquired 8,000 medical practices, according to a report from Avalere Health and the Physicians Advocacy Institute.[4] PAI also found that the while 25 percent of physicians were employed by hospitals or health systems in 2012, by 2018, 44 percent were.[5]

It's no coincidence that health-care costs have soared alongside increasing consolidation. At nearly 18 percent of our nation's gross national product,[6] Americans spend nearly one out of every five dollars they earn to pay for health care. Since the ACA went into effect, national health spending has gone from $2.6 trillion in 2010 to over $3.7 trillion.[7] The cost is financially crippling families and hurting businesses.

Consolidation hurts patients, doctors and communities.

Regardless of what the merging parties say about streamlining care and greater efficiencies, when healthcare entities merge, costs only go one way: up. When hospitals merge, price increases of 20 percent to 30 percent are common, and can exceed 50 percent, said Carnegie Mellon economist Martin Gaynor.[8] What's more, many studies have found that patient health outcomes are substantially worse at hospitals in concentrated markets that have less competition.

When the hospital acquiring the medical practice is a nonprofit hospital or health system, as 62 percent of the hospitals in this country are, communities suffer further financial harm.[9] Nonprofit hospitals pay no taxes. They pay no income tax, no sales tax, and no property tax. When they buy

medical practices that were operating as small business and paying taxes into their communities, those taxes come off the tax rolls.

In exchange for paying taxes, these tax-exempt hospitals are supposed to plough what they would have paid back into the community in the way of free medical care, but that's not what happens. Instead they use their financial advantage to pay their executives seven-figure salaries, and to buy more medical practices. Their growing size decreases market competition and increases their market power, allowing them to negotiate higher payments from insurers, and add facility fees, which independent doctors don't charge.

In fact, a recent study[10] out of Johns Hopkins University found that for profit hospitals provide more charitable care than their nonprofit counterparts. This is hurting America, and must stop.

As to how consolidation further harms patients and doctors, consider these current examples:

- A 72-year-old seamstress in Cleveland, who gets steroid injections in her fingers once a year to ease her arthritis, was stunned to find her bill jump from $30 to $300,[11] after her doctor had become a hospital-employed physician.

- A medical group of 14 independent heart and vascular doctors had their hospital privileges revoked[12] when a large health system in St. Louis, where the group had been on staff for three decades, employed an outside group of physicians to bring all the heart and vascular services in house. Imagine how many patients will be displaced because the hospital wants to increase its profits.

When health-care entities merge, the only parties who benefit are the executives at the top. Meanwhile, consumers foot the bill in the way of higher medical bills, higher premiums, higher copays, and more tax dollars going to pay for health care.

The path toward lowering costs, increasing competition and stopping consolidation, which is this Subcommittee's focus, begins with systemwide health-care price transparency.

Hospitals and insurance companies profit excessively from keeping their prices and their patients in the dark. However, if consumers could see the price of their care before they get their bill, and shop and compare prices, more would choose lower-priced providers.

Price transparency would usher competition into the market, causing prices to come down and quality to go up. When patients can see, for instance, that a colonoscopy[13] by an independent doctor in a freestanding clinic in Virginia costs $775, and the same procedure performed by the same doctor across the street in an outpatient hospital setting costs $4,000, they will steer the market toward the lower cost provider. When hospitals can no longer get away with their excessive prices, they will be less inclined to acquire medical practices and employ doctors.

Price transparency would also move us toward site-neutrality[14] by exposing facility fees, which hospitals tack onto their employed doctors' services that add zero value, yet that can drive up costs three to five times.[15] When hospitals can no longer get away with these extra charges, they will lose much of their financial incentive for hiring doctors. Then we can slow, if not unwind, the rampant consolidation trend in health care.

Where the Subcommittee can help.

In January, the Dept. of Health and Human Services' Hospital Price Transparency Rule[16] went into effect, requiring hospitals to show all their prices online. Hospitals are not complying. In fact, *Wall Street Journal* reporters[15] have found hospitals are actually imbedding software that prevents Google search engines from finding prices. We need Congress to act to require hospitals (and next year insurers) to follow the rule as it is written and to stiffen the penalties if they don't.

This is a golden moment for the Biden Administration and the 117th Congress to build on the price transparency initiative, which has its roots in the ACA, and which puts consumers in charge of their health-care spending.

A recent national Marist survey found that 91% of Americans[17] believe that hospitals should be legally required to post all their prices in an easy-to-access format. Clearly, price transparency is not a red or blue issue. It's an American issue. It's a unifying issue. And it would cost taxpayers nothing.[19]

The Subcommittee can further help by pushing for legislation that either revokes the tax-exempt status of nonprofit hospitals and health systems that behave like for profits and abuse their tax-exempt status, or by holding them to a far higher charitable care benefit standard.

In closing, I urge this Subcommittee to work to enact legislation that would reinforce systemwide price transparency, which would encourage competition, and both discourage and unwind health-care consolidation.[20,21] Until that happens, hospitals and health systems will just continue to merge, grow, gain market share, increase their bargaining power with payers, drive up prices and squash competition.

On behalf of my members and other independent doctors nationwide, I would like to thank the Subcommittee for addressing this problem, and for your service to our country.

Most Sincerely,

Marni J. Carey

Marni Jameson Carey
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marni@aid-us.org

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Mr. CICILLINE. Before I close, I just want to say thank you, again, to our extraordinary panel of Witnesses for your testimony that I think really helped to inform the work of this Committee and will allow us to really make some progress on reducing the cost of prescription drugs in this country in a bipartisan way.

So, with deep, deep gratitude, I thank you for your presence here today.

Without objection, all Members will have 5 legislative days to submit additional written questions for the Witnesses or additional materials for the record.

With that, the hearing is hereby adjourned.

[Whereupon, at 3:53 p.m., the Subcommittee was adjourned.]

APPENDIX

The Neglected Concern of Firm Size in Pharmaceutical Mergers

84 ANTITRUST LAW JOURNAL __ (forthcoming 2021)

Patricia M. Danzon[*] and Michael A. Carrier[**]

I. Introduction

Pharmaceutical markets are complex. Multiple agents, including doctors, insurers, and pharmacies, play critical roles that affect competition between manufacturers and patient choice between drugs. This complexity, however, is neglected in standard antitrust analysis. In evaluating proposed mergers, the antitrust agencies have focused almost exclusively on whether the merging firms have potentially competing products in specific drug markets in the firms' portfolios. If they do, the remedy sought in nearly every case is divesture of the overlapping products.[1]

In many cases, such an approach adequately addresses the competitive concerns by ensuring that the combined entity does not have increased market power in specific drug markets and that the buyer of the divested product can compete with the merged entity.[2] Such settlements can be viewed as a natural outgrowth of pre-merger notification systems such as the Hart-Scott-Rodino Antitrust Improvements Act, which, in providing the federal antitrust agencies ("agencies") with the ability to review transactions before completion, "create[s] a natural opportunity for negotiation as the government identifies possible problems and brings them to the attention of the merging parties."[3] A market-by-market analysis also can be viewed as the result of prospective merger reviews, together with the burden on the agencies to show a "likely effect" of "substantially [] lessen[ing] competition"[4] in a setting in which courts do not always appreciate theories of harm that push the boundaries.[5]

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[**] Distinguished Professor, Rutgers Law School. We are grateful to anonymous referees from the Antitrust Law Journal for very helpful comments.

[1] *See, e.g.*, FTC, NEGOTIATING MERGER REMEDIES 4 (Jan. 2012) ("Anticompetitive horizontal mergers are most often remedied by a divestiture."), https://www.ftc.gov/system/files/attachments/negotiating-merger-remedies/merger-remediesstmt.pdf.

[2] *See* FTC, *Frequently Asked Questions About Merger Consent Order Provisions*, https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/mergers/merger-faq (last visited Mar. 23, 2021) (explaining divestiture packages, buyers, and goal "to preserve fully the existing competition in the relevant market").

[3] ANDREW I. GAVIL, WILLIAM E. KOVACIC, JONATHAN B. BAKER, & JOSHUA D. WRIGHT, ANTITRUST LAW IN PERSPECTIVE: CASES, CONCEPTS AND PROBLEMS IN COMPETITION POLICY 867 (3d ed. 2017).

[4] *Statement of Chairman Joseph J. Simons, Commissioner Noah Joshua Phillips, and Commissioner Christine S. Wilson Concerning the Proposed Acquisition of Allergan plc by AbbVie Inc.*, at 1, May 5, 2020. *See FTC v. Procter & Gamble Co.*, 386 U.S. 568, 577 (1967) ("The core question is whether a merger may substantially lessen competition, and necessarily requires a prediction of the merger's impact on competition, present and future.").

[5] *See* Jonathan B. Baker & Carl Shapiro, *Detecting and Reversing the Decline in Horizontal Merger Enforcement*, 22 ANTITRUST 29, 32 (2008) (criticizing *United States v. Oracle*, 331 F. Supp. 2d 1098 (N.D. Cal. 2004), for "clear error in economic reasoning" in applying unilateral-effects theory by requiring plaintiff to "prove a relevant market in which the merging parties would have essentially a monopoly or dominant position").

But there is unease with an analysis focusing solely on overlapping products. For example, Commissioner Rohit Chopra dissented from the majority's analysis in AbbVie's acquisition of Allergan, lamenting that "[t]he FTC's strategy of focusing on whether pharmaceutical companies have any overlaps in their drug product lineup is narrow, flawed, and ineffective" as it "fails to account for how executives make decisions about their drug product portfolios, how larger portfolios can suppress new entry, and how companies use portfolios to increase bargaining leverage across the supply chain."[6] Similarly, then-Commissioner (and current Acting Chair) Rebecca Kelly Slaughter dissented from the majority's disposition of Bristol-Myers Squibb's (BMS) acquisition of Celgene, "support[ing] the Commission's effort to remedy [the] drug-level overlap" but "remain[ing] concerned that this analytical approach is too narrow" and that "the Commission should more broadly consider whether any pharmaceutical merger is likely to exacerbate anticompetitive conduct by the merged firm or to hinder innovation."[7]

A recent comprehensive report by the American Antitrust Institute (AAI) found that between 1994 and 2020, the Federal Trade Commission (FTC) "challenged 67 drug mergers worth over $900 billion, moved to block only one, and settled virtually all of the remainder subject to divestitures."[8] As AAI explained, the result of this narrow focus on drug-specific markets has been "the swapping of assets within a relatively small group of large and increasingly powerful firms."[9]

This Essay examines potential inadequacies of the traditional merger analysis by evaluating the firm-wide effects of mergers, particularly those involving large firms. By focusing on individual product markets in isolation, the agencies neglect the advantages of overall firm size and the potential for spillover or cross-market effects across product markets. Size, measured by a firm's number of products and overall sales value, conveys significant advantages in negotiations, marketing, and financing that a large firm can exploit to impede entry and thwart competition in multiple drug markets. Mergers and acquisitions (hereinafter "mergers") involving large firms exacerbate these size advantages.[10] These cross-market effects, however, are not considered in the standard antitrust analysis that focuses narrowly on increased concentration in individual drug markets to determine whether – as the Clayton Act provides –

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[6] Dissenting Statement of Commissioner Rohit Chopra, *In the Matter of AbbVie, Inc. / Allergan plc, Comm. File No. 1910169*, at 3, May 5, 2020.

[7] Dissenting Statement of Commissioner Rebecca Kelly Slaughter, *In the Matter of Bristol-Myers Squibb and Celgene, Comm. File No. 191-0061*, at 1, Nov. 15, 2019. *But see* Statement of Commissioner Noah Joshua Phillips, *In the Matter of Bristol-Myers Squibb and Celgene, Comm. File No. 191-0061*, at 2, Nov. 15, 2019. ("we need to articulate a viable theory of harm to competition posed by the merger and produce evidence to support that theory" and "must convince a judge that [a merger] violates the law").

[8] AMERICAN ANTITRUST INSTITUTE, FROM COMPETITION TO CONSPIRACY: ASSESSING THE FEDERAL TRADE COMMISSION'S MERGER POLICY IN THE PHARMACEUTICAL SECTOR [AAI REPORT] 10, Sept. 3, 2020.

[9] *Id.* at 3.

[10] Our observations on size apply equally to mergers and acquisitions.

the merger threatens to "substantially lessen competition."[11] After examining all 67 pharmaceutical mergers the FTC challenged between 1994 and 2020, AAI concluded that the largest companies "have grown through hundreds of mergers and acquisitions."[12]

In this Essay, we first document the stability of leading firms in the pharmaceutical industry and contend that mergers, not innovation, have enabled these firms to maintain their dominance. We then identify three characteristics of prescription drug markets in the United States that lead to advantages related to overall firm size. First, insurance and reimbursement create size advantages in negotiations for formulary placement and pricing. Second, size conveys benefits in detailing, marketing, and sales to physicians. Third, size-related advantages in retained earnings provide a relatively low-cost source of financing for acquisitions. In all three contexts, any real efficiency savings are unlikely to be passed on to consumers through lower prices because insurance undermines competition on the final price.[13]

After explaining the advantages possessed by large firms, we outline a framework for applying these considerations to the antitrust analysis of pharmaceutical mergers. When two large firms (roughly the top 10 firms ranked by global pharmaceutical sales) merge, the already significant advantages each firm has are compounded in a manner likely to harm competition across many drug markets in the firm's portfolio (not just markets with overlapping products). This tends to entrench the enlarged firm's dominance and effectively block smaller rivals from competing.

As a result of these size-related advantages, we suggest a presumption that a merger between two large firms substantially lessens competition. Mergers involving mid-size firms (roughly the second decile) are less likely to harm competition, with the extent of harm depending on the size of the merged entity and whether dominant products are involved. We therefore recommend heightened scrutiny of mergers involving mid-size firms, especially where one of the merging firms has a dominant product. We recommend the continuation of the current approach for mergers involving small firms.

Our analysis applies primarily to the originator brand-drug industry. But similar concerns about cross-market effects may apply to mergers in other industries in which large firms span multiple markets. Vistnes and Sarafidis[14] and Dafny et al.[15] have shown that even if there is no

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[11] 15 U.S.C. § 14.

[12] AAI REPORT, *supra* note 8, at 11. For example, during the period, Johnson & Johnson and Roche each made more than 40 acquisitions while Pfizer made more than 30. *Id.*

[13] Further research is needed to quantify these effects but is impeded by data confidentiality.

[14] Gregory S. Vistnes & Yianis Sarafidis, *Cross-Market Hospital Mergers: A Holistic Approach*, 79 ANTITRUST L. J. 253 (2013).

[15] *See* Leemore Dafny, Kate Ho, & Robin S. Lee, *The Price Effects of Cross-Market Mergers: Theory and Evidence from the Hospital Industry*, 50 RAND J. ECON. 286, 286-87 (2019) and references cited therein. S*ee also* Case No COMP/M.2220 – General Electric/Honeywell, Regulation (EEC) No 4064/89 Merger Procedure ¶ 353 (July 3, 2001), https://ec.europa.eu/competition/mergers/cases/decisions/m2220_en.pdf (noting ability of GE and Honeywell to "cross-subsidise discounts across . . . products composing the packaged deal").

increase in concentration in separate product markets, mergers of hospitals in different geographic or diagnostic markets can increase the leverage of the merged hospitals in bargaining with insurers and lead to higher prices. Such cross-market effects are expected when the two merging firms contract with an intermediary (such as an insurance company) that serves customers with demand for both hospitals, for example, employers with employees in both areas. In such contexts, failure to reach a bargaining agreement with the merged hospital system increases the loss incurred by the insurer, relative to bargaining with each hospital separately, which enables the merged hospital system to extract higher prices in a simple Nash bargaining context.[16] Dafny et al.'s empirical analysis confirms that mergers of hospitals in unrelated markets raised prices more than similar hospitals not involved in mergers. Lewis and Pflum[17] find similar price-increasing effects of cross-market mergers on prices charged by target hospitals, which they also attribute to increased bargaining weight. Similarly, mergers of two hospitals in distinct therapeutic niches, for example, pediatrics and geriatrics, may increase the hospitals' market power in bargaining with insurers because loss of the combined system would reduce the insurers' appeal to employers and/or families who anticipate needing either service.

Our analysis breaks new ground in considering similar cross-market concerns in the context of branded pharmaceuticals, where large firms' product portfolios span multiple therapeutic markets that increase their bargaining leverage in negotiations with pharmacy benefit managers (PBMs). As in the hospital context, consumer price-sensitivity is blunted by extensive insurance coverage. But pharmaceutical markets raise unique issues due to the role of PBMs as agents for insurers/payers, physicians as dual agents for patients and payers, and patients who are poorly informed about the range of products potentially available.[18] These factors make exclusionary contracts hard to detect and undermine customer price-sensitivity and competitive pressures to pass through any efficiency savings from mergers.

Granted, some of the potential harms we discuss can in theory be addressed directly through enforcement actions outside the merger setting. As discussed below, plaintiffs have filed lawsuits challenging exclusionary contracts as monopolization.[19] The confidentiality of pharmaceutical contracts and rebates, however, is a significant barrier to potential plaintiffs bringing such suits, as the factual data needed to support a case can only be obtained through discovery. The agencies should therefore also consider the potential for anticompetitive, cross-market effects as part of their analysis of mergers, in particular, those involving large firms. Such an analysis would limit the harm of cross-market mergers and reduce the need for costly

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[16] Nash bargaining describes a simple bargaining situation in which two rational, self-interested actors decide how to share a surplus that they can generate.

[17] Matthew S. Lewis & Kevin E. Pflum, *Diagnosing Hospital System Bargaining Power in Managed Care Networks*, 7 AMERICAN ECONOMIC JOURNAL: ECONOMIC POLICY 243 (2015); Matthew S. Lewis & Kevin E. Pflum, *Hospital Systems and Bargaining Power: Evidence from Out-of-Market Acquisitions*, 48 RAND J. ECON. 579 (2017).

[18] We use the term "payer" to refer to both insurers and self-insured employers who contract directly with PBMs.

[19] *See infra* notes 60-61 and accompanying text.

litigation that takes years to resolve and that comes after a company's increased size has exacerbated the problem.

II. Persistence of Large Firms: Acquisitions vs. R&D

If the competitive advantage of individual drugs in their specific markets were the sole determinant of firm success, we would expect to see continual turnover of leading firms in the industry. Market leadership would change, reflecting each firm's relative success in research and development (R&D) of new products that are essential to survival and growth, as older drugs face patent loss and product obsolescence. In contrast to this expectation of only individual drugs mattering, the pharmaceutical industry is characterized by the persistent dominance of the same large firms over time. The Top 20 pharmaceutical firms in 2019, by global pharmaceutical sales, are remarkably similar to the Top 20 in 2009, with modest shifts in ranking driven more by acquisition of other firms with innovative product portfolios and/or blockbuster products than by discoveries of their own R&D departments. Of the 20 top firms in 2009, three firms in the top decile (Pfizer, Merck, and Roche) each acquired one firm in the second decile (Wyeth, Schering, and Genentech, respectively) and another second-decile firm (Astellas) exited the group. This made space for four new entrants to the 2019 Top 20 firms, and two of these (Allergan and Celgene) have already been acquired by larger firms (AbbVie and Bristol Myers Squibb (BMS)).

Table 1
Top 20 Biopharmaceutical Companies, by Global Pharmaceutical Sales, 2009 and 2019

Company	2009 Rank[i]	Company	2019 Rank[ii]
Pfizer	1	Pfizer	1
Sanofi-Aventis	2	Roche	2
GlaxoSmithKline	3	Novartis	3
Novartis	4	Johnson & Johnson	4
AstraZeneca	5	Merck & Co.	5
Merck	6	Sanofi	6
Johnson & Johnson	7	Abbott Labs/AbbVie	7
Roche	8	GlaxoSmithKline	8
Eli Lilly	9	Takeda	9
Bristol Myers Squibb	10	Bristol Myers Squibb	10
Wyeth [a]	11	AstraZeneca	11
Schering-Plough[b]	12	Amgen	12
Abbott Labs	13	Gilead	13
Amgen	14	Eli Lilly	14
Takeda	15	Bayer	15
Bayer	16	Novo Nordisk	16
Boehringer-Ingelheim	17	Allergan[d]	17
Genentech[c]	18	Boehringer-Ingelheim	18
Astellas	19	Celgene[e]	19
Novo Nordisk	20	Biogen	20

[i] Source: 2009 *Top 20 Pharmaceutical Companies Report,* Contract Pharma at https://www.contractpharma.com/issues/2009-07/view_features/2009-top-20-pharmaceutical-companies-report/. And *2009 Top 10 Biopharmaceutical Companies Report,* Contract Pharma at https://www.contractpharma.com/issues/2009-07/view_features/2009-top-10-biopharmaceutical-companies-report/?widget=listSection. Accessed Jan. 14, 2021. Based on 2008 pharma revenues.

[ii] Source: *The 2020 Top 25 Pharma and Biopharma Companies,* Contract Pharma at https://www.contractpharma.com/issues/2020-07-01/view_top-companies-report/top-25-pharma-and-biopharma-companies-751659/ Accessed Jan. 14, 2021. Data from EvaluatePharma, June 2020.
We omit Teva (ranked 17 in both years) because generics account for a large share of its sales.
[a] Wyeth was acquired by Pfizer
[b] Schering-Plough was acquired by Merck
[c] Genentech was acquired by Roche
[d] Allergan was acquired by AbbVie in 2020
[e] Celgene was acquired by BMS in 2020

These top firms in 2009 already owed their persistent industry dominance to M&A, as has been noted by previous authors.[20] For example, Pfizer acquired Warner-Lambert to obtain its blockbuster statin, atorvastatin (Lipitor), and then, when the Lipitor patent approached expiration, acquired Wyeth to obtain its pneumococcal conjugate vaccine (Prevnar) and other biologics in 2009. Other recent mergers include Merck with Schering-Plough (Schering's five lead products disappointed but pembrolizumab (Keytruda) became an unexpected blockbuster); BMS with Celgene (both built on prior acquisitions, especially in cancer); and AbbVie with Allergan, both built on prior acquisitions, and with AbbVie's lead product, adalimumab (Humira, obtained through the acquisition of Knoll Pharmaceuticals), now approaching patent expiry and Allergan's Botox (obtained from an ophthalmologist) also facing competition.

In contrast to this success in M&A, the in-house innovation of these large firms has played a modest and declining role in their continued success. Large firms' share of the New Active Substances (NAS) submitted each year to the U.S. Food and Drug Administration (FDA) declined from 30 percent in 2009 to roughly 20 percent in 2018; by contrast, the share of NAS originated by very small "emerging" firms has increased to roughly 70 percent.[21] Many of these very small firms are formed around promising research compounds, often spun out from academic laboratories funded by the National Institutes of Health (NIH). Similarly, in its comprehensive report, AAI found that the industry's "pattern of consolidation" in the past 30

[20] The twelve leading pharmaceutical firms, ranked by worldwide sales in 2010, were influenced by 19 significant mergers and acquisitions from 1989 to 2011, not including smaller consolidations. William S. Comanor and F.M. Scherer, *Mergers and Innovation in the Pharmaceutical Industry*, 32 J. HEALTH ECON. 106 (2013).

[21] New Active Substances (NAS) are a measure of innovative, novel compounds, in contrast to new formulations and new indications that simply extend use for older compounds. Data from IQVIA Institute, *The Global Use of Medicine in 2019 and Outlook to 2023* (Jan. 2019). Companies are assigned to segments based on 2018 revenues or 2017 R&D spending (because the smallest firms have no sales revenues). Segments are defined as: Large > $10 billion; Mid $5-10 billion; Small $500 million-$5 billion; Emerging < $500 million or R&D Spending < $200 million. If multiple companies are involved in a project, it is assigned to the larger segment.

years "reveals the extent to which many pharmaceutical companies have expanded through M&A, as opposed to through organic growth and innovation."[22]

This disconnect between small firm dominance in innovating new compounds and a stable pack of large firms dominating product sales is reconciled by the extensive, industry-wide pattern of acquisition, as mid-size firms acquire smaller firms and large firms acquire small, mid-size, and large firms. This chain of acquisition serves large firms' need for products and small firms' need for financing and expertise. Although small firms discover and do early development on most new drugs, they may lack the financing and expertise needed to develop their drugs through large clinical trials and regulatory approval, and then market and sell the drugs nationally and globally. The R&D cost of bringing a new drug through regulatory approval at the FDA has been estimated to range between $790 million[23] and $2.7 billion.[24] Small firms typically obtain initial funding from venture capital (VC) and other sources of private and public equity. But for funding costly late-stage clinical trials and undertaking sales and marketing, many small firms either out-license their drugs or accept acquisition by larger companies that need new drugs as patents expire on their older drugs and their in-house R&D fails to replenish their product pipelines. Early-stage investors in small firms also welcome such acquisition as a financial exit that enables them to recoup a return on their investment.

This pattern of acquisition of innovation-focused small firms by larger firms with expertise in marketing and sales can create real resource savings. And it generally poses no significant antitrust concerns, as we discuss below. By contrast, when mergers occur between larger firms that each already has significant sales revenues and marketing expertise, the efficiency gains are less and the risks of harm to competition are greater due to the potential increase in size-related bargaining leverage we elaborate below.

Although large pharmaceutical firms often rationalize their mergers by claiming synergies in R&D and marketing, the evidence on the declining R&D productivity of large firms relative to smaller firms, despite the large firms' sequence of mergers, casts doubt on both the claimed scale economies and the effectiveness of large mergers in enhancing R&D efficiency.[25] Empirical studies confirm that larger pharmaceutical mergers are often a response to patent

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[22] AAI REPORT, *supra* note 8, at 12.

[23] Vinay Prasad and Sham Mallankody, *Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues after Approval*, 177(11) JAMA INTER MED. 1569 (2017). This median estimate appropriately includes the cost of failures and cost of capital prior to launch; however, it is unrepresentative because it is based solely on very small firms.

[24] Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20 (2016). This mean estimate appropriately includes the cost of failures and cost of capital prior to launch; however, it is unrepresentative because it is based solely on the largest firms, and it uses proprietary data that cannot be verified.

[25] Comanor & Scherer, *supra* note 20, argue that the pharmaceutical merger waves between 1989 and 2011 may have contributed to the decline in R&D productivity over the same time period, reflected in the declining number of new drug approvals despite rising aggregate R&D spending, as the consolidation of large firms reduced the number of independent pathways seeking to solve major medical problems.

expirations on a large firm's major products and gaps in its own pipeline of follow-on products. Such patent expirations generate excess capacity in the firm's administration, sales, and marketing functions and threaten to erode its future revenues and profitability. Large acquisitions are a strategy to acquire new compounds and to cut costs through restructuring that is at least partially imposed on the target company.

The empirical data, however, provide no evidence that such mergers improve the firms' underlying R&D productivity through economies of scale or scope,[26] and much of the cost-cutting in marketing and sales is not merger-specific, in other words, is possible without the merger. One possible exception occurs if one firm brings global expertise and marketing reach that the other firm lacked, as the synergies in such a case would be merger-specific. On the other hand, size also brings the potential for increased bargaining leverage that may benefit the merged firm and enhance its market dominance, but to the possible detriment of consumers. Unfortunately, no studies have attempted to tease out how much each of these effects—real efficiencies vs. increased leverage—contributes to the continued dominance of incumbent large firms. Our objective here is simply to explain how mergers increase the bargaining leverage of large pharmaceutical firms and to point out that these potential harms of size-increasing mergers should be considered alongside any claimed synergies in evaluating such mergers.

The next sections describe how the institutional contexts of pharmaceutical markets in the United States create competitive advantages for large firms and reveal potential anticompetitive effects not captured absent the consideration of overall firm size in merger analysis.

III. Negotiating with Insurers for Reimbursement[27]

Size is an advantage for drug companies in their dealings with insurance payers in healthcare markets. Insurance is a "necessary evil" that creates a third-party payer norm in these

[26] Patricia M. Danzon, Sean Nicholson, Andrew J. Epstein. *Mergers and Acquisitions in the Pharmaceutical and Biotech Industry*, 28 MANAGERIAL & DECISION ECON. 307 (2007) confirms that mergers tend to be undertaken by firms that anticipate distress (low expected earnings growth as measured by Tobin's Q). This implies that measurement of the effects of mergers must adjust for the non-random selection of merging firms. In a study of 202 biotech and pharmaceutical mergers between 1988 and 2001 and controlling for merger propensity, Danzon et al. found that firms that merged experienced, in the subsequent three years, a similar change in enterprise value, sales, employees, and R&D, and had slower growth in operating profit, compared to similar firms that did not merge. A more limited sample of 160 R&D-related acquisitions by 60 public firms between 1994 and 2001 also found that firms with a high "desperation index" (expected years of patent life including marketed drugs and pipeline products) were more likely to acquire another firm. This study found that pre-merger alliances between the parties were positively correlated with both announcement period abnormal returns and one-year post-merger pipeline improvement. They conclude that pre-merger alliances are a means to reduce information asymmetries. M.J. Higgins and D. Rodriguez, *The Outsourcing of R&D through Acquisitions in the Pharmaceutical Industry.* 80 J. FINANCIAL ECON. 351 (2006).

[27] For detail on the effects of insurance, reimbursement rules, and PBMs, see Patricia M. Danzon, *Differential Pricing of Pharmaceuticals: Theory, Evidence and Emerging Issues*, 36 PHARMACOECONOMICS 1395 (2018); Patricia M. Danzon, *Pharmacy Benefit Management: Are Reporting Requirements Pro or Anti-Competitive?*, 22(2) INTERNATIONAL J. ECON. BUS. 245 (2015); Patricia M. Danzon, *Pricing and Reimbursement of Biopharmaceuticals and Medical Devices in the USA*, in 3 ENCYCLOPEDIA OF HEALTH ECON. 127 (Anthony J. Culyer ed., 2014).

markets. Patients desire insurance as protection from the high and unpredictable costs of healthcare. But insurance means that "someone else is paying." This makes patients insensitive to price, which creates incentives for health care producers to raise prices unless insurers adopt constraints through their reimbursement rules.[28] In all high-income countries other than the United States, payers limit the prices they pay for pharmaceuticals, for example, using cost-effectiveness or other measures of a drug's value. By contrast, in the United States, pharmaceutical firms set their list prices freely. Private and public payers (insurers, employers, Medicare, and Medicaid) then use PBMs[29] to negotiate rebates off list prices, in return for favorable reimbursement.

In these reimbursement negotiations with insurers, size is an advantage for pharmaceutical firms. The mechanisms through which size advantage operates depend on the specifics of the payers' reimbursement rules, which differ across dispensing channels in the United States. We focus here on the two main channels, which together account for more than 80% of pharmaceutical sales: (1) pharmacy-dispensed drugs (pills, capsules, and liquids) and (2) physician-dispensed drugs (injections and infusions, such as cancer drugs).

A. Pharmacy-dispensed drugs

Most private payers and Medicare Part D plans (which cover outpatient drugs for seniors) use PBMs to manage price negotiations and make payments to drug firms and drug-dispensing pharmacies. PBMs establish tiered formularies (lists of covered drugs), with drugs on preferred tiers having lower co-payments as an inducement to patients. This ability to steer patients to preferred drugs through formularies enables PBMs to negotiate rebates off drug companies' list prices in return for preferred and/or more exclusive formulary position and, consequently, larger market share.[30] This PBM strategy is effective at reducing costs without significant harm to patients in crowded drug classes (such as anti-ulcerants) in which several drugs are close therapeutic substitutes, such that patients and physicians are willing to switch to the preferred drugs in response to lower cost-sharing. By contrast, for specialty drugs that are more expensive and more differentiated, patients and physicians are unwilling to change treatment plans for modest co-payment differences, and formulary exclusions or barriers to access for some drugs can cause harm to consumers. PBMs generally place these specialty drugs on separate tiers with

[28] Although most insured patients are responsible for co-payments, such cost-sharing is usually modest and capped by an annual "catastrophic" limit on a patient's out-of-pocket expenses.

[29] Medicare Part D uses intermediaries called Prescription Drug Plans (PDPs) that are similar to PBMs but bear some insurance risk. We include this category in PBMs. As discussed below, *see infra* note **Error! Bookmark not defined.**, Medicaid obtains mandatory discounts off list prices.

[30] For example, a formulary with only two drugs per class on the preferred tier will get larger rebates from drug firms than a formulary with five preferred drugs per class, because each of the two preferred drugs on the more restrictive formulary will gain larger market share than each of the five drugs on the less restrictive formulary.

high co-insurance (20% to 30% of the list price) and may impose other barriers to coverage, such as prior authorization or step edits,[31] which may be linked to rebates.

PBM contracts with insurers or self-insured employers, for whom PBMs act as agents, typically require that most rebates related to formulary structure are passed through to the payers. The confidentiality of these drug-specific rebates has been deemed necessary to preserve the incentives of drug firms to offer competitive rebates.[32] But the full pass-through of rebates is unlikely and indeed would undermine the incentives of PBMs to negotiate rebates.

These arcane details of pharmaceutical markets have important implications for the analysis of mergers. First, because consumers are heavily insured and price-insensitive, PBMs act as agents for payers – and ultimately for consumers – to negotiate drug rebates on behalf of payers and consumers. Price competition in these markets operates through drug firms offering confidential rebates off their freely-set list prices, in return for preferred placement on a payer's formulary. One unfortunate by-product of this competitive mechanism is that drug firms and PBMs both have incentives to prefer a strategy of high list prices and large rebates, rather than lower list prices and smaller rebates. This incentive structure contributes to the high and rising list prices for brand-name drugs and the increasingly acrimonious debate over rebates.

A second unfortunate by-product of competition through rebates rather than list prices is that it creates advantages for large firms. Specifically, a drug company with a large portfolio of products, including blockbuster drugs (with high sales and potentially large rebate volume), has more leverage and flexibility in negotiating with PBMs than a company with fewer or smaller products.[33] This size advantage can be used in ways that are harmful to competition and to consumers. For example, a large, multi-product firm with blockbuster products that generate significant rebate revenue for a PBM can leverage the blockbuster through a bundled rebate strategy to gain more exclusive positioning with less rebate for its own products or, in the extreme, require exclusivity on the preferred tier for one or more of its drugs, which effectively

[31] Prior authorization means that, as a condition of reimbursement, the physician must obtain the insurer's approval prior to treatment. Step edits require that a patient fail on a preferred drug before gaining coverage of a less-preferred drug.

[32] George J. Stigler, *A Theory of Oligopoly*, 72 J. POLITICAL ECON. 44 (1964); Congressional Budget Office Cost Estimate: "H.R. 1 Medicare Prescription Drug and Modernization Act of 2003 as passed by the House of Representatives on June 27, 2003 and S. 1 Prescription Drug and Medicare Improvement Act of 2003 as passed by the Senate on June 27, 2003, with a modification requested by Senate conferees" (July 22, 2003). https://www.cbo.gov/sites/ default/fles/108th-congress-2003-2004/costestimate/hr1s100.pdf; Danzon, *Differential Pricing of Pharmaceuticals*, *supra* note 27. For a discussion of the interchangeability of rebates with other "financial benefits" provided to PBMs, see Michael Carrier, *A Six-Step Solution To The PBM Problem*, HEALTH AFFAIRS BLOG (Aug. 30, 2018).

[33] In a Nash bargaining model, a firm with a large portfolio, including a "must-have" blockbuster product with high sales and rebate volume, can impose a large loss of rebate revenue if it fails to reach agreement with the PBM, compared to a small firm with a single product with small sales.

blocks entry of a new drug to preferred status in these classes for the customers of this PBM, even if the new drug has therapeutic advantages and/or offers a lower list and net price.[34]

How a large firm would allocate its bargaining leverage between increased exclusivity and higher prices in theory depends on the characteristics of the drug class, including price elasticities. Despite this, several generalizations are possible. First, any increase in price would take the form of lower rebates with specific PBMs, rather than an increase in list price because a higher list price applies to all customers and may trigger an excess inflation rebate that a firm must pay to Medicaid for list price increases that exceed inflation. Second, any use of bargaining leverage to reduce the rebates offered would be very difficult to measure, as the reduction is relative to the unobservable counterfactual of what would have been required to achieve a given level of exclusivity in the absence of the bargaining leverage.

Third, for an incumbent firm with a leading product in a class, an exclusive contract that obstructs the entry of a potential competitor, especially a superior competitor, would likely be more profitable to both the firm and the PBM than raising its price to the PBM by reducing its rebates because a competitor would reduce the incumbent's revenues by stealing share and likely reduce class-wide revenues, assuming the competitor enters at a lower list price and that class-level demand is price-inelastic, due to both extensive insurance and disease-related limits on most classes. Essentially, competitive entry is zero or even negative sum for the incumbent firm and for the PBM, if class-level demand is price-inelastic and entry reduces average prices.

Fourth, the negative effect of entry on the potential surplus to be split between incumbent and PBM is true *a fortiori* if the new entrant is a biosimilar competitor for the incumbent producer of a biologic blockbuster that is nearing patent expiry. An incumbent has strong incentives to use exclusive contracting, including bundled rebates, to bar entry of biosimilar competitors for that blockbuster, whereas it is generally futile for a firm to attempt to block generic entry following patent expiry on a blockbuster chemical drug. Under the Hatch-Waxman Act, generic versions of chemical drugs can be approved by showing bioequivalence to the originator drug.[35] Bioequivalent generics are substitutable by pharmacies, unless the physician expressly requires the originator brand. PBMs generally place generics on their lowest co-

[34] The pharmaceutical firm may make a large rebate on a high volume, "must have" blockbuster product conditional on each of its products being one of at most two preferred drugs in their respective classes on the formulary. If the PBM were to add a new drug to any of these classes as a third option, it would forgo large rebate revenue on the blockbuster drug that it could not make up from a low-volume new entrant, especially if the entrant has a lower price and lower rebate. In *Shire v. Allergan*, for example, Shire has alleged that Allergan made its rebates on its dry eye drug, Restasis, and rebates on its glaucoma eye products conditional on Restasis being the sole preferred drug on formularies of most large Medicare Part D drug plans, which allegedly blocked the adoption by Medicare Part D plans of Shire's superior drug for dry eye, Xiidra. 375 F. Supp. 3d 538 (D.N.J. 2019). Shire has argued that it would be required to offer its drug below average cost in order to compensate the PBM for its loss of rebate revenue from Allergan which was conditional on preferred tier exclusivity for Restasis. This differs from standard predation because the incumbent is not offering its product below cost; rather, it relies on its large volume and product bundling to offer a combined rebate that Shire could not match and cover its average cost. Unlike standard predation, this is a sustainable strategy for the incumbent.

[35] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. §355).

payment tier, to encourage patient acceptance of these cheaper products. Moreover, PBMs profit directly from generic substitution through their own mail-order pharmacies. Given pharmacy substitution of generics, it would be futile for the producer of the originator brand to attempt to bar generic entry through an exclusive contract with a PBM, because pharmacies can substitute, even if the brand is prescribed.

Biosimilars, on the other hand, are not bioequivalent and are not substitutable for the originator biologic by pharmacies. Thus, biosimilars' ability to compete by offering lower prices depends critically on PBMs' willingness to place them on preferred formulary tiers. But given their lower list prices and their low expected initial volumes, biosimilars cannot offer rebate revenue to PBMs comparable to that offered by the incumbent originator. As a result, both the originator and the PBM can gain by agreeing to a contract that excludes the biosimilar, as, for example, the plaintiffs alleged in *Pfizer Inc. v. Johnson & Johnson*, discussed below.[36]

In short, although large firms may use their bargaining leverage to either reduce rebates or exclude competitor products, exclusion is likely to be the more profitable strategy if the large firm has products in classes with few competitors and inelastic class-level demand, especially if the large firm has biologics approaching patent expiry. Of course, some large firms may have bargaining leverage based on prior mergers or even unrelated to mergers; nevertheless, permitting large mergers that expand the portfolios and sales of already large firms exacerbates these risks.

A group of unions and consumer and public interest organizations raised such concerns in objecting to the recent proposed merger between AbbVie and Allergan.[37] The groups warned that the merger "would enable AbbVie to use exclusionary practices . . . to limit the ability of rivals to expand and enter."[38] In particular, they pointed to "rebate wall[s]," which occur when "a manufacturer leverages its market-dominant position to secure preferred formulary access for its products by offering lucrative incentives to PBMs and health insurers in the form of volume-based rebates."[39] The rebates "are often offered across multiple products, indications, and therapeutic specialties, the breadth of which cannot be matched by new and innovative therapies."[40] The groups worried that "combining AbbVie's blockbuster drugs with Allergan's is likely to exacerbate . . . anticompetitive conduct, because the merged firm will have an increased ability to bundle rebates across its enlarged drug portfolio in order to keep competing branded drugs, generics, and biosimilars off of PBMs' and insurers' preferred position on their drug formularies."[41]

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[36] 333 F. Supp. 3d 494 (E.D. Pa. 2018).
[37] Letter from Families USA et al. to The Honorable Joseph J. Simons, Sept. 12, 2019, https://www.fdanews.com/ext/resources/files/2019/09-16-19-LetteronMerger.pdf?1568653634.
[38] *Id.* at 4.
[39] *Id.*
[40] *Id.*
[41] *Id.* at 5.

One final advantage large firms can exploit comes from Medicaid. The "best price" rule requires that a drug company give Medicaid the "best price" it offers to private buyers.[42] This benefits large firms, which can allocate their rebates across products to achieve a given overall price concession to the PBM with minimum revenue losses. A smaller firm with only a single drug lacks the flexibility to allocate its rebates strategically across a portfolio of products and thus has less leverage and faces higher overall contracting costs. This places small firms at a competitive disadvantage relative to larger firms in bargaining for formulary placement. Although in theory the enforcement of Medicaid best price rebates is the responsibility of Medicaid, it is simply not practical for Medicaid to monitor evasions that occur through the bundling of rebates across drugs in complex, multiproduct contracts that are confidential. As a result, even though an antitrust issue is not presented by the use of bundled rebating to avoid paying Medicaid best price, it is relevant to determining the competitive effects of mergers.

In summary, mergers between large firms can expand their ability to use bundled rebate strategies as an effective barrier to coverage or preferred tier status for competitor drugs in multiple therapeutic categories, thereby blocking new drugs from smaller companies from the preferred tier status that is needed to gain widespread adoption by patients, even if the new drugs are superior, lower-priced, or both. The potential for such portfolio contracting to generate cross-market effects from mergers of large firms is neglected by traditional, market-specific merger analysis.

B. Physician-administered drugs

A drug firm's overall size can convey similar advantages in negotiating to sell physician-administered drugs that are covered under a private insurer's medical benefit or Medicare Part B (for seniors or the disabled). Traditionally, these drugs – infusions and injections that require special handling – were distributed by specialty pharmacies that delivered them to the dispensing physicians, who "buy and bill" the insurers directly. "Buy and bill" means that dispensing physicians can profit (or incur loss) from the margin between the drug's acquisition cost and reimbursement. Most payers follow Medicare, which reimburses physicians at the "Average Sales Price (ASP)" + 6%, where a drug's average sales price in quarter t is calculated as the manufacturer's average price to all customers net of all discounts, lagged 2 quarters. This reimbursement rule creates incentives for firms to set high initial list prices, because the 6% margin has greater absolute value to dispensing customers on a high-priced product. The rule

[42] Brand drugs are required to give Medicaid a discount equal to the greater of 23.1% or the "best price" given to private buyers. A large firm that wants to give, say, a 30% rebate on drug A to PBM X may avoid having to give the same 30% discount to Medicaid on drug A if the equivalent rebate value is achieved through a bundled rebate contract with PBM X that simultaneously specifies, say, a 20% rebate on several drugs including but not limited to A. This bundled contract could achieve the same overall rebate revenue for the PBM while allowing the drug company to avoid paying a "best price" rebate to Medicaid beyond the required 23.1%. Firms are required to report their rebates to Medicaid, but in this case the 20% rebate on all drugs would appear within allowable limits and not trigger any best price penalty.

also discourages discounting, because any discounts in quarter t would reduce the ASP that is reimbursed to all customers two quarters later.

Again, however, large firms may have advantages not available to smaller firms. A small, single-product firm that wishes to provide a rebate on a drug, in order to get the business of a large customer, may be deterred because this rebate would reduce its ASP and hence the future reimbursement for *all* customers.

By contrast, a larger, multi-product firm may be able to bundle the desired rebate for the large customer over a portfolio of products. The large firm might even be able to shift some of the rebate to the firm's pharmacy-dispensed drugs, for which there is no ASP effect—on the contrary, rebates on these drugs would *increase* their appeal to the PBM. Such contracting across physician- and pharmacy-dispensed drugs entails higher administrative costs and is almost certainly much less common than portfolio rebating across only pharmacy-dispensed drugs described earlier, as physician-dispensed drugs were traditionally distributed and managed by specialty pharmacies that contracted directly with physicians, with no role for PBMs. But as PBMs have acquired specialty pharmacies, contracting across pharmacy- and physician-dispensed drugs has become more feasible. Thus, M&A in the PBM-pharmacy-distribution space has increased contracting advantages of size for large drug firms with portfolios of drugs that span both pharmacy- and physician-dispensed platforms. These advantages of overall firm size are neglected in traditional merger analysis.

IV. Marketing and Selling

A second context in which portfolio size brings advantages to large drug firms is in marketing and selling to physicians. Physicians have traditionally been considered the primary customers for drugs because physicians advise patients on drug choice and write the prescriptions that are required to obtain all prescription drugs.[43] And in the United States, as discussed above, certain physicians also buy, dispense, and bill for some drugs requiring infusion or injection. Drug companies therefore invest significant resources in marketing to physicians. This section discusses three related contexts in which a firm's size, specifically the number and sales value of its overall product portfolio, can convey marketing advantages over smaller firms: detailing to physicians, contracting with physician groups, and portfolio rebating. The potential competitive harms from increasing these size effects are neglected by traditional merger analysis.

A. Scale Economies in Detailing to Physicians

The primary marketing tool used by drug companies to persuade physicians to prescribe their drugs is detailing, that is, the practice of sending representatives to physicians' offices to provide information about the drugs and leave free samples for patients. Detailing is expensive. It requires knowledgeable representatives who spend time traveling between offices and awaiting

[43] PBMs are now also important customers because, as discussed above, insurance coverage is necessary for patients to afford expensive drugs.

openings on doctors' busy schedules. Relationships between representatives and physicians are crucial and are built through frequency and scope of contact.

In this context, a large, multi-product company that has two or more drugs that can be promoted on the same visit saves time and adds more value for the company and the physician, compared to a smaller company with only one product relevant for a particular physician's specialty. Although the small company can seek some benefits of scale by hiring a contract marketing organization that markets drugs produced by multiple, smaller firms, such a strategy offers each small firm less control over the timing and messaging of detail visits. As a result, contract marketing is considered less effective than an in-house sales force trained and dedicated to a company's products. Gaining access to a large company's sales force and expertise in marketing is a major reason why small companies out-license their products to larger companies.

B. Scope Economies in One-Stop Shopping for Groups

In recent years, most physicians have organized into large, multi-specialty groups, for example, multiple oncology specialties in one center. Marketing to large, multi-specialty groups increases the potential for a large firm to realize economies of scope in marketing their drugs across multiple therapeutic areas. A large firm with a broad portfolio of drugs can offer one-stop-shopping convenience to these multi-specialty customers, for example, drugs to treat multiple cancers. This size advantage can create a barrier to entry for a smaller company with only one or two products for one disease, say breast cancer, even if the small company offers lower prices on its few drugs. A merger analysis that focuses solely on whether the merging companies have overlapping products in breast cancer ignores the merged company's enhanced marketing advantage from the number and importance of its products across multiple cancers. Focusing only on breast cancer will underestimate the merger's adverse effects on potential entry for other firms in breast cancer and other disease classes where the merged entities do not have overlapping products but where the merged firm has an increased size advantage due to its overall portfolio breadth and the one-stop-shopping convenience it offers.

C. Portfolio Rebating to Multi-Specialty Groups

Large drug companies also can exploit advantages in multi-product negotiations with large, multi-specialty physician groups for physician-dispensed drugs that they buy and bill. In such negotiations, a large company can strategically allocate rebates across a product portfolio. The rebating opportunities increase with portfolio size, benefitting large firms relative to smaller firms. These size-related advantages spill over across product lines, including those for which the merging firms may have no overlapping products. These effects for physician-dispensed drugs are analogous to the portfolio rebating advantages large firms enjoy in dealing with PBMs for pharmacy-dispensed drugs. Again, the increased leverage of a large firm in these price/access negotiations could be used by the firm to gain higher prices for a given exclusivity level, or could be used to increase exclusivity for the firm's products, which reduces patients' access to new products from smaller companies. Confidentiality of these contracts makes it very difficult for

harmed patients or competitors to document and challenge such harms after the event. Expanding the traditional product-by-product merger analysis to consider these potential cross-market harms before they occur therefore seems warranted.

In evaluating the antitrust implications of these size-related economies of scale and scope in marketing, it could be argued that at least the detailing advantages may entail real resource savings for drug companies and their physician customers that could be considered cognizable efficiency savings from a merger. While acknowledging this potential, we suggest two offsetting factors that warrant consideration. First, any such efficiencies are unlikely to be passed on to consumers; rather, they are likely to be captured by large drug firms as increased market share and ultimately profits for their products. In normal price-competitive markets, marketing efficiencies might be passed on as firms lower their prices to compete for price-sensitive customers. But as discussed above, patient price-sensitivity in drug markets is very low because insurance covers most of the price, with the patient paying only a modest co-payment that is often independent of the drug price and is capped by "catastrophic" annual limits on a patient's out-of-pocket cost. Moreover, patients lack information about the relative merits of alternative drugs; rather, their drug choices are heavily influenced by physicians and by PBMs that may benefit from higher list prices with larger rebates, not lower list prices.

This lack of price-sensitivity of patients, PBMs, and physician customers to a drug's list price means that any cost savings related to marketing are likely to be realized as profit to pharmaceutical companies and physician groups, not passed on to consumers as lower drug prices. Moreover, to the extent that increased size also enhances a firm's bargaining leverage, there is offsetting potential to either raise prices or increase the exclusivity of the firm's products. Separating these effects empirically would be extremely difficult and, unfortunately, we know of no empirical evidence that has attempted to measure economies of scale and scope in pharmaceutical marketing or the likely associated increases in leverage.

Second, the U.S. pharmaceutical industry's expenditure on marketing and sales is already very large, driven by the huge margins between prices and marginal cost.[44] While some marketing is informative, providing physicians and consumers with information about new products, heavy marketing of well-established products is more likely intended to persuade and promote brand loyalty, which is of questionable social value, particularly for healthcare products that are heavily tax-subsidized. For these reasons, all developed countries except the United States place significant restraints on the volume and forms of pharmaceutical marketing. A full evaluation of pharmaceutical marketing is beyond the scope of this paper. But to the extent that the antitrust evaluation of pharmaceutical mergers involves weighing efficiency savings against the risks of anticompetitive harm, claimed efficiency savings from spending on marketing

[44] Estimates of total marketing spend as a percent of sales is very sensitive to whether the cost of free samples is measured at input cost or full potential sales price.

functions of questionable social value call into question their treatment as standard cognizable efficiencies under merger analysis.

V. Financing

The third advantage of size is that large firms with portfolios of marketed drugs generate huge revenue flows from current sales. Large firms use these retained earnings to fund their marketing and in-house R&D and acquisitions of small- and mid-size firms, turning to external capital markets only if additional funding is needed for the largest acquisitions. By contrast, smaller firms with few or no marketed products must raise funds from external capital markets to undertake costly pre-clinical and clinical trials required for drug approval and to develop in-house marketing and sales functions. Most start-ups rely on venture capital and private equity to fund drugs through early R&D but then turn to public capital markets and licensing or acquisition deals with larger companies to fund the more costly late-stage clinical trials and drug commercialization.

This flow of retained earnings from marketed products gives large firms a lower cost of capital than is available to smaller firms that must raise capital from external private or public equity.[45] Indeed, high drug prices are often defended as necessary to fund the next generation of innovation.[46] This claim ignores the fact that small firms lacking marketed products can and do raise their R&D funding from external capital markets. But the claim recognizes that retained earnings provide a cheaper source of funding for R&D than raising external funds through capital markets.

This advantage of retained earnings also facilitates large firms' acquisitions of other firms, both large and small. The lower cost of retained-earnings financing might be considered a real efficiency saving that large firms bring to their mergers. But such saving benefits consumers *only* if it is passed through as lower drug prices. As argued earlier, the lack of price-conscious customers in the industry makes savings pass-through unlikely in U.S. pharmaceutical mergers.

Nevertheless, in considering the appropriate antitrust posture towards mergers in the pharmaceutical industry, it is important to recognize the reality that small- and even mid-size firms may lack retained earnings and expertise needed to fund R&D and build marketing/sales capabilities, and this is a motive for selling their companies to larger firms that already have retained earnings and sales capabilities. In this context, larger firms' acquisition of smaller firms can offer efficiencies by eliminating the building of additional regulatory, marketing, and sales

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[45] Stewart Myers & Nicholas Majluf, *Corporate financing and investment decisions when firms have information that investors do not have*, 13 J. FIN. ECON.187 (1984).

[46] *E.g.*, Information Technology and Innovation Foundation, *Price Controls Would Harm Drug Discovery and Innovation* (Nov. 5, 2018), https://itif.org/publications/2018/11/05/price-controls-would-harm-drug-discovery-and-innovation-new-report-shows#:~:text=Price%20Controls%20Would%20Harm%20Drug%20Discovery%20and%20Innovation%2C%20New%20Report%20Shows,-November%205%2C%202018&text=%E2%80%9CPrice%20controls%20and%20other%20steps,critical%20to%20new%20drug%20discovery.%E2%80%9D.

functions by smaller firms. Instead, the merged entity can realize economies of scale and scope by using the large firm's established capabilities—indeed, large firms often seek out acquisitions to replenish their pipelines of new products when they anticipate excess capacity in their overhead and sales capabilities relative to their in-house products. In such contexts, acquisitions of smaller firms may bring new drugs to market more quickly, even if the savings are not reflected in lower prices. And as noted, larger firms' acquisition of smaller firms also provides a financial exit for VC and private equity investors in the smaller firms when they sell their shares to the acquiring firm. Such exit potential is important to induce early-stage investors to continue investing in risky small firms. Where a small company's lead product(s) have already been licensed to a large firm, that same large firm is the only likely acquiror of the small firm and the efficiency case for merger is even greater.[47]

These efficiency arguments, based on efficiencies in R&D financing through retained earnings and avoiding duplication of marketing and sales capabilities, argue in favor of allowing large firms to acquire small firms. Such rationales, however, do not apply to mergers between large firms that each already have marketed products that generate retained earnings for funding future R&D and established marketing and sales capabilities.

VI. Antitrust Implications

In this Essay, we have described the significant advantages of overall firm size in the pharmaceutical industry that have contributed to the continued dominance of the largest firms and that threaten to undermine competition. Size conveys advantages to large firms in negotiating with insurance payers for both pharmacy-dispensed and, in some cases, physician-administered drugs. Size conveys marketing advantages in detailing to physicians, and contracting and portfolio rebating with physician groups that dispense drugs. And size assures a stable flow of retained earnings, providing a relatively low-cost source for financing R&D and acquisitions. While these advantages may offer some real resource efficiencies, any efficiency savings are unlikely to be passed on to consumers as lower prices, and they may in fact be used to exclude competitors and harm competition.

An important implication of this thesis, that overall firm size conveys advantages, is the inadequacy in certain cases of traditional merger analysis, which focuses narrowly on increased concentration in specific drug markets, with divesture of specific overlapping products as the only remedy and condition for merger approval. Market-by-market analysis is an important first step, and the divestiture of overlapping products may be necessary to preserve market-specific competition. But this should not be the *only* consideration. Cross-market effects across individual product markets of the merged entity should also be considered. These effects may enable

[47] For example, Medarex's lead product had been licensed to BMS before BMS acquired Medarex, and this licensing deal made BMS the only likely acquiror of Medarex. Disclosure: Patricia Danzon was on the Medarex board when it was acquired by BMS.

mergers to "substantially lessen competition," contrary to the Clayton Act, in the various settings to which we now turn.[48] At the core of our proposals is the size of the merging entities.

What constitutes "large" or "midsize" for these purposes may depend on not only total sales but also such portfolio characteristics as, for example, the number and relatedness of therapeutic areas, possession of blockbuster or "must have" products, and involvement of biologic products rather than chemical drugs susceptible to generic entry.[49] As a first approximation, we suggest that "large" includes the top 10 firms and "mid-size" includes at least the next decile, ranked by global pharmaceutical sales as in Table 1 above.

Our proposed approach fits comfortably in the agencies' recent recognition of potential harms based on unilateral effects. The traditional theory of competitive harm has been based on coordinated effects: that in reducing the number of firms in a market, a merger would make it easier for the remaining firms to collude.[50] But the agencies have explained that "[t]he elimination of competition between two firms that results from their merger may alone constitute a substantial lessening of competition."[51]

Central to unilateral effects is the concept of incentives. By "eliminating competition," a merger "gives the merged firm incentives different from those of the merging firms."[52] The Merger Guidelines note that "[a] merger between two competing sellers prevents buyers from playing those sellers off against each other in negotiations," which "can significantly enhance the ability and incentive of the merged entity to obtain a result more favorable to it."[53]

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[48] 15 U.S.C. § 18.
[49] This is an important subject for future research.
[50] U.S. DEPT. OF JUSTICE & FED. TRADE COMM., HORIZONTAL MERGER GUIDELINES ¶ 7.1 (2010) (analyzing "whether a merger is likely to change the manner in which market participants interact, inducing substantially more coordinated interaction").
[51] *Id.* ¶ 6.
[52] FED. TRADE COMM. & U.S. DEPT. OF JUSTICE, COMMENTARY ON THE HORIZONTAL MERGER GUIDELINES 25 (2006); *see also id.* ¶ 1 (mergers "enhance[] market power" if they "harm customers as a result of diminished competitive constraints or incentives").
[53] *Id.* ¶ 6.2.

The FTC has used the concept of bargaining leverage in settings as varied as hospitals,[54] pharmacy chains and insurers,[55] and broadband.[56] Leverage refers to the ability of one party in the bargaining context to harm the other party by refusing to deal. As we discuss above,[57] mergers between pharmaceutical firms that are large, in terms of total sales and/or number of products, enhance their leverage in negotiations with PBMs and in marketing to physician customers.

A. Mergers Between Large Firms

The most significant concern is presented by mergers between two large pharmaceutical companies. We suggest that these mergers be presumed to harm competition. The reason stems from large firms' unique advantages, as detailed above. In particular, a large firm benefits from spillover advantages across product classes through bundled contracting with PBMs and detailing and contracting advantages with physician customers. Since these advantages increase with the number of products in the individual firm's portfolio, they are magnified when two large firms merge. The harms to competition can include bundled contracts/rebates by which the larger firm takes advantage of flexibilities not available to smaller competitors or, more egregiously, imposes contract/rebate provisions that set limits on the number or formulary positioning of

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[54] *ProMedica Health System, Inc. v. FTC*, 749 F.3d 559, 563 (6th Cir. 2014) (noting larger hospitals' greater bargaining leverage over insurers known as managed care organizations (MCOs) and explaining that "[i]t is harder for an MCO to exclude the county's most dominant hospital system than it is for the MCO to exclude a single hospital that services just one corner of the county"); FTC, *Price Increases May Result from Combination of the Two Full-service Hospitals in Slidell, Louisiana*, Sept. 13, 2006, *available at* http://www.ftc.gov/opa/2003/04/lahospmerger.htm (full-service acute care hospital's proposed acquisition of the only other such hospital in the area would have confronted insurers with "the choice of either meeting [the acquirer's] price terms or excluding [the two hospitals] from their provider network"); *FTC v. OSF Healthcare System*, 852 F. Supp. 2d 1069, 1083, 1084 (N.D. Ill. 2012) (explaining that "the merger of two closely substitutable hospitals will increase the combined system's bargaining leverage," that this leverage "would in turn allow the combined entity to extract higher prices," and that a defense based on "large, sophisticated insurance companies . . . defeat[ing] any threatened post-merger price increases" by refusing to contract with the merged entity "ignores the current realities of the health insurance market").

[55] FTC, MERGER GUIDELINE COMMENTARY, *supra* note 52, at 35-36 (noting that a merger between the two largest U.S. retail drug store chains, Rite Aid and Revco, would have left "less attractive options for assembling networks that did not include the merged firm," which would have led the merged firm to "unilaterally . . . demand[] higher dispensing fees as a condition of participating in a network"); U.S. Dept. of Justice, *Revised Competitive Impact Statement in U.S. v. Aetna Inc. and The Prudential Ins. Co.* (N.D. Tex., filed Aug. 3, 1999), at 13, https://www.justice.gov/atr/case-document/file/483491/download (explaining that Aetna's proposed acquisition of health insurance assets from Prudential would give it "the ability to unduly depress physician reimbursement rates, . . . likely leading to a reduction in quantity or degradation in the quality of physicians' services").

[56] Cecilia Kang & Emily Steel, *Regulators Approve Charter Communications Deal for Time Warner Cable*, N.Y. TIMES, at B1, Apr. 25, 2016, https://www.nytimes.com/2016/04/26/technology/charter-time-warner-cable-bright-house-cable-deal.html (noting that merged company resulting from Charter Communications' acquisition of Time Warner Cable and Bright House Networks "would have greater incentive and ability to impose or broaden contractual restrictions on programmers that limit their ability to distribute their content through [online video distributors]").

[57] *See supra* Parts III through V.

competitor products with which the PBM may contract, in one or more classes, as a condition of access to the merged firm's products.

These risks are most pronounced when a large firm has one or more "must have" blockbuster products that they can leverage to gain an advantage in other classes with few competitors. The notion of must-have blockbuster pharmaceutical products that cannot be excluded from a PBM's formulary is analogous to the notion of a dominant hospital system that cannot be excluded from a health insurer's contract.[58] By contrast, classes that already include multiple similar products are less vulnerable to anticompetitive contracting strategies, particularly if generics are or will soon become available for one or more products in a class.

Recent lawsuits outside the merger setting illustrate how incumbents can use rebate contracting to impede new competitors' entry.[59] One example involves Pfizer's claims that Johnson & Johnson (J&J) and its subsidiary Janssen Biotech, to protect the market share of its tumor necrosis factor (TNF) blocker infliximab (Remicade), employed exclusionary contracts, bundled discounts, and coercive rebates with insurers aimed at thwarting Pfizer's biosimilar Inflectra and future entrants from gaining market share.[60] In a second example, Shire alleged that Allergan impeded the marketing of Shire's dry eye disease product, lifitegrast (Xiidra), through bundled discounts that were so aggressive that Medicare Part D plans would not purchase Shire's product even if it were offered for free.[61]

In these cases, the alleged exclusionary behavior is tied to rebate volume on a blockbuster product and bundled discounts on other products in the incumbent firm's portfolio. The more products there are in a firm's portfolio, the greater are the opportunities to use bundling for anticompetitive effects. Combining two large firms increases the potential for such anticompetitive behavior, particularly when the merged entity has widely-used blockbuster products that a PBM cannot exclude from its formulary. Even if the merger has offsetting efficiencies in marketing or overhead, any savings are unlikely to result in lower prices for consumers because, as discussed above, insurance blunts consumer price-sensitivity, and PBMs benefit from higher, not lower, list prices.

As a result, we suggest a presumption that a merger between large firms is anticompetitive, with the burden on the merging parties to demonstrate cognizable, merger-specific efficiencies that outweigh the significant risks of anticompetitive effects. The standard efficiencies that acquirors have claimed in order to rationalize megamergers have been the

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[58] *See supra* note 54.

[59] We provide these allegations in lawsuits as the best available evidence on anticompetitive rebate contracts. The confidentiality of all rebate contracts precludes public access to hard data on these agreements.

[60] *Pfizer Inc. v. Johnson & Johnson*, 333 F. Supp. 3d 494 (E.D. Pa. 2018).

[61] *Shire US, Inc. v. Allergan, Inc.*, 375 F. Supp. 3d 538 (D.N.J. 2019). For additional discussion of these cases, see HERBERT HOVENKAMP, MARK D. JANIS, MARK A. LEMLEY, CHRISTOPHER R. LESLIE & MICHAEL A. CARRIER, IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 15.03[D] (2019 Supp.)

elimination of duplicative R&D, administration, and sales functions.[62] As discussed earlier in section II, larger firms have usually undertaken large acquisitions when they face patent expiry on their blockbuster product(s) and gaps in their own pipeline of new products to replace the expiring products, which implies excess capacity in administration, sales, and other functions.[63] Significant cost-cutting in support functions is thus arguably inevitable and largely not specific to the opportunities created by the merger, as required by the notion of cognizable efficiencies. Moreover, post-merger integration is also disruptive, consumes resources, and may lead to the exit of the most productive individuals who have the best external opportunities.

The evidence presented in section II shows that sequential large acquisitions have enabled the dominant firms to replenish their product pipelines and survive until the next acquisition becomes necessary and that shareholders of acquired firms have captured abnormal returns in the form of acquisition premia. However, even if the announcement of abnormal returns for the combined merged entities are weakly positive, that could reflect increases in market power that are of concern here rather than efficiency savings. Unfortunately, we cannot observe the counterfactual of what might have happened had these large mergers been blocked, permitting the upcoming firms to remain independent and perhaps become market leaders, rather than be absorbed into existing larger entities that have, at best, survived. As a result, we propose that mergers between two large firms be treated as anticompetitive, with the burden of proof shifted to the firms to rebut such a presumption by, for example, showing synergies from cross-national complementarity of assets or better utilization of excess capacity in manufacturing without risk of increased market power in negotiations or sales.

B. Mergers Involving Mid-Size Firms

When a large pharmaceutical firm merges with a mid-size firm, there also should be heightened scrutiny, albeit not rising to the level of a presumption of harm to competition. Firms that are mid-size by revenues and number of marketed products (roughly, those ranked 11 through 20 in industry rankings by sales) play an important competitive role in the pharmaceutical industry, serving as viable competitors for the largest firms in marketing and as potential acquirors of smaller firms.

These mid-size firms typically have proven competence of their own with in-house drug discovery and development, marketing and sales, and partnerships with or acquisitions of smaller

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[62] For example, AbbVie anticipated that its acquisition of Allergan "will provide annual pre-tax synergies and other cost reductions of at least $2 billion in year three while leaving investments in key growth franchises untouched." AbbVie continued: "The synergies and other cost reductions will be a result of optimizing the research and early stage portfolio, and reducing overlapping R&D resources (~50%), driving efficiencies in SG&A, including sales and marketing and central support function costs (~40%), and eliminating redundancies in manufacturing and supply chain, and leveraging procurement spend (~10%)," with this estimate "exclude[ing] any potential revenue synergies." AbbVie, *AbbVie to Acquire Allergan in Transformative Move for Both Companies*, June 25, 2019, https://news.abbvie.com/news/press-releases/abbvie-to-acquire-allergan-in-transformative-move-for-both-companies.htm.

[63] *See, e.g.*, Patricia M. Danzon, Sean Nicholson, & Andrew J. Epstein, *Mergers and Acquisitions in the Pharmaceutical and Biotech Industry*, 28 MANAGERIAL & DECISION ECON. 307 (2007).

companies. The mid-size firms are attractive acquisition targets for larger firms, as the mid-size firm's marketed products can provide rapid replenishment for gaps in the large firm's pipeline when its patents on lead products approach expiration or internal R&D fails. Mergers involving mid-size firms also remove a potential acquiror for smaller firms and competitor for the largest firms. Large firms' acquisition of mid-size firms assures the continued market dominance of the same large firms over time. At the same time, these large/mid-size acquisitions offer no obvious efficiency savings.

The likelihood of the agencies challenging a merger between a large and a mid-size firm should increase based on the combined entity's product portfolio. Concerns would be heightened when the merged entity has a must-have blockbuster product with large sales and few good substitutes that PBMs cannot exclude from their formularies, to which the firm can tie preferential treatment of its other products. Concern is heightened if there is a blockbuster product that is a biologic approaching patent expiry, with the potential for biosimilar entry that the incumbent may seek to block. AbbVie's acquisition of Allergan is a case in point, as AbbVie's Humira is a must-have blockbuster that PBMs cannot exclude and that will soon face potential biosimilar entry. Similarly, Allergan's Botox is a must-have blockbuster facing increased would-be competitors. We suggest that such a merger warrants careful scrutiny for the potential for anticompetitive contracting to obstruct potential competitors for both of these products.

BMS's acquisition of mid-sized Celgene provides a recent example involving a large and mid-size firm. On the positive side, the two firms' complementary portfolios of cancer products could create marketing synergies for the merged firm. But these marketing synergies may be employed to disadvantage competitors, especially new entrants and smaller firms with fewer products that are not able to offer competitive portfolio-wide deals. And as argued earlier, it is highly unlikely that any real efficiency savings in marketing that the merged firm realizes will be passed through to consumers as lower prices.[64]

Mergers between two mid-size firms warrant modestly less scrutiny than those involving a large firm, albeit still more attention than the usual concerns with overlapping products. Such mergers can create yet another relatively large firm, with increased portfolio power compared to the two stand-alone firms. One example is provided by Takeda's acquisition of Shire, with the new firm now ranking ninth industrywide. In particular, if the acquired firm has one or more must-have products with large sales and rebate volume, these may be leveraged over unrelated classes in the acquiror's portfolio. In addition, if the parties' drugs are predominantly in classes with few competitors, especially biologics that are protected from competition by restrictive rules for biosimilars, such classes are more vulnerable to anticompetitive behavior by powerful players.

[64] As described earlier, these physician-dispensed drugs are generally reimbursed at the firm's average selling price + X% (ASP + 6% for Medicare), which creates incentives for firms to compete by setting higher, not lower, prices.

On the other side, the parties might offer the defense that all the relevant products are in relatively crowded classes, preferably with (or at least subject to) generic entry, which mitigates the risk of anticompetitive contracting. Or they could contend that the mid-size firm has a promising, early-stage product that has the potential to address an unmet need, which the financing and expertise of the other mid-size or larger firm could help develop and bring to market more quickly. The weighing of potential benefits and risks is context-specific, with risks increasing based on must-have products and decreasing the smaller the merged entity.

C. Mergers Involving Small Firms

In general, mergers involving small firms do not require heightened scrutiny beyond the traditional concerns with overlapping products in specific markets.[65] Market-by-market analysis is still important in these settings to determine whether a small company's product could potentially compete with one owned by the large firm or create excessive concentration due to related products.[66] For example, in Roche's acquisition of Spark Therapeutics, Spark's pipeline gene therapy program for hemophilia A could reinforce Roche's existing share of that market based on its Hemlibra treatment. Antitrust agencies in the United States and United Kingdom carefully reviewed this acquisition before authorizing it. Such review reflects appropriate concern that the acquisition might give Roche undue power in that product market or even cause Roche to discontinue the gene therapy. The existence of other companies with competing gene therapy programs mitigated this risk.

Large firms' acquisitions of small firms can provide important efficiencies. As discussed above, large firms generally can provide a lower-cost source of financing for the small firm's R&D, compared to private or public equity, and an exit for early investors. Further, acquisition by a larger firm with established marketing experience eliminates the need for the small firm to develop its own marketing and sales functions. In particular, in contexts in which the large firm already has a licensing agreement with the small firm for either sole or shared development and marketing of the small firm's lead product, the large firm's acquisition of the smaller firm can eliminate costly coordination and duplication of functions.[67] Consistent with this, empirical evidence for merger efficiencies is strongest in cases where a prior licensing relationship already exists between the acquirer and the target, plausibly because this both provides information and the potential for elimination of duplicative, shared functions.

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[65] The discussion in the text focuses on mergers in product markets. But even mergers in "innovation markets" can present concern as a merger between the two companies closest to the market with a particular treatment could result in suppression of one of the research paths. *See* Michael A. Carrier, *Two Puzzles Resolved: Of the Schumpeter-Arrow Stalemate and Pharmaceutical Innovation Markets*, 93 IOWA L. REV. 393 (2008).

[66] We assume that, where required as a condition of approval, divested products are sold to companies that are plausible strong and committed competitors. This depends on such factors as having related products that can yield synergies in marketing and rebating across categories.

[67] For example, BMS's acquisition of Medarex eliminated potentially duplicative co-marketing of ipilumimab provided for in BMS's licensing agreement for ipilumimab. *See supra* note 47.

More generally, even without a prior licensing arrangement, acquisition by a larger firm with experience and retained earnings can accelerate the development of the small firm's promising product(s). For example, Gilead, a mid-size firm with extensive experience in developing and marketing drugs to treat HIV/AIDS, was an effective acquiror for Pharmacyclics, a small firm with early stage products to treat Hepatitis C. Gilead was able to rapidly develop and launch these acquired compounds to become the first effective treatments for Hepatitis C. Gilead has remained an important competitive player in the Hepatitis C market that would otherwise be dominated by a few large firms.[68]

In short, absent overlapping products, acquisitions of small firms by large and mid-size firms tend to offer cognizable efficiencies without posing significant anticompetitive threats.

D. Application to Other Industries

We have argued that the pharmaceutical industry warrants special consideration for merger analysis on account of the characteristics related to firm size discussed above. Although these characteristics combine and interact with patents to make pharmaceuticals an extreme case, some similar features exist in other industries and are worth noting although their full consideration is beyond the scope of this paper. We have already analogized the similarities to the cross-market effects of hospital mergers, especially those involving dominant hospitals. The potential for the use of bundled contracts to exploit cross-market leverage exists in other industries in which common customers use products from separate but linked markets.

As one example, Amazon Prime gives customers that use Amazon for mail-order book purchases an incentive to also use Amazon for other mail-order products, movies, and grocery deliveries.[69] This is somewhat akin to a large pharmaceutical company using its must-have blockbuster drug for disease X to gain a competitive advantage and/or restrict competition in diseases Y, Z, etc. Also, the broad scope of Amazon's product offerings enables it to offer one-stop-shopping convenience to customers that could act as a barrier to entry to smaller competitors with more limited product range.

There are important differences in the non-pharmaceutical space, however. For example, Walmart and other firms can offer their own free delivery programs on a broad range of products to compete with Amazon Prime and Amazon's broad product range. By contrast, in pharmaceutical markets, PBMs control access for consumers and the top 3 PBMs have roughly 75% market share.[70] Similarly, the potential for entry of other large rival drug firms offering similar products and size advantages is limited by the natural size limits on disease classes, stickiness in product switching, high R&D costs, and the role of patents and barriers to post-

[68] AstraZeneca recently proposed acquiring Gilead but abandoned the attempt.
[69] Amazon, *Amazon Prime*, https://www.amazon.com/gp/help/customer/display.html?nodeId=G6LDPN7YJHYKH2J6 (last visited Apr. 9, 2021).
[70] *E.g.*, Advisory Board, *Pharmacy benefit managers explained*, Nov. 13, 2019, https://www.advisory.com/en/daily-briefing/2019/11/13/pbms.

patent biosimilar entry that limit the market potential for competitor products in any therapeutic class. Further, consumers are largely unaware of new products until they are covered by insurance and prescribed by their physicians. Finally, in most industries there is a reasonable presumption that competition for price-sensitive consumers forces the pass-through of efficiency savings from mergers. By contrast, in the pharmaceutical context, insurance undermines consumer price sensitivity and informational asymmetries make it impossible for consumers to aggressively monitor the insurers, PBMs, and physicians that are supposed to act as consumer agents but in reality have opportunities and incentive to also serve their own interests.

VII. Conclusion

In this Essay, we have described the complex environment and structure of competition in the pharmaceutical industry. The industry is characterized by the persistent dominance of the same large firms, which have maintained their preeminence through acquisitions and the advantages of size, rather than innovation.

This perspective challenges the standard antitrust analysis of mergers, which focuses exclusively on increased concentration in specific markets and the divestiture of overlapping products. Although the agencies have long applied an analysis based on overlapping products in particular markets, we argue that overall firm size conveys advantages across product markets. These advantages appear in negotiations with payers, PBMs, and physicians. They also appear in marketing and selling to physicians. And they take the form of retained earnings advantages in financing all costly functions, especially R&D and acquiring other, promising firms.[71] Each of these elements increases with a firm's size, as measured by number of products and overall sales. This size can be used to the competitive detriment of smaller firms or those seeking to enter markets dominated by large firms.[72]

When two large firms merge, the presumption should be that the merger harms competition. When mergers involve mid-size firms, the agencies should carefully scrutinize effects outside the overlapping markets. And when a small firm is involved, the agencies should apply the typical market-by-market approach. Such a framework is more consistent with industry realities than the approach applied today and ensures that antitrust merger enforcement can play a vital role in the pharmaceutical industry.

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[71] Further research is needed to quantify these effects but is impeded by data confidentiality.

[72] As discussed above, see note 13 and accompanying text, although some of the conduct we consider in the merger context—such as rebate traps—can be challenged outside the setting of mergers, we believe it is important for the agencies to consider the conduct before approving combinations of firms that could exacerbate these competitive concerns.

An Antitrust Framework for False Advertising

Michael A. Carrier & Rebecca Tushnet***

ABSTRACT: Federal law presumes that false advertising harms competition. Federal law also presumes that false advertising is harmless or even helpful to competition. Contradiction is not unknown to the law, of course. This contradiction, though, is acute. For not only are both regimes at issue designed to protect competition, but they are both enforced by the same agency: the Federal Trade Commission, which targets "unfair competition" through antitrust and consumer protection enforcement.

Courts' treatment of false advertising in antitrust cases makes no sense. While courts have reasonably evidenced concern that not all false advertising violates antitrust law, the remedy is not to abandon the false advertising/antitrust interface. Instead, the solution is to focus on the actors most likely to harm the market: monopolists and attempted monopolists.

This Essay proposes an antitrust framework for false advertising claims. It introduces a presumption that monopolists engaging in false advertising violate antitrust law and a rebuttal if the false advertising is ineffective. The framework also applies to attempted monopolization by incorporating factors such as falsity, materiality, and harm inherent in false advertising law, along with competition-centered issues like targeting new market entrants.

Antitrust has dismissed false advertising that entrenches monopoly power for too long. This Essay seeks to resolve the contradiction in the law by showing how false advertising threatens the proper functioning of markets. Such an approach promises benefits for false advertising law, antitrust law, and consumers.

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I. INTRODUCTION

Federal law presumes that false advertising harms competition. Federal law also presumes that false advertising is harmless or even helpful to competition. Contradiction is not unknown to the law, of course. This contradiction, though, is acute. For not only are both the regimes at issue designed to protect competition, but they are both enforced by the same agency: the Federal Trade Commission ("FTC"), which targets "unfair competition" through antitrust and consumer protection enforcement.

Anticompetitive conduct, the focus of antitrust law, increases price and reduces quality. False advertising, the focus of much consumer protection law, deceives consumers and distorts markets. Both types of conduct harm consumers. Despite this overlap, nearly all courts have dismissed private antitrust claims based on false advertising. They have concluded that the conduct cannot violate antitrust law. Or they have presumed that the harm is *de minimis*. This makes no sense. As the Supreme Court has long established, "false or misleading advertising has an anticompetitive effect."[1]

1. Cal. Dental Ass'n v. FTC, 526 U.S. 756, 771 n.9 (1999) (citing FTC v. Algoma Lumber Co., 291 U.S. 67, 79–80 (1934)).

Courts' concerns stem from the reasonable notion that not every instance of false advertising violates antitrust law. And (usually implicitly) they have worried about applying antitrust's robust remedies of treble damages and attorneys' fees. These courts fear that antitrust liability will disincentivize companies from engaging in advertising that is merely questionable and that might provide useful information to some consumers. But false advertising law preserves a robust space for puffery and debatable opinions; overdeterrence concerns don't justify analysis that is inconsistent with both the economics and psychology of advertising and that, at a minimum, essentially makes it impossible to bring a successful antitrust case based on false advertising. Nor do the Lanham Act's remedies for false advertising fully address harms to competition. Reasoning that conduct that is already illegal on other grounds need not concern antitrust law ignores the multiple other contexts in which breaches of non-antitrust laws are considered to be potential antitrust violations.

One example illustrates how false advertising can entrench powerful positions that harm consumers and the market as a whole.[2] In 2010, AT&T was worried that it was about to lose its exclusivity as sole provider of the iPhone. So it adopted a bait-and-switch plan: it offered "unlimited" data to consumers who signed long-term contracts. But this was a ruse. The company wasn't planning to make good on its promise. It was already clear that smartphone-owning customers used much more data than previous customers had.

AT&T then began to throttle data to its consumers so that webpages took longer to load, streaming video failed to stream, and GPS and email failed.[3] To make the switch stick, AT&T imposed expensive termination fees on consumers who did not want to be bound by the deceptive "unlimited" contracts or encouraged them to buy far more expensive plans.[4] In short, AT&T used deceptive behavior to extend its competitive advantage over other carriers.

False advertising law allows consumers to receive some redress for the money they paid for "unlimited" data that wasn't,[5] but there's no obvious

2. For additional examples in an industry in which the problem is getting worse, see *infra* Section IV.D (discussing the biologics industry).

3. Complaint for Permanent Injunction and Other Equitable Relief at 4–7, FTC v. AT&T Mobility LLC, 87 F. Supp. 3d 1087 (N.D. Cal. 2015) (No. C-14-4785 EMC), *rev'd and remanded*, 835 F.3d 993 (9th Cir. 2016), *reh'g en banc granted*, 864 F.3d 995 (9th Cir. 2017).

4. Fed. Trade Comm'n, Statement of Commissioner Rohit Chopra re: AT&T Mobility, LLC, Commission File No. X150009 (Nov. 5, 2019).

5. With AT&T's false "unlimited promise," the FTC acted. But without government intervention, consumers likely would not have had options for redress because of mandatory arbitration that removes the ability to bring a consumer-protection class action. *See* AT&T Mobility LLC v. Concepcion, 563 U.S. 333, 350–52 (2011). The use of adhesion contracts to prevent consumers from obtaining restitution for false advertising is one significant distortion in the current competitive environment. The ironic result is that competitors may have an easier

remedy for the damage AT&T caused to the market as a whole. Antitrust law has been kneecapped by the courts and thus is powerless to act. In short, the law's neglect of the injuries caused by false advertising threatens structural harm to competitive markets.

In this Essay, we address these problems. We do so by focusing on the actors most likely to harm the market: monopolists and attempted monopolists. These actors are a numerically small percentage of businesses (and of false advertising defendants), but they can do great harm. Our emphasis on monopolists and attempted monopolists addresses courts' concerns of overbroad enforcement, preventing false advertising from morphing automatically into an antitrust violation. And it carves out a critical role for antitrust while embracing—rather than neglecting—antitrust's partner in fighting unfair competition, false advertising law.

We begin by introducing the laws of antitrust and false advertising, explaining the regimes' objectives and methods. We then survey the antitrust caselaw, critiquing three approaches courts considering false advertising claims have taken. Finally, we introduce our antitrust framework for false advertising claims. At the heart of the framework is a presumption that monopolists engaging in false advertising violate antitrust law, with that presumption rebuttable if the defendant can show that the false advertising was ineffective. The framework also applies to cases of attempted monopolization by incorporating factors (falsity, materiality, and harm) inherent in false advertising law, along with competition-centered issues on targeting new market entrants and entrenching barriers to entry. To illustrate how our framework should work, we apply it to an important area: advertising for biosimilars, which are pharmaceutical products with a substantial and growing role in treating numerous diseases.

False advertising that exacerbates monopoly power has been dismissed by antitrust law for too long. This Essay seeks to resolve the contradiction in the law by showing how false advertising threatens the proper functioning of markets.

II. ANTITRUST AND FALSE ADVERTISING

Antitrust and false advertising bear some overlap in goals and methods but operate in different ways. This Part separately considers antitrust and false advertising law before comparing the two.

time suing each other for false advertising than consumers do. But private antitrust enforcement has also been limited by arbitration. *See* Am. Express Co. v. Italian Colors Rest., 570 U.S. 228 (2013); Mark A. Lemley & Christopher R. Leslie, *Antitrust Arbitration and* Illinois Brick, 100 IOWA L. REV. 2115, 2116 (2015).

A. ANTITRUST

Antitrust's widely acknowledged goal is to promote competition.[6] A competitive market maximizes "consumer welfare."[7] Operationalizing this, antitrust law targets conduct that reduces competition and harms consumer welfare by increasing price, reducing output, or offering consumers inferior options.

One central element of a competitive market is advertising, which, as the Supreme Court has recognized, plays "an indispensable role . . . in a free enterprise system."[8] Restrictions on truthful advertising harm competition by "mak[ing] it more difficult for consumers to discover information about the price and quality of goods or services, thereby reducing competitors' incentives to compete with each other with respect to such features."[9] For that reason, the FTC sued 1-800 Contacts, the largest online U.S. retailer of contact lenses, for its "web of anticompetitive agreements with rival online contact lens sellers that suppress[ed] competition in certain online search advertising auctions and that restrict[ed] truthful and non-misleading internet advertising to consumers."[10]

The advertising cases courts have considered have addressed agreements between competitors. But antitrust law also scrutinizes single-firm conduct, which occurs when a firm unilaterally engages in false advertising.[11] The relevant law in this setting is Section 2 of the Sherman Act, which targets

6. *E.g.*, 1 PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 100a (4th ed. 2013).

7. *E.g.*, *id.*; Maureen K. Ohlhausen, Acting Chair, Fed. Trade Comm'n, Roundtable Conference with Enforcement Officials at the ABA Section of Antitrust Law Spring Meeting (Mar. 31, 2017), *in* ANTITRUST SOURCE, June 2017, at 1, 20. The consumer-welfare standard is under attack by the "neo-Brandeisian" movement, though it is unclear what standard would replace it. Herbert Hovenkamp, *Is Antitrust's Consumer Welfare Principle Imperiled?*, 45 J. CORP. L. 65, 67 (2019).

8. Bates v. State Bar of Ariz., 433 U.S. 350, 364 (1977).

9. Polygram Holding, Inc., 136 F.T.C. 310, 355 (2003); *see also* Brief of the Federal Trade Commission at 1, 1-800 Contacts, Inc. v. FTC, No. 18-3848 (2d Cir. Oct. 7, 2019) ("Without timely information about competing products and sellers, . . . consumers cannot make informed choices and markets cannot function properly.").

10. *1-800 Contacts, Inc., In the Matter of*, FED. TRADE COMM'N (Oct. 8, 2019), https://www.ftc.gov/enforcement/cases-proceedings/141-0200/1-800-contacts-inc-matter [https://perma.cc/CQ4C-LY5Q]; *see also Polygram Holding*, 136 F.T.C. at 354 (finding agreement among rivals not to advertise products was "presumptively anticompetitive").

11. Other examples of single-firm conduct include predatory pricing (in which a monopolist lowers its price below cost to drive a rival out of the market and then raises it), tying (in which a monopolist sells a product only on the condition that the buyer purchases a second product from it), and refusals to deal (in which a monopolist refuses to deal with a competitor). *See* HERBERT HOVENKAMP, FEDERAL ANTITRUST POLICY: THE LAW OF COMPETITION AND ITS PRACTICE ch. 6 (5th ed. 2016).

monopolization.[12] This offense has two elements: (1) monopoly power and (2) exclusionary conduct.

First, a plaintiff needs to show that a defendant has monopoly power, which has been defined as "the power to control prices or exclude competition."[13] Monopoly power can be shown in one of two ways. First, it can be proved indirectly by examining a defendant's market share along with barriers to entry that could entrench that market position.[14] Courts regularly hold that a 90 percent market share supports market power, with some courts finding a 75 percent share to be sufficient.[15] Second, monopoly power can be proved directly,[16] such as when a brand firm is able "to maintain the price of [a] drug . . . at supracompetitive levels without losing substantial sales."[17] Direct proof of monopoly power also can consist of observable effects on the market such as a price increase or output reduction.[18]

High market share alone, however, is not sufficient for the offense. The defendant also must engage in exclusionary conduct. Courts typically address this question by relying on the distinction in *United States v. Grinnell Corp.* between "the willful acquisition or maintenance of [monopoly] power" and "growth or development as a consequence of a superior product, business acumen, or historic accident."[19]

The monopolization caselaw has developed conservatively, with courts finding violations, for example, when the defendant's conduct does not bear any legitimate justification and where there are harms to the market as a whole. For example, in *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, the owner of three downhill skiing facilities in Aspen, Colorado failed to offer a justification for withdrawing from a joint ticketing arrangement with the owner of the only other facility.[20] The Supreme Court found that the monopolist was willing to forgo ticket sales and consumer goodwill in order to harm its smaller competitor.[21] Although monopolization claims often are

12. Section 2 punishes "[e]very person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States." 15 U.S.C. § 2 (2018).

13. United States v. E.I. du Pont de Nemours & Co., 351 U.S. 377, 391 (1956).

14. *See* HOVENKAMP, *supra* note 11, § 6.2b, at 359–60.

15. *Id.* § 6.2a, at 357.

16. I ABA SECTION OF ANTITRUST L., ANTITRUST LAW DEVELOPMENTS 70 (Jonathan I. Gleklen et al. eds., 7th ed. 2012) (noting that "direct proof has provided the basis for findings of substantial anticompetitive effects in some prominent cases").

17. *In re* Nexium (Esomeprazole) Antitrust Litig., 968 F. Supp. 2d 367, 389 n.19 (D. Mass. 2013); *see also, e.g.*, *In re* Aggrenox Antitrust Litig., 94 F. Supp. 3d 224, 246 (D. Conn. 2015) ("[W]hen direct evidence is available that a party profitably charges supracompetitive prices, the existence of market power can be established from that fact alone.").

18. Michael A. Carrier, *Sharing, Samples, and Generics: An Antitrust Framework*, 103 CORNELL L. REV. 1, 22 (2017); *see* Broadcom Corp. v. Qualcomm Inc., 501 F.3d 297, 307 (3d Cir. 2007).

19. United States v. Grinnell Corp., 384 U.S. 563, 570–71 (1966).

20. Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585, 608–11 (1985).

21. *Id.* at 608.

brought by competitors, consumers also can sue for harm caused by exclusionary conduct.

B. FALSE ADVERTISING

The goal of false advertising law is to protect consumers and competitors from decisions distorted by deception. When consumers make purchasing choices based on sellers' false or misleading claims, they lose and so do honest competitors.[22] There are multiple possible enforcers of false advertising law. Federal and state regulators can sue businesses for deceptive advertising under the Federal Trade Commission Act and similar state "little FTC" acts. Businesses can sue other businesses under the federal Lanham Act, which covers trademark infringement and false advertising. And consumers can bring state-law claims under consumer protection laws barring deceptive trade practices.[23]

Public enforcers have highly limited resources and responsibility for entire markets. They tend to focus on outright scams and on situations in which no single competitor suffers so greatly that it has an incentive to sue. As a result, the most relevant body of law for the false advertising/antitrust interface is the Lanham Act, which allows private parties to challenge the use in commerce of

> any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which . . . in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities.[24]

Courts have added doctrinal flourishes to this broad language. Lanham Act plaintiffs must suffer injury to their interests as commercial entities, which means that consumers don't have standing, but victims of disparagement may even if they aren't direct competitors.[25] Courts have also interpreted the statute to make clear that the false or misleading advertising must be material—likely to influence a purchasing decision—and must deceive or be likely to deceive a substantial segment of the relevant audience.[26] When advertising is explicitly (also known as literally) false, courts presume that it is

22. Of course, the details can be contentious, raising questions like: What counts as deceptive? When is failure to disclose deceptive? How many consumers need be diverted for a remedy to be appropriate? But the core commitment to honesty in material claims is clear.

23. *See generally* REBECCA TUSHNET & ERIC GOLDMAN, ADVERTISING & MARKETING LAW: CASES AND MATERIALS ch. 3 (5th ed. 2020) (providing an overview of varying sources of regulatory authority).

24. Lanham Act § 43(a)(1)(B), 15 U.S.C. § 1125(a)(1)(B) (2018).

25. Lexmark Int'l, Inc. v. Static Control Components, Inc., 572 U.S. 118, 131–32, 138 (2014).

26. *See, e.g.*, Cashmere & Camel Hair Mfrs. Inst. v. Saks Fifth Ave., 284 F.3d 302, 310–11 (1st Cir. 2002).

deceptive. And when advertising is ambiguous but potentially misleading, courts generally require the plaintiff to show that a substantial number of consumers receive a false message, usually by a consumer survey.[27] Lanham Act liability is strict; even an advertiser's good-faith belief in the truth of its claims is no defense.[28]

C. COMPARATIVE ASSESSMENT

The primary goal of antitrust law is to enhance consumer welfare by targeting anticompetitive conduct. The primary goal of false advertising law is to provide consumers with truthful information so that rivals can compete on the merits. Both can be seen as variants of a general idea of "unfair competition." But the mechanisms of the unfairness targeted differ.

On the most general level, there is a higher bar to the application of antitrust law, as harm is required to the market as a whole. False advertising, in contrast, can occur even if just an individual competitor is injured (along with the deceived consumers who are both the mechanisms by which harm is inflicted on a competitor and victims in their own right). Reciprocally, there are significant barriers to proving a monopolization claim. Demonstrating monopoly power involves the challenges of defining a market and showing power within that market. And showing exclusionary conduct also presents hurdles, such as rebutting procompetitive justifications the defendant offers. When these stringent requirements are satisfied, antitrust comes down hard on the defendant, who is potentially liable for treble damages, attorneys' fees, and costs.[29]

False advertising is more granular than antitrust law in protecting against not only structural harms to the market, but also economic injuries to individual competitors. It does so even if other competitors remain and the particular competitor (though not unscathed) survives. For consumers, protection against false advertising serves a number of goals that could be described in general terms as "consumer welfare." Harms from false advertising can be economic, when deceived consumers are deprived of the benefits of their bargains. The harms also can be physical, when safety or

27. *See, e.g.*, Design Res., Inc. v. Leather Indus. of Am., 789 F.3d 495, 501 (4th Cir. 2015); C.B. Fleet Co., Inc. v. SmithKline Beecham Consumer Healthcare, L.P., 131 F.3d 430, 434 (4th Cir. 1997).

28. *See, e.g.*, AMCO Ins. v. Inspired Techs., Inc., 648 F.3d 875, 882 (8th Cir. 2011) (noting that neither knowledge nor intent is an element of false advertising under the Lanham Act); Vector Prods., Inc. v. Hartford Fire Ins., 397 F.3d 1316, 1319 (11th Cir. 2005) (per curiam) ("It is well-settled that no proof of intent or willfulness is required to establish a violation of Lanham Act § 43(a) for false advertising. Rather, Section 43(a) provides a strict liability tort cause of action." (footnote omitted) (citations omitted)); Castrol Inc. v. Pennzoil Co., 987 F.2d 939, 944 (3d Cir. 1993) (holding that even false statements made with a reasonable, but wrong, basis are actionable).

29. 15 U.S.C. § 15.

health characteristics are involved. And they can be moral, when an advertiser deliberately deceives and thus disrespects the autonomy of consumers.[30]

False advertising can also harm markets and competitors in a more general way. Consumers expecting false advertising are likely to distrust even truthful claims. The false advertiser thus erects barriers to the success of truthfully advertising competitors, creating a "market for lemons."[31] Bad advertising, that is, is likely to drive out good. This principle is generally accepted (indeed, it won George Akerlof, who coined the phrase "market for lemons," a Nobel prize in economics). False advertising law implements the idea that promoting the flow of truthful information can prevent a destructive cycle of consumer cynicism and lower investment in truthful claims.[32] As one court recently explained, "the harm the Lanham Act addresses is one shared by all competitors in the market—the encroachment on the ability to compete in a fair market."[33] This makes it even more puzzling that courts in antitrust cases have explicitly endorsed the contrary proposition.

III. ANTITRUST'S FALSE ADVERTISING FAILURE

For several reasons, antitrust courts have not sufficiently recognized the harms presented by false advertising. One reason seems to be the perceived comparative ease of alleging false advertising claims, which makes courts hesitant to allow such allegations to form the basis for antitrust claims. A related rationale is antitrust's powerful remedies that include treble damages, or three times the damages suffered. Courts' hesitation to award such damages often affects their substantive analysis of whether an antitrust violation has occurred.

This skepticism of antitrust claims based on false advertising, however, is fundamentally dishonest when it maintains, as too many cases do, that false advertising is never or rarely a competitive concern. This rationale for excluding false advertising from antitrust coverage flies in the face of the Supreme Court's longstanding acknowledgement "[t]hat false or misleading advertising has an anticompetitive effect, as that term is customarily used."[34]

The idea that antitrust's powerful remedies should be reserved for the worst cases is not inherently dubious. But greater honesty about that rationale

30. *See, e.g.*, TUSHNET & GOLDMAN, *supra* note 23, ch. 4; Lee Goldman, *The World's Best Article on Competitor Suits for False Advertising*, 45 FLA. L. REV. 487, 494 (1993).

31. *See generally* George A. Akerlof, *The Market for "Lemons": Quality Uncertainty and the Market Mechanism*, 84 Q.J. ECON. 488 (1970) (analyzing "the interaction of quality differences and uncertainty" in the labor market and "the economic costs of dishonesty").

32. *See, e.g.*, Howard Beales, Richard Craswell & Steven C. Salop, *The Efficient Regulation of Consumer Information*, 24 J.L. & ECON. 491, 513 (1981).

33. Boltex Mfg. Co. v. Ulma Piping USA Corp., No. 4:17-CV-01400, 2020 WL 598284, at *6 (S.D. Tex. Feb. 7, 2020).

34. Cal. Dental Ass'n v. FTC, 526 U.S. 756, 771 n.9 (1999) (citing *FTC v. Algoma Lumber Co.*, 291 U.S. 67, 79–80 (1934), which held a false advertisement to be unfair competition).

would allow courts to confront directly the question of when false advertising is poisonous to competition. Even accepting that most instances of false advertising do not violate antitrust law, it doesn't make sense to immunize conduct when monopolists controlling the market entrench their power by engaging in false advertising. And as a baseline principle, the presence of one set of remedies is not preclusive of another set when the facts implicate both bodies of law.[35]

Cases addressing the false advertising/antitrust intersection fall into three groups. The first category completely absolves false advertisers of antitrust liability. The second assumes that false advertising causes *de minimis* harm. The third offers a "case by case" approach. This Part introduces and critiques the tests.

A. ABANDONED ANALYSIS

The U.S. Courts of Appeals for the Fifth and Seventh Circuits offer examples of the first approach: an abandonment of antitrust analysis. These courts have reasoned that false statements enhance competition in advertising markets and that antitrust claims based on disparaging rivals are not actionable. For example, the Seventh Circuit in *Sanderson v. Culligan International Co.* stated bluntly that "[c]ommercial speech is not actionable under the antitrust laws."[36] In particular, the court asserted that "[a]ntitrust law condemns practices that drive up prices by curtailing output" but that "[f]alse statements about a rival's goods do not curtail output in either the short or the long run," but instead "just set the stage for competition in a different venue: the advertising market."[37]

Similarly, the Fifth Circuit in *Retractable Technologies v. Becton Dickinson* drew a distinction between "business torts, which harm competitors, and truly anticompetitive activities, which harm the market," and stated that "absent a demonstration that a competitor's false advertisements had the potential to eliminate, or did in fact eliminate, competition, an antitrust lawsuit will not lie."[38] The court found that the plaintiff "may have lost some sales or market share because of [the defendant's] false advertising, but it remains a vigorous competitor" and did not face "barriers to entry" from the conduct.[39]

The court endeavored to support its conclusion that "false advertising alone hardly ever operates in practice to threaten competition" based not only

35. *See, e.g.*, POM Wonderful LLC v. Coca-Cola Co., 573 U.S. 102, 112–13 (2014) (holding that the Lanham Act and Food, Drug, and Cosmetic Act both apply to regulate advertising claims about food and finding that a Lanham Act claim is not precluded even if the FDA has also issued regulations about the relevant advertising); *see infra* Section IV.A.2 (discussing antitrust cases based on non-antitrust causes of action).

36. Sanderson v. Culligan Int'l Co., 415 F.3d 620, 624 (7th Cir. 2005).

37. *Id.* at 623.

38. Retractable Techs., Inc. v. Becton Dickinson & Co., 842 F.3d 883, 895 (5th Cir. 2016).

39. *Id.*

a "dearth of Fifth Circuit precedent but [also] by two other considerations."[40] First, it relied on *Culligan* to assert that "false or misleading advertising generally sets competition into motion."[41] And second, it found it "difficult to determine whether such false statements induced reliance by consumers and produced anticompetitive effects, or whether the buyer attached little weight to the statements and instead regarded them as biased and self-serving," which might occur where "the relevant consumers are sophisticated."[42]

The Fifth and Seventh Circuits correctly conclude that some (in fact, many) instances of false advertising will not violate antitrust law and that the receivers of the information will have different abilities to assess it. But the answer to these scenarios is not to abandon antitrust analysis. The fact that most acts of false advertising—or arson or bribery—don't violate the antitrust laws says nothing about how to identify the subset that could.

By engaging in deception that resembles exclusionary conduct, a company—in particular, a monopolist—could entrench its position in the market. There is not, in fact, a "rigid distinction" "between business torts, which harm competitors, and truly anticompetitive activities, which harm the market," since competitors make a market.[43] For one thing, many false statements are made about the defendant's *own* products; a false superiority claim, like AT&T's false "unlimited" data promise, can discourage consumers from trying *any* competitor. For another, many false claims can readily be repurposed when a new competitor appears. Further undermining the Seventh Circuit's rationale, deceptive disparaging statements could readily depress demand for the criticized product, thereby reducing output and increasing price: classic antitrust concerns.[44]

The deeper problem is the premise that misleading advertising "generally sets competition into motion."[45] This reasoning makes "competition" an empty term and specifically erases the governing concept of *unfair* competition. Burning a building down generally sets firefighters into motion and can trigger insurance payouts and new construction, but we don't think that makes arson productive for the overall economy. At best, misleading advertising forces competitors to fight back on unfair ground, expending resources defending truth against falsehood instead of investing

40. *Id.*

41. *Id.*

42. *Id.*

43. Shubha Ghosh, *The Antitrust Logic of Biologics*, 2018 U. ILL. L. REV. ONLINE 46, 53 (quoting *Retractable Techs.*, 842 F.3d at 895).

44. *See* Kevin S. Marshall, *Product Disparagement Under the Sherman Act, Its Nurturing and Injurious Effects to Competition, and the Tension Between Jurisprudential Economics and Microeconomics*, 46 SANTA CLARA L. REV. 231, 253 (2006) (finding it "short-sighted to conclude that the intentional dissemination of false information about a rival's product does not constitute a restraint of trade" since it "restrains the autonomous forces of supply and demand, and is therefore injurious to competition").

45. *Retractable Techs.*, 842 F.3d at 895.

them elsewhere, harming their overall ability to compete. The Supreme Court has reasoned similarly: false and misleading advertising harms competition because it can confuse consumers and make it harder for them to believe any claim they encounter.[46] Furthermore, as one of us has written elsewhere, "corrective advertising, especially by an inherently-less-credible-because-self-interested competitor, is unlikely to fix all the damage of false advertising."[47] That is why false advertising law recognizes that self-help is not a sufficient remedy and intervenes on the side of the victim.

The Fifth and Seventh Circuits also expressed concerns that defendants shouldn't be punished just for promoting their own products.[48] We agree, and so does false advertising law, which requires showings of falsity and materiality, and which has developed a number of doctrines identifying the type of proof required in particular situations.

The Fifth Circuit in *Retractable Technologies* additionally reasoned that advertising that was "wrong, misleading, or debatable" was "indicative of competition on the merits," as opposed to, for example, bribery.[49] But by definition, false advertising is *not* competition "on the merits" because it is deceptive about the merits. And on the Fifth Circuit's theory, if competitors also have the ability to engage in bribery, antitrust should not worry about that either—it is all fair game, and the parties compete on their ability to most effectively seduce or bribe officials (or burn down each other's factories).

A better conclusion would be that both bribery and false advertising are unlawful and that both lead to decisions based on something other than the actual merits of the parties' products. Stated differently, both bribery and false advertising undermine trust and corrode the actual mechanisms of marketplace competition.

The strongest distinction between bribery and false advertising involves an epistemological intuition: factfinders might be wrong about whether false advertising occurred, and if they were wrong, then they might block truthful

46. Cal. Dental Ass'n v. FTC, 526 U.S. 756, 771 n.9 (1999); *see id.* at 773–74 (providing that "reducing the occurrence of unverifiable and misleading . . . advertising" would promote competition).

47. Rebecca Tushnet, *Fifth Circuit Reverses Multimillion-Dollar Antitrust Verdict Based on False Advertising, Remands*, TUSHNET.COM (Dec. 6, 2016), https://tushnet.com/2016/12/06/fifth-circuit-reverses-multimillion-dollar-antitrust-verdict-based-on-false-advertising-remands-2 [https://perma.cc/7KVC-GNEY]; *see* Akerlof, *supra* note 31, at 495 (explaining that "dishonest dealings tend to drive honest dealings out of the market"); Stephan Lewandowsky, Ullrich K.H. Ecker, Colleen M. Seifert, Norbert Schwarz & John Cook, *Misinformation and Its Correction: Continued Influence and Successful Debiasing*, 13 PSYCH. SCI. PUB. INT. 106, 124 (2012) (discussing the many difficulties of correcting misinformation); *cf.* Richard Craswell, *Static Versus Dynamic Disclosures, and How Not to Judge Their Success or Failure*, 88 WASH. L. REV. 333, 345 n.21 (2013) (noting that studies of corrective advertising ordered as a remedy for false advertising "typically show small but non-zero effects on consumer beliefs" (citations omitted)).

48. *E.g.*, Sanderson v. Culligan Int'l Co., 415 F.3d 620, 623 (7th Cir. 2005); Stearns Airport Equip. Co. v. FMC Corp., 170 F.3d 518, 526 (5th Cir. 1999).

49. *Retractable Techs.*, 842 F.3d at 894 (quoting *Stearns*, 170 F.3d at 523–25).

advertising, which is good for competition. Of course, factfinders might also be wrong about whether bribery occurred, but if they were wrong, it is less likely they would have deterred procompetitive conduct. Given recent Supreme Court precedents, one could characterize many bribery situations as businesses merely giving their opinions to regulators on matters of policy and engaging in First Amendment-protected political speech through money, but that is not (yet) accepted by the courts.[50] Still, the intuition remains that the competitive consequences of factfinders being wrong about false advertising are more dangerous than those accompanying errors about bribery.

We think this concern is vastly overstated. Because false advertising already is illegal, there are well-recognized mechanisms for identifying falsifiable and false statements in advertising. Moreover, this concern should be confronted directly, rather than being buried in statements about the good that false advertising can do.[51] In other areas of antitrust law, the idea that there are procompetitive reasons for conduct does not immunize that conduct from antitrust scrutiny. False advertising is anticompetitive conduct that is theoretically confusable with procompetitive truthful advertising. The solution is to work on minimizing that confusion, not to abandon the field.

B. DE MINIMIS APPROACH

The second approach, represented by the Second, Sixth, Ninth, Tenth, and Eleventh Circuits, applies a presumption that the exclusionary effects of false advertising are *de minimis*.[52]

50. For example, the Court narrowed the "official acts" that can justify a bribery charge so that arranging a meeting only if a constituent agrees to pay is not itself an "official act." McDonnell v. United States, 136 S. Ct. 2355, 2372 (2016); *cf.* McCutcheon v. FEC, 572 U.S. 185, 227 (2014) (holding that "corruption" requires a quid pro quo exchange); Fred Wertheimer, *Symposium:* McDonnell *Decision Substantially Weakens the Government's Ability to Prevent Corruption and Protect Citizens*, SCOTUSBLOG (June 28, 2016, 12:38 PM), https://www.scotusblog.com/2016/06/symposium-mcdonnell-decision-substantially-weakens-the-governments-bbility-to-prevent-corruption-and-protect-citizens [https://perma.cc/2K8K-5TYZ].

51. The term "falsifiable" signifies that it is capable of being proved false, as opposed to a statement that is so vague or ambiguous that it cannot reasonably be deemed either true or false. An unfalsifiable statement is often labeled "puffery," which is nonactionable. *See, e.g.*, Southland Sod Farms v. Stover Seed Co., 108 F.3d 1134, 1145 (9th Cir. 1997).

52. *See* Nat'l Ass'n of Pharm. Mfrs., Inc. v. Ayerst Lab'ys, 850 F.2d 904, 916 (2d Cir. 1988); Am. Council of Certified Podiatric Physicians & Surgeons v. Am. Bd. of Podiatric Surgery, Inc., 323 F.3d 366, 370 (6th Cir. 2003); Am. Pro. Testing Serv., Inc. v. Harcourt Brace Jovanovich Legal & Pro. Publ'ns, Inc., 108 F.3d 1147, 1152 (9th Cir. 1997); Lenox MacLaren Surgical Corp. v. Medtronic, Inc., 762 F.3d 1114, 1126–28 (10th Cir. 2014); Duty Free Ams., Inc. v. Estée Lauder Cos., 797 F.3d 1248, 1268–69 (11th Cir. 2015).

1. Introduction: The Treatise and Its Framework

The *de minimis* framework originated in the leading antitrust treatise, *An Analysis of Antitrust Principles and Their Application.*[53] First introduced in 1978 by Philip Areeda and Donald Turner and continued by Areeda and Herbert Hovenkamp, the treaty's influence is unmatched.[54] Justice Breyer has remarked that "most practitioners would prefer to have two paragraphs of Areeda's treatise on their side than three Courts of Appeals or four Supreme Court Justices."[55] "Courts commonly quote portions of the treatise at length . . . . And courts will often explicitly adopt propositions offered by the treatise as law."[56]

The skepticism of antitrust's application to false advertising claims traces back to the 1978 version of the treatise, written at a time before courts had developed robust doctrines establishing the boundaries of Lanham Act false advertising.[57] In considering the relationship between false advertising and antitrust, the treatise highlights the "key problem" presented by "the difficulty of assessing the connection between any improper representations and the speaker's monopoly power."[58] It posits that the "more typical deception defendant is the smaller firm or recent entrant that makes its false claims, collects the payments from deceived consumers, and then disappears or becomes judgment-proof."[59] In contrast, the "false claim leading to or perpetuating durable market power by a firm capable of being sued is much less likely."[60] Relying on these claims, the treatise then concludes that "[b]ecause the likelihood of significant creation of durable market power is so small in most observed instances—and because the prevalence of arguably improper misrepresentation is so great—the courts would be wise to regard misrepresentations as presumptively de minimis."[61]

Before analyzing the treatise's suggested test, it is worth noting that its description of the "typical deception defendant" is not reflected in the case law. Although public enforcers often go after such fly-by-night entities, they

53. *See* 3 PHILLIP E. AREEDA & DONALD F. TURNER, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶¶ 738c, 739 (1978).

54. *See* Rebecca Haw Allensworth, *The Influence of the Areeda–Hovenkamp Treatise in the Lower Courts and What It Means for Institutional Reform in Antitrust*, 100 IOWA L. REV. 1919, 1921 (2015).

55. Justice Stephen Breyer, *In Memoriam: Phillip E. Areeda*, 109 HARV. L. REV. 889, 890 (1996).

56. Allensworth, *supra* note 54, at 1922 (footnote omitted).

57. AREEDA & TURNER, *supra* note 53, ¶ 738c, at 281 (finding a "serious de minimis test" to be "[e]ssential" and "go[ing] further" to "suggest that [disparagement] claims should presumptively be ignored").

58. 3B AREEDA & HOVENKAMP, *supra* note 6, ¶ 782b, at 351.

59. *Id.*

60. *Id.*

61. *Id.*

also successfully challenge household names like Kellogg and AT&T.[62] Lanham Act false advertising cases are rarely brought against judgment-proof defendants and, in the cases we are concerned with, are brought against monopolists or plausible attempted monopolists—entities distinct from those that concern the treatise—whose market power and durability themselves make their claims more credible and thus more harmful than the claims of unknown market entrants.[63] The treatise accurately describes a set of fraudsters, and we agree that those actors are not good targets for antitrust law. But it does not capture the full scope of consumer deception—nor, in all likelihood, the vast majority of damages done by false advertising. AT&T can take a lot more money from consumers than a small dietary supplement seller that operates only until discovered.[64]

The treatise (again, beginning in 1978) suggests that a plaintiff can rebut the *de minimis* presumption by showing that the alleged anticompetitive conduct is (1) clearly false, (2) clearly material, (3) clearly likely to induce reasonable reliance, (4) made to buyers without knowledge of subject matter, (5) continued for prolonged periods, and (6) not readily susceptible of neutralization or other offsets by rivals.[65] Although it is appropriate to ensure that the vast majority of false advertising, perpetuated by firms lacking market power, does not automatically violate antitrust law, the *de minimis* approach overshoots the mark by making it nearly impossible to find antitrust liability even for monopolists bringing about substantial competitive harm. Below, we directly address the concern that animates the test—that most false advertising is not carried out by firms with market power—by focusing on false advertising by firms with monopoly power or a real threat of becoming monopolists.

Although courts have not explicitly invoked it to defend their test, the *de minimis* approach's best theoretical defense comes from an advertising model in which what matters to consumers is merely the fact of advertising rather than its content, meaning that consumers don't actually believe specific

62. *See, e.g.*, Complaint for Permanent Injunction and Other Equitable Relief, *supra* note 3, at 1–2; *Kellogg Settles FTC Charges that Ads for Frosted Mini-Wheats Were False*, FED. TRADE COMM'N (Apr. 20, 2009), https://www.ftc.gov/news-events/press-releases/2009/04/kellogg-settles-ftc-charges-ads-frosted-mini-wheats-were-false [https://perma.cc/R7UJ-WVHP].

63. *See generally* Anne L. Roggeveen & Gita Venkataramani Johar, *Perceived Source Variability Versus Familiarity: Testing Competing Explanations for the Truth Effect*, 12 J. CONSUMER PSYCH. 81 (2002) (discussing strong evidence that repetition of an advertising message increases belief).

64. *See* Rory Van Loo, *Broadening Consumer Law: Competition, Protection, and Distribution*, 95 NOTRE DAME L. REV. 211, 214–15 (2019) (noting that deceptive conduct by major entities such as Amazon, Facebook, and credit card companies substantially harms consumers, with these harms likely underestimated).

65. Am. Council of Certified Podiatric Physicians & Surgeons v. Am. Bd. of Podiatric Surgery, Inc., 323 F.3d 366, 371 (6th Cir. 2003) (citing AREEDA & TURNER, *supra* note 53, ¶ 738a, at 278–79). Courts are not consistent on whether a plaintiff must show each of the six factors. *See, e.g.*, *id.* ("[W]e decline to consider each element or hold that all elements must be satisfied to rebut the *de minimis* presumption.").

factual claims in advertising.[66] In the content-is-meaningless account, the fact that the advertiser is spending money touting its products is credible evidence that the advertiser believes it has something worth consumers' money, and that general assertion is the only thing consumers are likely to rely on.[67] In this theory, extensive advertising is like the biologically costly peacock's tail that demonstrates reproductive fitness to potential mates: costly advertising evidences marketplace fitness, with the specific claims just window dressing for consumers. If this were true, then we could indeed expect that the effects of false advertising would be *de minimis*.

The content-indifferent approach, however, contradicts what courts, advertisers, and marketing researchers think about the power of advertising generally. Advertisers don't just buy ad space and tell consumers how much they spent on it. Instead, they routinely focus on product features that consumers care about, from price to health and safety, revealing their own expectations that factual claims in advertising influence consumers.[68] Advertisers carefully test marketing claims, and a persuasive claim can drive changes in market share.[69] In fact, false advertising/antitrust claims often arise in highly concentrated markets with consumers who, despite a generally high level of sophistication, lack the ability to verify technical claims. For example, product manufacturers who pay intermediaries to put promotional material in grocery stores care very much about how well the stores implement the promotions, but cannot necessarily perform nationwide audits themselves, making them vulnerable to misrepresentations about competitors' performance.[70]

2. Specific Problems with the Multifactor Test

Not only does the *de minimis* approach conflict with false advertising law, but the individual factors themselves also are not justified, as they are

66. *See* Lillian R. BeVier, *Competitor Suits for False Advertising Under Section 43(a) of the Lanham Act: A Puzzle in the Law of Deception*, 78 VA. L. REV. 1, 8 (1992); Phillip Nelson, *Advertising as Information*, 82 J. POL. ECON. 729, 730–31 (1974); Phillip Nelson, *The Economic Consequences of Advertising*, 48 J. BUS. 213, 214 (1975).

67. BeVier, *supra* note 66, at 10–11.

68. *See* Beales et al., *supra* note 32, at 492–95; Goldman, *supra* note 30, at 491–94; Roger E. Schechter, *Additional Pieces of the Deception Puzzle: Some Reactions to Professor BeVier*, 78 VA. L. REV. 57, 68–79 (1992); *see also* Schick Mfg., Inc. v. Gillette Co., 372 F. Supp. 2d 273, 278 (D. Conn.) ("Because of the expense of television advertising, companies have a very short period of time in which to create a 'reason to believe' and are generally forced to pitch only the key qualities and characteristics of the product advertised."), *modified*, No. 3-05-cv-174 (JCH), 2005 WL 8168764 (D. Conn. June 20, 2005); *id.* at 286–87 ("Gillette's employees testified that television advertising time is too valuable to include things that are 'unimportant.'").

69. *See, e.g.*, Novartis Consumer Health, Inc. v. Johnson & Johnson–Merck Consumer Pharms. Co., 290 F.3d 578, 584, 595–96 (3d Cir. 2002) (detailing how the new antacid product claiming nighttime superiority has quickly gained market share).

70. *See* Insignia Sys., Inc. v. News Am. Mktg. In-Store, Inc., 661 F. Supp. 2d 1039, 1049–53 (D. Minn. 2009).

disconnected from the ways in which false advertising does harm. As we discuss the elements of the *de minimis* approach, we will explain why false advertising law's simpler framework accommodates the relevant concerns without discounting the damage false advertising can do.

The first factor requires the advertising to be "clearly false." Although antitrust courts have never had to explain exactly what they mean by that factor, it seems to be something like "not capable of some innocent interpretation."[71] But false advertising law has long recognized that statements that are misleading—literally true[72] or ambiguous, but which induce consumers to reach false conclusions—are actionable.[73] It makes sense for false advertising law to cover both literally false and literally true but misleading claims. Claims that mislead a substantial number of consumers can cause the same kinds of harm as literally false statements. In fact, the literature shows that implications can be *more* persuasive than literal statements, even when they convey the same message to consumers: by making the relevant inferences, consumers essentially persuade themselves.[74] Indeed, the

71. In theory, it could also mean something like "false or misleading by clear and convincing evidence," but that's an awkward way to specify a quantum of evidence, and courts have not provided a reason for requiring a higher standard of proof for antitrust claims based on false advertising.

72. For example, the truthful statement "BMW vehicles passed their emissions tests" implies that their emissions were within legal limits, but this implication is false when BMW designed its vehicles to pass the tests while otherwise emitting unlawful amounts of pollutants. *Cf. Volkswagen to Spend up to $14.7 Billion to Settle Allegations of Cheating Emissions Tests and Deceiving Customers on 2.0 Liter Diesel Vehicles*, FED. TRADE COMM'N (June 28, 2016), https://www.ftc.gov/news-events/press-releases/2016/06/volkswagen-spend-147-billion-settle-allegations-cheating [https://perma.cc/DK2Z-KTDH].

73. All three types of advertising regulation (FTC/state regulators, competitor Lanham Act claims, and state consumer protection law allowing consumer suits) prohibit both false and misleading claims. *See, e.g.*, Hickson Corp. v. N. Crossarm Co., 357 F.3d 1256, 1260–61 (11th Cir. 2004) (applying the Lanham Act); FTC v. Roca Labs, Inc., 345 F. Supp. 3d 1375, 1384–85 (M.D. Fla. 2018) (following usual FTC practice of alleging "false or misleading" claims); Hoang v. Reunion.com, Inc., No. C-08-3518 MMC, 2010 WL 1340535, at *5 (N.D. Cal. Mar. 31, 2010) ("Historically, many states have enacted consumer protection laws prohibiting the dissemination of false or misleading statements made in connection with the advertising of products or services, and have not required the plaintiff to prove actual reliance on the false or misleading statement, but, rather, to prove that the false or misleading statement is, objectively, the type of statement likely to deceive a reasonable consumer."); *cf.* 15 U.S.C. §§ 52, 55 (2018) (defining "false advertisement" for "food, drugs, devices, services, or cosmetics" as any advertisement that is "misleading in a material respect").

74. "Consumers are less likely to argue against associations they came up with themselves, and more likely to remember and act on them." Edward F. McQuarrie & Barbara J. Phillips, *Indirect Persuasion in Advertising: How Consumers Process Metaphors Presented in Pictures and Words*, ASS'N FOR CONSUMER RSCH., https://www.acrwebsite.org/web/acr-content/749/indirect-persuasion-in-advertising-how-consumers-process-metaphors-presented-in-pictures-and-words.aspx [https://perma.cc/LW8V-8J3D] (summarizing Edward F. McQuarrie & Barbara J. Phillips, *Indirect Persuasion in Advertising: How Consumers Process Metaphors Presented in Pictures and Words*, J. ADVERT., Summer 2005, at 7); Alan G. Sawyer, *Can There Be Effective Advertising Without Explicit Conclusions? Decide for Yourself*, *in* NONVERBAL COMMUNICATION IN ADVERTISING 159, 170

Supreme Court has specifically recognized that confusing and misleading advertising can harm competition, both by distorting consumer decisions and by clouding the market generally, eroding consumers' willingness to rely on advertising.[75]

The factor of clear falsity seems to be motivated by the concern that courts should not impose antitrust liability unless they are absolutely certain it is justified. The treatise worries that "distinguishing false statements on which buyers do, or ought reasonably to, rely from customary puffing is not easy."[76] But 70 years of Lanham Act precedents (and an even longer record of FTC enforcement) establish that false advertising law maintains a robust doctrine of puffery that excuses claims that are too vague or multivalent to be falsifiable, while identifying claims that are capable of being proven false. When an advertiser makes a factual, falsifiable claim, that claim should be true, and if it is not, the advertiser proceeds at its peril.

Especially in combination with the other factors, the first factor works to preclude liability if there is any way the defendant can spin its advertising, regardless of how the relevant consumers actually understood the message. It is a mistake, however, to ignore how the market in fact reacted to the advertising. If we are hesitant to impose antitrust liability, we should choose a limiting principle focused more on the actual market effects than on the difference between that which is "clearly" false and that which is misleading. The law of false advertising itself strikes an appropriate balance in requiring a showing of falsity or misleadingness—both of which can be shown by a preponderance of the evidence—to a substantial number of reasonable consumers.

The second factor requires the false advertising to be "clearly material." Again, it's not entirely clear what this means; it could be something like "material to every consumer." This is another example of antitrust stepping in with its own formulation of a test that false advertising law has already developed. The ordinary standard for materiality in false advertising law provides that the fact at issue must be one (like a medication's effectiveness or price) that reasonable consumers would consider relevant to purchase decisions.[77] Materiality focuses on whether a claim is likely to influence a

(Sidney Hecker & David W. Stewart eds., 1988) ("Research . . . offers strong evidence that audience members will spontaneously strive to make inferences and conclusions under certain conditions. . . . [A]dvertising audiences are also very likely to 'complete' ambiguous advertising statements or claims. Under conditions [where consumers aren't paying extremely careful attention], . . . subjects tended to make false conclusions . . . which, if the advertiser could or should be considered as the cause of the incorrect conclusion, would be judged deceptive." (footnote omitted) (citations omitted)).

75. Cal. Dental Ass'n v. FTC, 526 U.S. 756, 778 (1999) (noting the "procompetitive effect" of "preventing misleading or false claims that distort the market").

76. 3B AREEDA & HOVENKAMP, *supra* note 6, ¶ 782d, at 356.

77. *See, e.g.*, U.S. Healthcare, Inc. v. Blue Cross of Greater Phila., 898 F.2d 914, 922 (3d Cir. 1990) (requiring that misrepresentations in advertisements be "likely to influence the purchasing

reasonable consumer's decision, not whether *every* consumer's behavior is changed as a result.[78] False advertising law offers a definition of "reasonable" consumers as ordinary consumers entitled to their preferences, whether those preferences are rational or not.[79] And false advertising law makes clear that not every consumer needs to be affected for there to be serious competitive injury.[80] Indeed, it's easy to imagine scenarios in which competition could be suppressed particularly effectively by targeting specific subgroups, such as price-sensitive consumers (as AT&T did with its false claims), early adopters, or risk-averse consumers.

Another reason why clear materiality is not needed is that false advertising already has a harm causation requirement. A plaintiff is required to show that they suffered (or is likely to suffer) a real injury from the false advertising, though that injury need not be precisely quantifiable.[81] If there was more than a trivial injury from the false advertising, it naturally follows that consumers were in fact deceived by the falsity: They acted on it.[82] In short, an additional requirement that the false advertising be "clearly material" is not necessary.

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decision[s]" of the public to satisfy the materiality requirement (quoting Toro Co. v. Textron, Inc., 499 F. Supp. 241, 251 (D. Del. 1980))); AT&T Co. v. Winback & Conserve Program, Inc., 42 F.3d 1421, 1428 n.9 (3d Cir. 1994) (holding that materiality should be assessed from the consumer's perspective).

78. *See* Rebecca Tushnet, *Running the Gamut from A to B: Federal Trademark and False Advertising Law*, 159 U. PA. L. REV. 1305, 1345 (2011) ("Materiality is an intuitive part of harm, because harm only comes when there is a causal link between the falsehood and consumers' behavior. Materiality is now generally enumerated as a separate requirement in the more elaborate modern multifactor test for false advertising." (footnote omitted)).

79. FTC v. Colgate-Palmolive Co., 380 U.S. 374, 389 (1965); *cf.* Benton Announcements, Inc. v. FTC, 130 F.2d 254, 255 (2d Cir. 1942) (per curiam) ("[P]eople like to get what they think they are getting, and courts have steadfastly refused in this class of cases to demand justification for their preferences. Shoddy and petty motives may control those preferences; but if the buyers wish to be snobs, the law will protect them in their snobbery.").

80. Most strikingly, courts routinely find false advertising when 15 percent or more of consumers are deceived (net of a control group not exposed to the accused advertising); there is no required percentage of deception, but it is clear that deceiving a majority of the relevant consumers is not required for liability. J. THOMAS MCCARTHY, MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 32:193 (5th ed. 2021).

81. *See, e.g.*, Groupe SEB USA, Inc. v. Euro-Pro Operating LLC, 774 F.3d 192, 204 (3d Cir. 2014) (accepting lost control of reputation and lost goodwill caused by false comparative advertising as irreparable harm); PBM Prods., LLC v. Mead Johnson & Co., No. 3:09-CV-269, 2010 WL 957756, at *1 (E.D. Va. Mar. 12, 2010) (evidence of harm to goodwill and lost market share resulted in $13.5 million in damages).

82. Again, one could argue that there is residual uncertainty: Maybe the consumers did not really rely on the false advertising and the harm shown by the plaintiff resulted from something else. But if courts seek to impose a clear and convincing standard on false advertising/antitrust cases, they should do so outright, and explain why the ordinary preponderance of the evidence standard is unjustified or why factfinders shouldn't be allowed to make causation judgments based on the evidence before them.

The third factor provides that the false advertising must be "clearly likely to induce reasonable reliance." On its face, such a requirement may sound justifiable. But it duplicates the materiality factor while overemphasizing the fraud-like idea of "reasonable" reliance. Consumers are not required to treat advertising like the testimony of a hostile witness, parsing each statement for small ambiguities and investigating each one.[83] They need not do this because hundreds of years of history have shown that they don't and won't treat ads with that level of suspicion.[84] As a result, false advertising law has long recognized that protecting consumers from deception requires a standard other than that appropriate for a lawyer in an adversarial process. And while there are reasons that consumers might disbelieve advertising, even about factual and material claims, there is no reason to presume such disbelief. Once again, a requirement to show actual harm from the false advertising more directly addresses the question of whether the false advertising worked.

Fourth, the false advertising must be directed to buyers without knowledge of the subject matter. This, however, is just a reason that consumers might believe claims made to them. There's no need for a separate requirement. If a statement is false or misleading, material, and actually deceived consumers, their knowledge of the subject matter demonstrably was not enough to protect them from deception.[85] For example, in a recent false advertising case, the sellers falsely advertised to large, experienced oil and gas companies about the characteristics of their carbon steel flanges, which are used to attach parts together in, among other things, oil and gas pipelines. As the court pointed out, the technical claims made by the defendant about its production process were difficult to verify; buyers had no practical alternative to relying on the sellers' representations, which included falsified test

83. *See, e.g.*, Am. Home Prods. Corp. v. FTC, 695 F.2d 681, 689 (3d Cir. 1982) (declining to require ordinary consumers to read ads with "sedulous" attention).

84. *See generally* DEE PRIDGEN, RICHARD M. ALDERMAN & JOLINA C. CUARESMA, CONSUMER PROTECTION AND THE LAW § 2:10 (2020) (discussing policymakers' reasons for removing traditional stringent fraud requirements in modern consumer protection law); Jessica M. Choplin, Debra Pogrund Stark & Jasmine N. Ahmad, *A Psychological Investigation of Consumer Vulnerability to Fraud: Legal and Policy Implications*, 35 L. & PSYCH. REV. 61 (2011) (discussing how consumers fall for fraud because they do not carefully evaluate details).

85. One consequence of this factor's disconnection from reality is that courts will interpret it in varying ways. In *Chase Mfg., Inc. v. Johns Manville Corp.*, No. 19-cv-00872-MEH, 2020 WL 1433504, at *13 (D. Colo. Mar. 23, 2020), for example, the court held that buyers in a highly concentrated, sophisticated market lacked firsthand knowledge of the "subject matter" primarily because most of them had never bought the plaintiff's product, and it was not clear that the plaintiff's advertising of its own test results was widely disseminated or that it covered the alleged misrepresentations about asbestos content. The real issue was not that these parties lacked information about the product, but that the plaintiff was a new market entrant and that the defendant's alleged misrepresentations related to product safety and litigation risk, where buyers might be particularly cautious. *Id.*

results.[86] Again, the underlying intuition might be that correcting the record should be easy with knowledgeable consumers, and thus that antitrust remedies are heavy-handed and unnecessary. But there is no reason to make such an assumption. (Indeed, the flange manufacturer instead doubled down and sent letters to customers accusing the plaintiff of lying; only years later did it admit the truth.[87]) And, as we noted in the previous Section, there are many reasons why misinformation can be hard to correct, especially for new entrants that do not yet have an established base of customers.[88]

Fifth, the false advertising must be continued for prolonged periods. This factor also seems to be a rough proxy for likelihood and amount of harm. But it does not justify duration as an independent requirement and does not offer a metric by which duration could be measured.[89]

Finally, the false advertising must not be readily susceptible of neutralization by rivals. Like other factors, this one duplicates deceptiveness and harm. If the false advertising worked, then it damaged the fair functioning of the marketplace, regardless of what theoretically could have happened. Relatedly, this factor, like the fourth factor, is inconsistent with what we know about the difficulty of correcting a misperception once established.[90] Presuming that neutralization is possible does not reflect marketplace reality.[91]

As a final point, putting the burden on competitors to correct material falsehoods is inconsistent with the basic antitrust concept that incumbents shouldn't be able to erect barriers to market entry just to deter rivals. To the contrary, the multifactor test, as well as the no-liability rule, bakes in the idea that it is legitimate for entrants to face additional costs to overcome exclusionary false advertising. False advertising law is designed to take false advertising off the table as a method of competition. It substitutes for counterneasures because, among other things, of the waste and lack of trust such free-for-all systems generate. Antitrust should not undercut false advertising law by presuming that already-illegal conduct is easy to correct.

In short, false advertising doctrine makes clear that none of the factors in the current test justifies a presumption that harm to competition is *de minimis*. The factors and the general assumption that false advertising has only a minimal effect on competition have been influential but not supported by evidence.

86. Boltex Mfg. Co. v. Ulma Piping USA Corp., No. 4:17-CV-01400, 2020 WL 598284, at *5 (S.D. Tex. Feb. 7, 2020).

87. *Id.* at *3.

88. *See supra* notes 46–47 and accompanying text.

89. *See Chase*, 2020 WL 1433504, at *14 (finding that misstatements that occurred over a period of months, during the plaintiff's attempt to launch its business, were of sufficient duration).

90. *See supra* notes 46–47 and accompanying text.

91. *See* Maurice E. Stucke, *When a Monopolist Deceives*, 76 ANTITRUST L.J. 823, 829 (2010) ("If product disparagement is ineffectual, why would any firm, much less a monopolist, engage in it?").

C. CASE-BY-CASE APPROACH

A third group of courts, led by the Third, Eighth, and D.C. Circuits, takes a case-by-case approach in assessing whether the conduct violates antitrust law. For example, the Third Circuit in *West Penn Allegheny Health System, Inc. v. UPMC* explained "that anticompetitive conduct can include . . . making false statements about a rival to potential investors and customers" and that "defamation, which plainly is not competition on the merits, can give rise to antitrust liability, especially when it is combined with other anticompetitive acts."[92] Similarly, the D.C. Circuit in *Caribbean Broadcasting System, Ltd. v. Cable & Wireless PLC* noted that "fraudulent misrepresentations" are "well within" the recognition that there are multiple forms of anticompetitive conduct.[93] And the Eighth Circuit in *International Travel Arrangers, Inc. v. Western Airlines, Inc.* explained that a concerted campaign by an alleged monopolist involving newspaper advertisements, radio commercials, and a letter to customers was "a form of competition[,] and because competition is the object sought to be preserved by the antitrust laws, [courts] must be careful in drawing a line between fair competition, unfair competition and competition that is so unfair as to rise to the level of an unreasonable restraint of trade."[94]

Courts applying the case-by-case approach have appreciated that anticompetitive conduct takes "too many different forms, and is too dependent upon context, for any court or commentator ever to have enumerated all the varieties."[95] Under this approach, one relevant factor has been the role the conduct plays in a competitor's ability to finance itself. In one case, for example, the Third Circuit determined that false statements to investors about a competitor's financial health caused the rival to pay inflated financing costs on its debt and demonstrated anticompetitive conduct sufficient to survive a motion to dismiss.[96]

A second factor that courts have analyzed under the case-by-case approach is the extent to which false statements lock in decision-making. In *United States v. Microsoft Corp.*, for example, the D.C. Circuit found that deceptive statements to Java-based software developers about the interoperability of Windows-based systems with other platforms resulted in developers' inadvertently producing software compatible only with Windows and demonstrated anticompetitive conduct violating Section 2 of the Sherman Act.[97]

By analyzing conduct as a whole without requiring a showing exceeding *de minimis* harm, the case-by-case approach offers flexibility. This is the most justifiable of the three approaches. But the approach could be strengthened

92. W. Penn Allegheny Health Sys., Inc. v. UPMC, 627 F.3d 85, 109 & n.14 (3d Cir. 2010).
93. Caribbean Broad. Sys., Ltd. v. Cable & Wireless PLC, 148 F.3d 1080, 1087 (D.C. Cir. 1998).
94. Int'l Travel Arrangers, Inc. v. W. Airlines, Inc., 623 F.2d 1255, 1267 (8th Cir. 1980).
95. *Caribbean Broad.*, 148 F.3d at 1087.
96. *W. Penn Allegheny*, 627 F.3d at 109–10.
97. United States v. Microsoft Corp., 253 F.3d 34, 76–77 (D.C. Cir. 2001).

by highlighting relevant factors and drawing on learning from false advertising law.

IV. AN ANTITRUST FRAMEWORK

As the previous Part showed, antitrust could benefit from a new framework for false advertising. The approaches abandoning antitrust liability and applying a *de minimis* analysis are not justified: the law and practice of false advertising is far more consistent with antitrust's own general vision of the marketplace. And the case-by-case evaluation could use development.

The reasons courts have not applied approaches faithful to false advertising are not hard to see. The leading antitrust treatise has worried that "plaintiffs are often less disciplined in making tort-like claims in antitrust suits than in tort suits."[98] Courts also reasonably want to impose requirements that prevent every false advertising case from morphing into an antitrust case. Antitrust analysis could use assistance since the "exclusionary conduct" needed for monopolization doesn't have much content. This Part explains the need for antitrust and offers frameworks that courts can apply to monopolists and those seeking to become monopolists.

A. ANTITRUST'S NECESSITY

False advertising liability alone cannot address the marketwide harms caused by deceptive behavior. This Section first addresses antitrust's comparative advantage for marketwide harms. It then offers examples of antitrust properly targeting conduct that violates other, non-antitrust laws, demonstrating that antitrust's treatment of false advertising is an outlier. It concludes by showing that false advertising's remedies cannot fully protect competition on their own.

1. Antitrust's Comparative Advantage

An antitrust-based framework for false advertising claims is necessary because of the unique role that the discipline can play. When companies engaging in false advertising have monopoly power, they possess the ability to harm not only an individual competitor but also the market as a whole. The consequences can be significant, especially for nascent competitors not able to enter the market, as the deception of consumers deprives them of the opportunity to obtain lower prices, more options, or enhanced quality.

One way to understand the harms of false advertising to the market as a whole is revealed by George Akerlof's classic explanation of the market for lemons.[99] As Akerlof explains, in the absence of some way to guarantee the

98. 3B AREEDA & HOVENKAMP, *supra* note 6, ¶782a, at 345.

99. Akerlof, *supra* note 31, at 488–90. Akerlof focuses on information asymmetry, but if consumers trusted that producers were constrained to make only truthful claims, the asymmetry would disappear because producers with above-average products would be credible when they

truth of claims about products, such as a used car's quality, consumers reasonably respond by discounting all such claims. This distrust means that producers with actually superior products cannot charge the amount consumers would pay if they believed the superiority claim, which pushes superior (but more expensive to produce) products out of the market.

If truthful advertisers are not able to guarantee their claims, producers unable to compete on their product characteristics suffer. And consumers are harmed by an unattractive (and perhaps even harmful, in the case of false health or safety claims) mix of products. Meanwhile, many false advertising techniques can be readily repurposed for new uses, meaning that a false advertiser can go from success to success in the absence of false advertising liability.[100] Regulation that suppresses false claims—especially where such claims are most likely to have an effect—thus does more than protect individual consumers from fraud. It allows truthful producers to compete on a level playing field. In other words, addressing false advertising protects competition, not just competitors.

The Supreme Court relied on Akerlof's insights when it endorsed the pro-competitive effects of restrictions on false advertising. In *California Dental Ass'n v. FTC*, the Court addressed a dental association's attempts to restrict "false or misleading" advertising that imposed significant limits on advertising "low prices" or other general price claims.[101] The Court rejected the idea that such limits were inherently anticompetitive. Especially where information is hard to evaluate, even broad restrictions with the aim of preventing false advertising can be procompetitive.[102]

When false advertising threatens harms to the market as a whole, antitrust liability offers advantages over false advertising law. For starters, antitrust offers a more powerful toolkit deterring this conduct. Although false advertising law allows recovery of damages (albeit not as a penalty) and disgorgement of the profits from false advertising, courts impose high barriers to disgorgement, including requiring a showing of willfulness. In addition, courts have required plaintiffs to show a robust connection to the harm suffered to receive damages or disgorgement of profits. As a result, courts have denied awards in precisely the cases of concern: where there are a small number of potential competitors and where some of the monopolist's gains from false advertising likely came at the expense of the overall market rather

said so, and the failure to disclose quality information would itself be a worthwhile signal. As a result, falsity (either explicit or through implication) is a key driver of the degeneration in the market. *See* Beales et al., *supra* note 32, at 505–06, 510–11.

100. *Cf.* Telebrands Corp. v. FTC, 457 F.3d 354, 361 (4th Cir. 2006) (noting that certain falsities may be readily replicable).

101. Cal. Dental Ass'n v. FTC, 526 U.S. 756, 783 (1999).

102. *Id.* at 771–73 (noting that customers' access to information in the dental market was limited and the implemented restriction increased the reliability of the information consumers had).

than a single plaintiff, making it difficult to allocate false advertising-based damage awards.[103]

There are two key ways in which antitrust offers more powerful protection against monopolists' false advertising than federal false advertising law: remedies and eligible plaintiffs. First, antitrust offers the more powerful remedies of treble damages and automatic (as opposed to the Lanham Act's exceptional[104]) attorneys' fees that promise to provide robust deterrence against companies considering this behavior. Antitrust also offers injunctive relief preventing the continuation of the conduct. While a Lanham Act false advertising injunction generally is limited to the specific false claims that have been proven, an antitrust injunction could more generally target false advertising and marketwide harm to competition.[105] Antitrust offers a more expansive territorial jurisdiction.[106]

Second, unlike the federal Lanham Act, which denies consumers standing to sue despite the direct harm they suffer from false advertising, antitrust law, importantly, allows customers to challenge the harms they experience from false advertising. State consumer protection laws are limited in important ways, including state-law variation that makes multistate consumer class actions all but impossible[107] and restrictions in many states that preclude businesses from bringing claims in their roles as consumers[108] even though businesses are often important customers for the subset of false advertising cases involving monopolists and would-be monopolists. Thus, antitrust provides remedies that would otherwise be unavailable to plaintiffs who were themselves deceived by a monopolist or threatened monopolist's false advertising.

A separate and independently compelling reason to use antitrust where appropriate is that, in antitrust law, it would be possible to consider false advertising as part of an overarching scheme used to harm a competitor, something false advertising law by definition can't do. In fact, the inclusion of this behavior could push the range of conduct over the threshold of antitrust liability. For example, in *In re Suboxone Antitrust Litigation*, the court found that the plaintiff could not demonstrate that its claim that the defendant had

103. *See, e.g.*, Retractable Techs., Inc. v. Becton Dickinson & Co., 842 F.3d 883, 893–97 (5th Cir. 2016).

104. *See* 15 U.S.C. § 1117 (2018).

105. When the FTC sues, courts often recognize that a particular false advertising technique (e.g., false claims of efficacy) can readily be adapted to new products or situations. *See, e.g.*, *Telebrands Corp.*, 457 F.3d at 361–62. With its competition focus, an antitrust injunction could similarly protect against repurposing false advertising to exclude other competitors.

106. 3B AREEDA & HOVENKAMP, *supra* note 6, ¶782a, at 344 & n.1.

107. *See, e.g.*, Castano v. Am. Tobacco Co., 84 F.3d 734, 741 (5th Cir. 1996) ("In a multi-state class action, variations in state law may swamp any common issues and defeat predominance.").

108. *See, e.g.*, MacDonald v. Thomas M. Cooley L. Sch., 724 F.3d 654, 660–61 (6th Cir. 2013) (noting that the Michigan Consumer Protection Act does not protect against false advertising claims involving commercial purchases).

refused to participate in a safety program required by the U.S. Food and Drug Administration ("FDA") individually made out a violation of antitrust law.[109] But it found that "a plaintiff can allege a series of actions that when taken together make out antitrust liability even though some of the individual actions, when viewed independently, are not all actionable."[110] Such global assessment can allow consideration of a monopolist software provider's practices of promising "vaporware" that it couldn't deliver to prevent customers from turning to competing software alternatives and of creating fear, uncertainty, and doubt about the competition as part of a larger constellation of anticompetitive activities.[111] As the Third Circuit noted in *LePage's Inc. v. 3M*, "courts must look to the monopolist's conduct taken as a whole rather than considering each aspect in isolation."[112]

2. Need for Two Regimes

We suspect that much of the courts' hostility to considering false advertising as part of an antitrust claim comes from the conviction that antitrust remedies are harsh, and that false advertising remedies are thus more appropriate, even for false advertising with anticompetitive effects. This Section shows how this approach is inconsistent with antitrust's treatment of other illegal conduct. Indeed, to the extent that courts want to constrain antitrust's scope to avoid overdeterring legitimate behavior, it is illogical to be *less* willing to deter conduct that is already illegal than to deter conduct that is otherwise legal. Although there are some areas (specifically, parts of the telecommunications industry) in which competition is so closely regulated that antitrust has a limited role, that is not true across the wide range of industries where false advertising can be successful in harming competition.

109. *In re* Suboxone Antitrust Litig., No. 13-MD-2445, 2017 WL 36371, at *7–9 (E.D. Pa. Jan. 4, 2017).

110. *Id.* at *8; *see also, e.g.*, Abbott Lab'ys v. Teva Pharms. USA, Inc., 432 F. Supp. 2d 408, 428 (D. Del. 2006) ("Plaintiffs are entitled to claim that individual acts are antitrust violations, as well as claiming that those acts as a group have an anticompetitive effect even if the acts taken separately do not."); *In re* Gabapentin Pat. Litig., 649 F. Supp. 2d 340, 359 (D.N.J. 2009) ("If a plaintiff can allege that a series of actions, when viewed together, were taken in furtherance and as an integral part of a plan to violate the antitrust laws, that series of actions, as an overall scheme, may trigger antitrust liability."); *In re* Neurontin Antitrust Litig., MDL No. 1479, 2009 WL 2751029, at *15 (D.N.J. Aug. 28, 2009) ("The distinction is between analyzing individual acts or categories of anticompetitive conduct as contrasted with individual theories of liability derived from those acts.").

111. Caldera, Inc. v. Microsoft Corp., 72 F. Supp. 2d 1295, 1300–01, 1309–20 (D. Utah 1999) (discussing alleged use of vaporware and "fear, uncertainty, and doubt" to harm competitors); *cf.* Robert Prentice, *Vaporware: Imaginary High-Tech Products and Real Antitrust Liability in a Post-Chicago World*, 57 OHIO ST. L.J. 1163, 1172–73 (1996).

112. LePage's Inc. v. 3M, 324 F.3d 141, 162 (3d Cir. 2003); *see also, e.g.*, Cont'l Ore Co. v. Union Carbide & Carbon Corp., 370 U.S. 690, 698–99 (1962) (concluding that it is improper to treat antitrust claims as "separate and unrelated lawsuits" and that "plaintiffs should be given the full benefit of their proof without tightly compartmentalizing the various factual components and wiping the slate clean after scrutiny of each").

Thus, antitrust remedies are desirable even if false advertising remedies are also available.

Antitrust's hostility to false advertising as a basis for liability becomes even more puzzling when we look at the overall legal environment. There is a strong basis in twentieth century Supreme Court precedent for considering deception to be anticompetitive in the antitrust sense. For example, the Supreme Court in *FTC v. Winsted Hosiery Co.* found that false labeling that "deceive[d] a substantial portion of the purchasing public" constituted an "unfair method of competition" because "when misbranded goods attract customers by means of the fraud which they perpetrate, trade is diverted from the producer of truthfully marked goods."[113] The Court also held, in *FTC v. R.F. Keppel & Bro.*, that "[i]t would seem a gross perversion of the normal meaning of the word . . . to hold that the [conduct at issue] is not 'unfair'" when "it [was] clear that the practice is of the sort which the common law and criminal statutes have long deemed contrary to public policy."[114]

More broadly, as *Keppel* suggests, there are many examples of courts finding antitrust liability in cases in which the conduct also violates a separate legal regime. In one of the most oft-cited cases, the court in *Conwood Co. v. U.S. Tobacco Co.* upheld a jury verdict of monopolization based on tortious conduct in the moist snuff (smokeless tobacco) market.[115] In this market, point of sale advertising (through racks in stores containing the product) is crucial because of advertising restrictions.[116] One manufacturer, Conwood, challenged multiple types of tortious conduct by another, U.S. Tobacco Company ("USTC"), claiming:

> that USTC (1) removed racks from stores without . . . permission . . . and discarded and/or destroyed these racks, while placing Conwood products in USTC racks . . . to bury Conwood's products and reduce their facings; (2) trained their "operatives to take advantage of inattentive store clerks with various 'ruses' such as obtaining nominal permission to reorganize or neaten the moist snuff section," in an effort to destroy Conwood racks; (3) misused its position as category manager by providing misleading information to retailers in an effort to dupe retailers into believing, among other things, that USTC products were better selling so that retailers would carry USTC products and discontinue carrying Conwood products; and (4) entered into exclusive agreements with retailers in an effort to exclude rivals' products.[117]

113. FTC v. Winsted Hosiery Co., 258 U.S. 483, 493 (1922).

114. FTC v. R.F. Keppel & Bro., 291 U.S. 304, 313 (1934).

115. Conwood Co. v. U.S. Tobacco Co., 290 F.3d 768, 795 (6th Cir. 2002).

116. *Id.* at 774.

117. *Id.* at 783.

After a trial, the jury found that this behavior constituted "exclusionary conduct without a sufficient justification, and that USTC maintained its monopoly power by engaging in such conduct."[118] The Sixth Circuit affirmed the jury's verdict.[119] Similarly, the Fifth Circuit, in *Associated Radio Service Co. v. Page Airways, Inc.*, found exclusionary conduct from "evidence of foreign bribes" and "a contract [that] was the result of improper influence."[120]

The pharmaceutical industry has provided the setting for other examples of antitrust scrutiny of conduct that violates non-antitrust rules, particularly those relating to fraud. The *Walker Process*[121] line of cases holds that the fraudulent procurement of a patent or enforcement of a patent obtained by fraud can violate antitrust law.[122] Other cases involve the allegedly fraudulent listing of patents in the "Orange Book,"[123] an annual compilation of drugs and their associated patents.[124] And courts have recognized antitrust liability when a brand company makes "repeated and allegedly false patent descriptions" to the FDA.[125]

Despite these cases, one could conceivably argue that antitrust should not apply to actions that are also governed by a separate regulatory regime. In *Verizon Communications v. Law Offices of Curtis V. Trinko*, the Supreme Court indicated that where another regulatory regime is guaranteeing competition, there may not be a need for antitrust enforcement.[126] That case can only be fully understood, however, in relation to the industry in which it arose. The Court in the case was evaluating the Telecommunications Act, which provides the Federal Communications Commission ("FCC") with general—and *effective*—regulatory authority over the industry, including its competitive

118. *Id.* at 788.

119. *Id.* at 795; *cf.* Byars v. Bluff City News Co., 609 F.2d 843, 854 n.30 (6th Cir. 1979) (discussing allegations similar to *Conwood*'s that "if credited, could result in a finding of predatory conduct"). Nonetheless, shortly afterwards, the Sixth Circuit explicitly adopted the *de minimis* approach to false advertising. Am. Council of Certified Podiatric Physicians & Surgeons v. Am. Bd. of Podiatric Surgery, Inc., 323 F.3d 366, 370 (6th Cir. 2003).

120. Associated Radio Serv. Co. v. Page Airways, Inc., 624 F.2d 1342, 1354 (5th Cir. 1980).

121. Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172 (1965).

122. *See, e.g.*, *In re* Lipitor Antitrust Litig., 868 F.3d 231, 271 (3d Cir. 2017) (refusing to dismiss the "plausibl[e] alleg[ation] that the PTO did not find a lack of fraud in initial patent proceedings through its reissuance of the . . . [p]atent"); *In re* Loestrin 24 Fe Antitrust Litig., 261 F. Supp. 3d 307, 346 (D.R.I. 2017) (denying motion to dismiss because "[p]laintiffs plead sufficient underlying facts to support a reasonable inference of intent to deceive the PTO and materiality").

123. U.S. DEP'T OF HEALTH & HUM. SERVS., FDA APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (41st ed. 2021), https://www.fda.gov/media/71474/download [https://perma.cc/DZ8W-9D7H].

124. *E.g.*, *In re* Buspirone Pat. Litig., 185 F. Supp. 2d 363, 366–67 (S.D.N.Y. 2002).

125. *E.g.*, *In re* Actos End-Payor Antitrust Litig., 848 F.3d 89, 100 (2d Cir. 2017).

126. Verizon Commc'ns Inc. v. Law Offs. of Curtis V. Trinko, LLP, 540 U.S. 398, 411–12 (2004).

structure (e.g., restrictions on concentrated ownership and must-carry requirements).[127]

Other settings require more robust antitrust enforcement. For example, the FDA has very specific authority over drugs and medical devices, but it does not pervasively regulate industry structure in the way that the FCC does. Instead, the FDA has concluded "that issues related to ensuring that marketplace actions are fair and do not block competition would be best addressed by the FTC, which is the Federal entity most expert in investigating and addressing anticompetitive business practices."[128] Much more similar to the FDA than FCC, false advertising regulation lacks the pervasive control and monitoring, including reporting requirements, of telecommunications law.[129]

False advertising litigation cannot effectively stand in for the antitrust function. False advertising, unlike the FCC's jurisdiction, is broad rather than deep: it covers a wide variety of competitive situations, from mouthwash to specialized airline components, but only by barring falsity and deception rather than by pervasively dictating market structure. Of critical significance, moreover, false advertising law is itself underenforced. The FTC has substantial resource constraints. And consumers themselves are rarely able to sue for the harms they suffer. Consumer contracts typically contain mandatory arbitration provisions, making schemes like AT&T's market-shaping deception harder to fight. As a result, there is no "false advertising regime" that effectively fosters competition and negates the need for antitrust enforcement.[130]

127. For an argument supporting antitrust enforcement in settings covered by heavy regulation, see Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 TEX. L. REV. 685 (2009).

128. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., Opinion Letter for Docket No. FDA-2009-P-0266 (Aug. 7, 2013), at 7; *see also* Scott Gottlieb, Comm'r of Food & Drugs, Food & Drug Admin., Remarks at the FTC Workshop Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics (Nov. 8, 2017) (indicating frustration with conduct that "game[s] the system" in "mak[ing] it hard, or altogether impossible, for generic firms to get access to" samples needed to show equivalence); Transcript of Motions Hearing at 115–16, Actelion Pharms. Ltd. v. Apotex, Inc., 12-cv-05743-NLH (D.N.J. Oct. 17, 2013), ECF No. 96 (denying motion to dismiss on grounds that "[t]he FDA is not the FCC," "that there is no other potential remedy to a defendant suffering anticompetitive conduct," that "*Trinko* can't repeal Section 2," and that Section 2 "prevent[s] the improper maintenance and extension of a monopoly through improperly motivated conduct").

129. *See Verizon*, 540 U.S. at 412.

130. Nor would antitrust courts be forced to conduct a completely foreign analysis in determining issues related to false advertising. To pick a contrary example, courts considering "reverse payment settlements," in which brand drug firms pay generics to settle patent litigation and delay entering the market, would be forced to engage in a different—and more complex—analysis if they were forced to determine the merits of the patent litigation to assess the antitrust claim. *See* FTC v. Watson Pharms., Inc., 677 F.3d 1298, 1315 (11th Cir. 2012) (recognizing difficulty of courts "deciding a patent case within an antitrust case about the settlement of the patent case," which it analogized to the southern dish of turkey, duck, and chicken known as "turducken"), *rev'd and remanded sub nom.*, FTC v. Actavis, Inc., 570 U.S. 136 (2013).

B. FRAMEWORK FOR MONOPOLISTS

One concern courts have raised with making false advertising the basis for an antitrust violation is that much of this behavior does not affect the market as a whole. Courts are right that even if one company engages in this conduct, and even if an individual rival is harmed as a result, that does not mean that competition in the market as a whole is affected. But there is a simple solution to this concern: focus on the defendant's market power. Of all the actors employing false advertising, monopolists are the most likely to affect the market, with those attempting to monopolize making up the second-most-likely category. Targeting these two categories of actors recognizes that Section 2 of the Sherman Act provides the appropriate—and in fact only—framework for antitrust liability for unilateral conduct such as false advertising.

Focusing attention on only monopolists and attempted monopolists dramatically narrows the universe of false advertising/antitrust claims. Such an emphasis also is consistent with the approach taken in the Areeda/Hovenkamp treatise, which recognizes that antitrust may be appropriate when "the practice makes a durable contribution to the defendant's market power."[131] The treatise crafts a *de minimis* presumption because of the relative unlikelihood that any given false claim would "lead[] to or perpetuat[e] durable market power."[132] But the treatise also recognizes that "misrepresentations and organized deception by a dominant firm may have Section 2 implications when used against a nascent firm just as it is entering the market."[133] Once we understand that the treatise's concerns about overapplication of false advertising law are addressed by requiring monopoly (or, as discussed below, attempted monopoly) status, the treatise would lend support to liability when the defendant's monopoly power makes false advertising especially likely to affect the market as a whole and harm competition.

Our focus on monopolists and attempted monopolists also is consistent with antitrust injury doctrine. As the Supreme Court famously explained in *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, plaintiffs must prove "injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful."[134] In other words, plaintiffs must challenge a harm that affects the market as a whole. Limiting our scrutiny to monopolists and attempted monopolists helps effectuate *Brunswick*'s objectives.

We suggest a presumption that false advertising by monopolists constitutes monopolization. Crucially, the most fundamental critique against

131. 3B AREEDA & HOVENKAMP, *supra* note 6, ¶ 780, at 341.

132. *Id.* ¶ 782b, at 351.

133. *Id.* ¶ 782b, at 353.

134. Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 489 (1977).

applying antitrust to false advertising—that "false advertising" does not require marketwide effects—are addressed by the defendant's control over the market.

To satisfy the first of the two elements of a monopolization case, a plaintiff must show that the defendant has monopoly power. As discussed above,[135] a plaintiff can do so indirectly by showing a market share of at least 75 percent (and more likely 90 percent) along with barriers to entry that could entrench that market position. A plaintiff also can prove market power directly, such as by showing the defendant's power to impose price increases or output reductions.

Second, the plaintiff must show that the defendant engaged in false advertising. As a matter of underlying substantive law, liability for false advertising already requires findings that the defendant's conduct was literally false or misleading, was material, actually deceived or was likely to deceive consumers, and caused or was likely to cause harm to the plaintiff.[136] These elements are logically and practically linked to each other; they constitute the *wrong* of false advertising, just as an agreement to set prices constitutes the wrong of price fixing.

In particular, deception is generally presumed from literal falsity, or is demonstrated by showing misleadingness—if consumers receive a false message from a facially ambiguous or even literally true claim, they have been deceived. Likewise, once both deception and materiality have been shown, courts generally find a likelihood of harm, as consumers have been misled about facts that are likely to affect their decisions.

The false advertising foundation provides a unique advantage for antitrust law, one not available in other settings. The reason is simple. False advertising's underlying requirements focus on the bad conduct, show its relevance, and demonstrate the harm. These elements offer on a silver platter what antitrust needs to prove monopolization. In addition, materially false advertising by a monopolist threatens multiple concerns: it makes it more difficult to compete on the merits, can easily be repurposed to harm any competitor, and is hard to credibly rebut without souring consumers on factual claims more generally. Because of these harms and the satisfaction of false advertising's elements, a monopolist's materially false advertising should be presumed to affect the market as a whole.

A presumption that a monopolist using false advertising has engaged in illegal monopolization also is appropriate given the near certainty of anticompetitive effects. Unlike other lawbreaking by a monopolist such as tax

135. *See supra* text accompanying notes 13–18.

136. The Lanham Act additionally requires that the statements be made "in commercial advertising or promotion" and occur in interstate commerce. 15 U.S.C. § 1125(a)(1)(B) (2018); Cashmere & Camel Hair Mfrs. Inst. v. Saks Fifth Ave., 284 F.3d 302, 310 (1st Cir. 2002). Neither requirement is particularly demanding in this context, nor relevant to the harm of false advertising.

fraud, false advertising by definition harms at least one competitor, in what is a relatively small field. That is, by definition a monopolist controls most of the market, so there will be fewer competitors to harm. False advertising may even directly harm *all* the other competitors if the false claim is one of general superiority, or, as in the AT&T example, is directed at keeping existing customers from switching products. And by poisoning the informational environment, false advertising inherently threatens the key mechanism by which rivals can compete: by explaining to consumers what they can offer in a way that might persuade them. False advertising is also a technique that can easily be extended to the next competitor, further justifying a presumption that its use by a monopolist caused harm to competition.

Another way to frame the presumption of harm to competition centers on how we know that harm to actual entities has crossed into the legal category of "harm to competition." When an entity that meets the standards for monopoly power engages in materially false advertising that causes damage, we know that it is a monopolist and that it harmed identified victims (such as consumers or competitors) in a way likely to push the market as a whole toward an untrusting and untrustworthy market for lemons. When a monopolist introduces a valuable innovation to the market, in contrast, that can harm competitors, but it also produces social benefit, meaning that the harm should be tolerated. So too when a monopolist truthfully and non-misleadingly advertises a superior product. But when the ready-made template of false advertising law makes clear that a monopolist harms consumers' ability to trust information in the market and causes consumers to pay prices or buy products they otherwise wouldn't have chosen, at the very least the burden should be on the monopolist to show that it did no structural damage to the market.

The presumption we propose fits comfortably in antitrust analysis. Antitrust courts historically have applied two modes of analysis. The first, appropriate for conduct among competitors such as price fixing, agreements to limit output, and agreements to allocate markets, is viewed as *per se*, or automatically, illegal.[137] The second, the Rule of Reason, which is considerably more deferential and upholds nearly all agreements today,[138] considers an agreement's anticompetitive and procompetitive effects.[139] A

137. *E.g.*, United States v. Socony-Vacuum Oil Co., 310 U.S. 150 (1940) (price fixing); Hartford-Empire Co. v. United States, 323 U.S. 386 (1945) (output restrictions); Palmer v. BRG of Ga., Inc., 498 U.S. 46 (1990) (market allocation agreements).

138. *See* Michael A. Carrier, *The Rule of Reason: An Empirical Update for the 21st Century*, 16 GEO. MASON L. REV. 827, 828 (2009) ("Courts dispose of 97% of cases . . . on the grounds that there is no anticompetitive effect.").

139. Michael A. Carrier, *The Real Rule of Reason: Bridging the Disconnect*, 1999 BYU L. REV. 1265, 1268–69 (explaining that courts apply a burden-shifting analysis in which (1) "the plaintiff must show a significant anticompetitive effect," (2) "the defendant [must] demonstrate a legitimate procompetitive justification," (3) the plaintiff can "show either that the restraint is not reasonably necessary . . . or that the objectives could be achieved by" a less restrictive alternative,

third, intermediate, approach has more recently developed, called a "quick look" Rule of Reason or (as the FTC has applied it) "inherently suspect" analysis.

In these cases, the court presumes harm to competition even if a plaintiff does not show adverse effects or market power. For example, in *National Society of Professional Engineers v. United States*, the Supreme Court found that "an agreement among competitor[] [engineers] to refuse to discuss prices with potential customers until after" an engineer was selected may "not [be] price fixing as such," but "no elaborate industry analysis is required to demonstrate the anticompetitive character of such an agreement," which "operates as an absolute ban on competitive bidding . . . . and substantially deprives the customer of 'the ability to utilize and compare prices in selecting engineering services.'"[140] Similarly, in *NCAA v. Board of Regents of the University of Oklahoma*, the Court found that the NCAA's plan to limit the number of games that could be televised was a "naked restraint on price and output," which "requires some competitive justification even in the absence of a detailed market analysis."[141]

Similarly, as discussed above,[142] restrictions on truthful advertising harm competition by "mak[ing] it more difficult for consumers to discover information about the price and quality of goods or services, thereby reducing competitors' incentives to compete with each other with respect to such features."[143] In many cases, the FTC has relied on empirical studies finding that restrictions on truthful advertising "result in consumers' paying higher prices."[144] The agency thus treats restrictions on truthful advertising as inherently suspect, similar to a "quick look" analysis in presuming anticompetitive effects.[145] The Supreme Court's decision in *California Dental Ass'n v. FTC* also supports an abbreviated analysis. In that case, the Court

and (4) "the court balances the restraint's anticompetitive and procompetitive effects" (footnote omitted)).

140. Nat'l Soc'y of Pro. Eng'rs v. United States, 435 U.S. 679, 692–93 (1978) (quoting United States v. Nat'l Soc'y of Pro. Eng'rs, 404 F. Supp. 457, 460 (D.D.C. 1975)).

141. NCAA v. Bd. of Regents of the Univ. of Okla., 468 U.S. 85, 110 (1984); *see also* FTC v. Ind. Fed'n of Dentists, 476 U.S. 447, 448, 461 (1986) (finding "that a conspiracy among dentists to refuse to submit x rays to dental insurers for use in benefits determinations" resulted in "actual, sustained adverse effects on competition in those areas where [the] dentists predominated" and was "legally sufficient to support a finding that the challenged restraint was unreasonable even in the absence of elaborate market analysis").

142. *See supra* text accompanying notes 8–10.

143. Polygram Holding, Inc., 136 F.T.C. 310, 355 (2003); *see also* Brief of the Federal Trade Commission at 1, 1-800 Contacts, Inc. v. FTC, No. 18-3848 (2d Cir. Oct. 7, 2019) ("Without timely information about competing products and sellers, . . . consumers cannot make informed choices and markets cannot function properly.").

144. *Polygram*, 136 F.T.C. at 355.

145. Brief of the Federal Trade Commission at 51, *1-800 Contacts*, No. 18-3848; *see also Polygram*, 136 F.T.C. at 354 (finding agreement among rivals not to advertise products was "presumptively anticompetitive").

found that an association's broad restrictions on discount and non-discount advertising were "designed to avoid false or deceptive advertising."[146] As a result, the restrictions had a procompetitive justification as well as a potentially anticompetitive effect, and the Court applied a more expansive analysis than the "quick look" scrutiny but one less than the "fullest market analysis" of the Rule of Reason.[147]

As these cases show, it is possible to calibrate antitrust scrutiny based on the likelihood that a particular type of conduct is anticompetitive. For "per se" offenses, courts require no additional proof beyond showing that the defendant's behavior falls into a class of activities that is inherently dangerous to competition. For conduct satisfying "quick look" scrutiny, the plaintiff is relieved of certain showings and the burden is more quickly shifted to the defendant to justify the conduct. In both sets of cases, the expense and risks of "false negative" errors that would be entailed by additional proof requirements are unjustified.

When a monopolist's false advertising has already been shown to be likely to have harmed at least one competitor, a presumption of anticompetitive conduct adapts this type of intermediate approach to the unilateral conduct situation. The setting is not precisely the same as a coordinated agreement to limit truthful advertising. But truthful advertising, which lies at the core of a competitive market, is threatened not only by coordinated restrictions but also by the unilateral dissemination of false advertising.[148]

It's conceivable, however, that a false statement could be material and still not affect the market as a whole. For that reason, we would allow the defendant to rebut the presumption by showing that the false or deceptive statement was ineffective. In other words, the monopolist could show that, despite a *likelihood* of deception from a literally false or misleading claim, harm from deception did not materialize—where, for example, sophisticated consumers did their own testing and relied on their results rather than on the defendant's claims. Our approach, however, would not support immunity for false advertising by entities with market power simply because it's difficult to tell exactly how much harm was done to each member of a small group of competitors.

One example of how our approach could change outcomes is the Fifth Circuit's ruling in *Retractable Technologies, Inc. v. Becton Dickinson & Co.*[149] In that case, the court erroneously rejected an antitrust verdict against an

146. Cal. Dental Ass'n v. FTC, 526 U.S. 756, 771 (1999).

147. *Id.* at 779.

148. *See* Stucke, *supra* note 91, at 841–44 (suggesting quick-look standard for deception); Susan A. Creighton, D. Bruce Hoffman, Thomas G. Krattenmaker & Ernest A. Nagata, *Cheap Exclusion*, 72 ANTITRUST L.J. 975, 990 (2005) ("[T]ortious conduct . . . can be a cheap form of exclusion.").

149. *See generally* Retractable Techs., Inc. v. Becton Dickinson & Co., 842 F.3d 883 (5th Cir. 2016) (holding that false advertising cannot violate antitrust laws).

attempted monopolist because, even though it acknowledged that the plaintiff "may have lost some sales or market share" in the market for specialized medical syringes, the court adopted the blanket rule that false advertising can't violate the antitrust laws: The plaintiff lost its antitrust claim because the court said that false advertising harms only competitors, not competition.[150]

The court remanded on whether false advertising alone would permit a remedy. On remand, the district court ordered disgorgement of the defendant's profits under the Lanham Act, noting that at least some of the defendant's sales were attributable to its false advertising. The court of appeals reversed again, reasoning that, although it was true that the defendant had been proved to have *gained* from its false advertising, there were other potential competitors, and so the plaintiff was not able to sufficiently prove that all of the defendant's sales came at the plaintiff's expense. In other words, the plaintiff then lost its Lanham Act claim because the false advertising harmed *competition* generally.[151]

Applying our approach, the key question would have been whether the defendant/false advertiser was in fact a monopolist; if so, a presumption of monopolization would have been appropriate. The false advertising factors (false/misleading, materiality, deception, and harm) appeared to be satisfied. Nor would the rebuttal be met as there was no showing that the false advertising was ineffective. The plaintiff could not quantify how much it lost versus how much other competitors lost because of the false advertising—but that was because the false advertising was apparently successful across the board. In fact, as this example shows, it will often be the case that false advertising—even to sophisticated consumers—is effective in sustaining a monopolist's market share: The monopolist by definition is big, is credible because of its experience, and has sustained reach in the relevant industry.

Our proposal might not change the number of entities exercising monopoly power. Truthful and non-misleading or neither-true-nor-false advertising can also support market power, though it seems unlikely that it can do so quite as effectively as materially false claims. If, as a result of our proposal, monopolists spend less on advertising that might later give rise to falsity-based antitrust claims, they will not necessarily decrease resources devoted to advertising in general. But because American antitrust policy accepts that some monopolies can persist legitimately, it is not a problem that nondeceptive advertising can be effective at maintaining monopoly power. Our proposal could allow more confidence that monopolists' advertising

150. *Id.* at 895. The court reasoned that, because the plaintiff had survived the false advertising without being driven out of the market, no competitive harm had occurred. *Id.* But this is illogical. In the absence of the false advertising the monopolist might have less of a monopoly—surviving as a competitor doesn't mean surviving with a fair competitive position.

151. Retractable Techs., Inc. v. Becton Dickinson & Co., 919 F.3d 869, 877 (5th Cir. 2019).

produces social benefits, and new entrants would have the same ability to use truthful and non-misleading or neither-true-nor-false claims.

C. FRAMEWORK FOR ATTEMPTED MONOPOLISTS

While antitrust liability is most appropriate for monopolists engaging in false advertising, it also could apply to actors seeking to control the market. Section 2 of the Sherman Act applies not only to monopolists but also attempted monopolists, which have been defined as those that (1) have a specific intent to achieve monopoly power, (2) have engaged in exclusionary conduct furthering its specific intent, and (3) have a dangerous probability of success.[152]

The three elements don't provide much guidance. Regarding the first factor, because "the essence of competition is the intent to triumph over one's rivals[,] [o]ne of the most perplexing problems in antitrust policy is discerning between illegitimate and legitimate intent."[153] For the second element, the nature of exclusionary conduct is similar in attempted monopolization as monopolization cases. And third, a dangerous probability of success is designed to determine whether the conduct is conducive to monopoly.[154] Some courts have articulated market share requirements of at least 30 percent (and more likely 50 percent) in most cases, though a leading hornbook explains that "it is impossible to generalize[] [since] some attempts to monopolize require the defendant to have significant market power while others do not."[155]

Because attempted monopolists, unlike monopolists, do not control the market, a rebuttable presumption of an antitrust violation is not appropriate. But neither is the skepticism that courts have applied to false advertising claims. For that reason, in determining the second element, whether the defendant engaged in exclusionary conduct, we suggest several factors that direct the most robust scrutiny to the situations most likely to present marketwide harms: (1) targeting a new entrant; (2) actual harm from the false or misleading advertising; (3) degree of materiality; and (4) interactions with other anticompetitive conduct.[156]

The first factor analyzes whether the conduct is aimed at a new, rather than established, market entrant. New entrants are particularly susceptible to the effects of false advertising. A nascent firm just entering the market "has

152. Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 456 (1993).

153. HOVENKAMP, *supra* note 11, § 6.5a, at 371.

154. *Id.* § 6.5b, at 374–75.

155. *Id.* § 6.5b2, at 376–77.

156. False advertising liability always requires falsity or misleadingness and, relatedly, likely or actual deception. Our framework is designed to draw courts' attention to the types of false advertising that are particularly likely to harm overall competition, leaving some false advertising that will be actionable as such, but not as an antitrust violation, where it harms competitors or consumers.

no established customer base and typically lacks the resources to answer the dominant firm's deception effectively."[157] A new entrant in a small field, such as the maker of a specialized blood collection device that only a few companies manufacture, likely would qualify as an appropriate plaintiff under our framework.[158] In contrast, Anheuser Busch's false advertising in the highly concentrated light-beer market that targets the other major competitor in that market would not.

The second factor examines whether the statements impose harm on the rival. The clearest case of harm will occur when the rival is prevented from entering the market. But it could also be satisfied when the rival is not able to expand its market share. In false advertising cases, courts often decline to award monetary damages (even when they enjoin future false advertising) unless the plaintiff shows not just that the false advertising is likely to deceive, but also that the deception has materialized in the form of diverted sales, which also proves materiality and harm.[159] Because attempted monopolists lack the control over the market that monopolists have, a similar requirement would be appropriate here.

The third factor focuses on whether the statements center on facts likely to be material to most of the relevant consumers. The usual standard of materiality asks "whether reasonable consumers would have a tendency to rely on th[e] misleading statement of fact in making their purchasing decisions."[160] Courts in false advertising cases have not generally distinguished between the materiality of the general topic to which the claim relates and the materiality of the difference between the claim and the truth. For example, where a company falsely claimed that its razor extended hair, creating a

157. 3B AREEDA & HOVENKAMP, *supra* note 6, ¶ 782b, at 353.

158. *See* Kurin, Inc. v. Magnolia Med. Techs., Inc., No. 3:18-cv-1060-L-LL, 2019 WL 5422931, at *1 (S.D. Cal. Oct. 23, 2019) (exemplifying a Lanham Act false advertising case brought by new entrant against earlier entrant).

159. *See, e.g.*, Pizza Hut, Inc. v. Papa John's Int'l, Inc., 227 F.3d 489, 497 (5th Cir. 2000); Balance Dynamics Corp. v. Schmitt Indus., Inc., 204 F.3d 683, 690 (6th Cir. 2000); U.S. Healthcare, Inc. v. Blue Cross of Greater Phila., 898 F.2d 914, 922 (3d Cir. 1990). Intentional deception can also justify a presumption of harm for purposes of receiving monetary damages. *See, e.g.*, Porous Media Corp. v. Pall Corp., 110 F.3d 1329, 1333 (8th Cir. 1997) (intentional deception), *superseded by statute on other grounds*, Trademark Amendments Act of 1999, Pub. L. No. 106–43, 113 Stat. 219; Southland Sod Farms v. Stover Seed Co., 108 F.3d 1134, 1146 (9th Cir. 1997) (holding that deliberate false advertising "gives rise to a presumption of actual deception and reliance" and "allow[s] monetary damages even without a showing of actual consumer confusion" (quoting U-Haul Int'l, Inc. v. Jartran, Inc., 793 F.2d 1034, 1040–41 (9th Cir. 1986))); George Basch Co., v. Blue Coral, Inc., 968 F.2d 1532, 1537 (2d Cir. 1992), *superseded by statute on other grounds*, Trademark Amendments Act of 1999, Pub. L. No. 106–43, 113 Stat. 219, *as recognized in* Cartier v. Aaron Faber, Inc., 512 F. Supp. 2d 165 (S.D.N.Y. 2007); *Balance Dynamics*, 204 F.3d at 694). And courts have generally held that in two-player markets, false comparative advertising also leads to a presumption of harm. *See, e.g.*, Dependable Sales & Serv., Inc. v. TrueCar, Inc., 377 F. Supp. 3d 337, 342 (S.D.N.Y.), *on reconsideration*, 394 F. Supp. 3d 368 (S.D.N.Y. 2019).

160. *Pizza Hut*, 227 F.3d at 502.

smoother shave, the court reasoned that, because the extension claim was material, misrepresentations as to the "magnitude and frequency of that effect" were necessarily also material.[161] This distinction, however, is usually not even raised in false advertising cases, as the materiality of the claim's general subject matter (e.g., safety, price, durability) typically suffices.

The specificity with which materiality must be proved can, however, be calibrated to ensure that only the most market-threatening false advertising can support an attempted monopolization claim. For example, for monopolists, who by definition control the market, a five percent misrepresentation about price deserves no more legal protection from antitrust liability than a 50 percent misrepresentation. False advertising inherently threatens competition, price is generally material to consumers, and if consumers are likely to act on the misrepresentation, then harm should be presumed.

In contrast, for attempted monopolists, who by definition have not yet achieved monopoly power, courts could reasonably demand more specificity about materiality. If price is misrepresented by five percent, an antitrust plaintiff should be required to show that a substantial number of consumers would be affected (which certainly might be the case, as some groups of consumers are extremely price sensitive). Common sense also has a role to play in the amount of additional specificity courts should demand. Because price is a central product characteristic and the magnitude of the difference between the advertising and the truth is so much greater, a 50 percent misrepresentation needs less, if any, extrinsic evidence of materiality. But not all material claims will rise to that magnitude qualitatively or quantitatively. A searching materiality inquiry—which has resonance with the "clearly material" requirement from the multifactor test discussed above[162]—thus appropriately constrains antitrust law.

This inquiry should recognize that statements about risk are particularly important and likely to have a broad impact. For example, a safety claim may almost always be material—consumers predictably and reasonably value even a one percent lower chance of death quite highly.[163] Alternatively, companies could falsely claim that there are capacity issues preventing a rival from

161. Schick Mfg., Inc. v. Gillette Co., 372 F. Supp. 2d 273, 287 (D. Conn.) (denying preliminary injunction in part and granting in part), *modified*, No. 3-05-cv-174 (JCH), 2005 WL 8168764 (D. Conn. June 20, 2005); *see also* Kraft, Inc. v. FTC, 970 F.2d 311, 327 (7th Cir. 1992) (applying similar reasoning to misleading calcium content claims for processed cheese slices). *But see* Danone, US, LLC v. Chobani, LLC, 362 F. Supp. 3d 109, 118–19 (S.D.N.Y. 2019) (denying preliminary injunction and distinguishing between materiality of a general claim and materiality of the difference between the truth and the advertising, where the advertiser had overclaimed an actual superiority in sugar content of yogurt).

162. *See supra* notes 77–82 and accompanying text.

163. *See In re* Figgie Int'l, Inc., 107 F.T.C. 313, 389 (1986) ("Even a very small amount of additional protection from death or serious injury caused by fire would no doubt be considered significant by some consumers.").

meeting customers' supply needs—a different risk, but one that is highly salient.

Materiality interacts with the other factors. Where the plaintiff is a new market entrant, claims about risk may be particularly persuasive in deterring customers from switching to the competition.[164] And where the plaintiff can show that it suffered substantial harm as a result of the misrepresentation, that is itself strong evidence of a high degree of materiality.

Finally, courts should consider whether false advertising in a near-monopoly situation is accompanied by other types of exclusionary conduct, which can amplify or reinforce the effects of false advertising.[165]

In any given case, courts should balance these factors to see if there is a reason to treat the false advertising at issue as exclusionary. Consider, for example, *Insignia Systems* v. *News America Marketing In-Store, Inc.*[166] This long-running case involved the in-store promotions and advertising business. The parties contracted with product manufacturers to sell them promotional materials like end-cap displays, inserts in grocery carts, and floor stickers, and they also contracted with retailers like grocery stores for the right to place those materials in their stores. Defendant NAMI told manufacturers that the plaintiff successfully placed materials in less than 20 percent of the retail stores with which it had contracts, while claiming for itself "compliance rates of 90-95%."[167] The court reasoned that, if NAMI deliberately deceived customers with the intent to enforce a monopoly, it could be liable for attempted monopolization.[168]

We agree with the court's outcome, but our framework more readily explains what made this particular false advertising actionable in antitrust. In our framework for attempted monopolization, the court could have pointed to the evidence that NAMI's allegedly false advertising caused actual harm to two competitors—apparently the only two competitors in that space—as well as to the overriding materiality of NAMI's compliance claim to manufacturers. As NAMI itself asked, "how effective can an in-store program be if it's not actually seen in-store?"[169] In addition, although the plaintiff apparently wasn't a new entrant, NAMI combined its allegedly false advertising with other

164. In this setting, it may be harder to prove that the defendant made a falsifiable statement given that predictions about the future are often held to be nonactionable opinion.

165. *See, e.g.*, Associated Radio Serv. Co. v. Page Airways, Inc., 624 F.2d 1342, 1356 (5th Cir. 1980) ("Probably no one of the instances of improper conduct [including bribery and contracts resulting from improper influence], standing alone, would lead to section 2 liability. Taken together, however, they show a pattern of exclusionary behavior sufficient to support the jury's verdict." (footnote omitted)); *infra* text accompanying note 188.

166. Insignia Sys., Inc. v. News Am. Mktg. In-Store, Inc., 661 F. Supp. 2d 1039 (D. Minn. 2009).

167. *Id.* at 1050.

168. *Id.* at 1062. The court also denied the defendant's motion to dismiss the monopolization claim on similar grounds. *Id.* at 1061.

169. *Id.* at 1050. The plaintiff, meanwhile, alleged "that its [actual] compliance rate was 75% or higher." *Id.* at 1049.

exclusionary conduct such as exclusive contracts with retailers.[170] This constellation of facts supports allowing an antitrust claim to proceed.

In short, our suggested factors apply a competition lens to false advertising. If the activity targets nascent rivals or imposes barriers to entry, it reveals competitive harm. And if it targets claims that are nearly universally material, it can readily harm the market as a whole.

* * *

Our restriction of antitrust claims for false advertising to defendants that are monopolists or attempted monopolists is consistent with Section 2 of the Sherman Act. Our approach cabins the reach of antitrust liability for false advertising in a manner that addresses overreach concerns, recognizing that most false advertising will not violate the antitrust laws. At the same time, a rebuttable presumption against monopolists engaging in false advertising captures the general anticompetitive market harm from the behavior while still giving the monopolist a chance to show that the statement was ineffective. And focusing on the most relevant factors presented by false advertising and marketwide harm addresses the ways in which attempted monopolists can harm competition through false advertising.

D. AN EXAMPLE: BIOSIMILARS

An example illustrates our framework. The pharmaceutical industry is marked by high barriers to entry. It is expensive to enter the market, and there are significant hurdles such as receiving approval from the FDA. These barriers are even higher in the biologics setting. Compared to the "small molecule" drugs that have made up the pharmaceutical market for the past several decades, biologic products are more complex and less predictable. As a result, unlike the near-identical relationship between brand and generic drugs, the connection between biologics and "follow-on biosimilars" is not as direct.[171]

The relevant statute, the Biologics Price Competition and Innovation Act ("BPCIA"),[172] requires a biosimilar to be "highly similar to" the biologic and have "no clinically meaningful differences" in relation to "safety, purity, and potency."[173] But the uncertainty surrounding the products has resulted in biologic manufacturers stating or implying that biosimilars are unsafe, sometimes by omitting relevant information about their functional

170. *Id.* at 1051.

171. Michael A. Carrier & Carl J. Minniti III, *Biologics: The New Antitrust Frontier*, 2018 U. ILL. L. REV. 1, 8.

172. Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, 124 Stat. 804 (2010).

173. 42 U.S.C. § 262(i)(2) (2018).

equivalence with the reference biologics.[174] In a setting in which even the most minute differences between products could be enough to dissuade patients from trying new medications, the assertions at least implied dissimilarities that could have significant safety effects.

For example, Genentech noted on its "Examine Biosimilars" website that "FDA requires a biosimilar to be highly similar, but not identical to the [reference product]."[175] More explicitly, Amgen tweeted: "Biologics or biosimilars? It's not just apples to apples. While #biosimilars may be highly similar to their #biologic reference products, there's still a chance that patients may react differently."[176]

Given the context of life-saving medications, it's easy to imply dire consequences. For example, Amgen created a YouTube video asserting that a switch "carries risks, given that no two biologic medicines are identical," which suggests that they "can behave differently in the body."[177] Amgen also cautioned that "[s]witching drugs is not a good idea if your medicine is working for you" and that "an inadvertent substitution . . . is not appropriate care."[178] Finally, some biologic manufacturers have warned that patients could face "additional risks" by taking biosimilars or even "could end up in the emergency room."[179]

These claims raise several concerns. Most significant, the statements at issue imply that biosimilars create serious risks, failing to disclose that the FDA approves a biosimilar only when "there are no clinically meaningful differences [from] the biologic product."[180] To the contrary, biologic and biosimilar products are required to have the same safety and effectiveness

174. As a manufacturer of biosimilars, Pfizer filed a citizen petition with the FDA that referenced many of these statements. Citizen Petition from Pfizer Inc. to the Food & Drug Admin. (Aug. 22, 2018), https://www.bigmoleculewatch.com/wp-content/uploads/sites/2/2018/08/Citizen_Petition_from_Pfizer.pdf [https://perma.cc/9849-SRT6].

175. *Id.* at 7 (alteration in original) (quoting Genentech, *Examine Biosimilars – Biosimilars vs. Generics*).

176. Ned Pagliarulo, *Pfizer Calls Out Pharma Peers for 'Scare Tactics' on Biosimilars*, BIOPHARMA DIVE (Aug. 29, 2018, 11:48 AM), https://www.biopharmadive.com/news/pfizer-calls-out-pharma-peers-biosimilar-scare-tactics-fda-guidance/531214 [https://perma.cc/5E4J-BMQ6] (quoting @AmgenBiosim, TWITTER (Apr. 13, 2018)).

177. Citizen Petition from Pfizer, *supra* note 174, at 8 (quoting Amgen, *The Arrival of Biosimilars – What's in a Name*, YOUTUBE).

178. *Id.*

179. Hillel P. Cohen & Dorothy McCabe, *Combatting Misinformation on Biosimilars and Preparing the Market for Them Can Save the U.S. Billions*, STAT (June 19, 2019), https://www.statnews.com/2019/06/19/misinformation-biosimilars-market-preparation [https://perma.cc/AJE2-7Z7S] (quoting Christopher Rowland, *'Marketers Are Having a Field Day': Patients Stuck in Corporate Fight Against Generic Drugs*, WASH. POST (Jan. 9, 2019, 8:00 PM), https://www.washingtonpost.com/business/economy/drugmakers-alleged-scare-tactics-may-hold-back-competition/2019/01/09/612ac994-046d-11e9-9122-82e98f91ee6f_story.html [https://perma.cc/D2DL-H7ER]).

180. 42 U.S.C. § 262(i)(2)(B) (2018).

profile.[181] Evidence from Europe, which has witnessed robust biosimilar entry, has confirmed that "over 700 million patient days of treatment" demonstrated "that clinical outcomes with biosimilars match the outcomes of the reference biologics."[182] This evidence also has revealed that "patient switching from the reference biologic to the biosimilar . . . is not of concern" since the more than 14,000 switches from biologic to biosimilar resulted in "[n]o change in clinical outcomes."[183]

Given significant development costs, regulatory barriers, thickets of dozens of (or even more than 100) patents,[184] and exclusive contractual arrangements,[185] biologic manufacturers are likely to have monopoly power.[186] Taking the absence of clinically meaningful differences in FDA-approved biosimilars as a given, plaintiffs challenging false statements are likely to satisfy our presumption if they can show that, under false advertising law, the statements (or omissions) are false and material, and therefore are likely to deceive consumers and cause harm. False advertising principles establish that biologic manufacturers will not be liable unless their statements are false or mislead substantial numbers of relevant consumers. But, if falsity or misleadingness are established, they are not likely to be able to rebut the presumption of anticompetitive conduct given the significance of health risk claims to consumers.

Even for attempted monopolists, as long as a plaintiff establishes falsity or misleadingness, the factors would seem to favor liability. Given the lack of biosimilar entry to date, in many cases biosimilars will be seeking to enter the market. The statements, which focus directly on risk, pose significant barriers to entry, as doctors and consumers are not likely to take a chance on drugs that have even the possibility of safety concerns. It is hard to think of examples that would more concretely affect consumers than warnings that drug products are potentially unsafe. In fact, the FTC recently issued warning letters to a number of plaintiff-side law firms for advertising that linked FDA-approved drugs with serious side effects, potentially frightening patients away

181. *Patient Materials*, FOOD & DRUG ADMIN., https://www.fda.gov/drugs/biosimilars/patient-materials [https://perma.cc/VDE3-XS95] (last updated Oct. 7, 2020).

182. BIOSIMILARS F., STRUCTURAL MARKET CHANGES NEEDED IN U.S. TO ACHIEVE COST-SAVINGS FROM BIOSIMILARS 8 (2019), https://biosimilarsforum.org/PDF/BIosimilars_WhitePaper-final.pdf [https://perma.cc/U5SE-2X2A].

183. *Id.*

184. *Humira Patent Fortress at Center Stage During Pharma Execs' D.C. Showdown*, CRAIN'S CHI. BUS. (Feb. 26, 2019, 2:28 PM), https://www.chicagobusiness.com/health-care/humira-patent-fortress-center-stage-during-pharma-execs-dc-showdown [https://perma.cc/GL3Y-3EX9] (noting that AbbVie has 136 patents on arthritis- and Crohn's-treating Humira).

185. *See infra* text accompanying note 188.

186. *E.g.*, Carrier & Minniti, *supra* note 171, at 3.

from useful medications.[187] In addition, a biologic manufacturer's disparagement of a biosimilar rival may be part of a broader range of anticompetitive conduct. For example, disparagement could entrench barriers to entry that convince insurance companies to favor biologics through potentially anticompetitive exclusive dealing, bundling, and rebates.[188]

In short, false advertising law provides useful tools for determining if substantial numbers of relevant consumers are being misled to their detriment. And our framework would likely find that a biologic manufacturer's proven false advertising that raises safety concerns against a biosimilar constitutes monopolization.

V. CONCLUSION

In their fear of being overrun by false advertising claims, antitrust courts have veered in the opposite direction, essentially making it impossible to bring these actions. But they have overshot the mark. To say that most false advertising claims don't constitute antitrust violations is not to say that antitrust law should reject false advertising claims brought against monopolists or attempted monopolists. Most bribery doesn't violate the antitrust laws either, but antitrust courts still understand that bribery is relevant when it's used to sustain or approach monopoly.

Underlying courts' hesitancy to use antitrust law is likely a sense that false advertising may not be all that bad. Courts may also think that it is difficult enough to identify truly false advertising that they risk accidentally suppressing truthful advertising. In other words, the risk of overenforcement reaching truthful advertising justifies allowing a certain amount of false advertising to go unscathed. But false advertising is already defined by a robust body of case law. And when a monopolist or attempted monopolist is engaging in the behavior, we believe underdeterrence is much more dangerous to consumers and markets, especially given the significant burdens on plaintiffs bringing antitrust claims to show monopoly power or a realistic threat of monopoly power. In this Essay, we have argued for a revival of antitrust's deterrent role in policing anticompetitive false advertising that harms marketwide competition.

The frameworks we construct for monopolists and attempted monopolists promise to employ the learning of false advertising law in a conservative manner in the antitrust realm. Such an approach would benefit false advertising law by removing contradictory assumptions about the effects

187. *FTC Flags Potentially Unlawful TV Ads for Prescription Drug Lawsuits*, FED. TRADE COMM'N (Sept. 24, 2019), https://www.ftc.gov/news-events/press-releases/2019/09/ftc-flags-potentially-unlawful-tv-ads-prescription-drug-lawsuits [https://perma.cc/PTV5-QJ4H].

188. *See, e.g.*, Michael S. Sinha, Gregory D. Curfman & Michael A. Carrier, *Antitrust, Market Exclusivity, and Transparency in the Pharmaceutical Industry*, 319 JAMA 2271, 2271–72 (2018).

of false advertising now prevalent in antitrust cases. It would benefit antitrust law by removing its blind spots about how false advertising harms markets. Most important, it would benefit consumers, who would be subject to less false advertising and who would gain more competitive markets.

PRODUCT HOPPING: A NEW FRAMEWORK

Michael A. Carrier & Steve D. Shadowen

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PRODUCT HOPPING: A NEW FRAMEWORK

Michael A. Carrier & Steve D. Shadowen***

ABSTRACT

One of the most misunderstood and anticompetitive business behaviors in today's economy is "product hopping," which occurs when a brand-name pharmaceutical company switches from one version of a drug to another. These switches, benign in appearance but not necessarily in effect, can significantly decrease consumer welfare, impairing competition from generic drugs to an extent that greatly exceeds any gains from the "improved" branded product.

The antitrust analysis of product hopping is nuanced. It implicates the intersection of antitrust law, patent law, the Hatch-Waxman Act, and state drug product selection laws. In fact, the behavior is even more complex because it occurs in uniquely complicated markets characterized by doctors who choose the product but don't pay for it, and consumers who buy the product but don't choose it.

It is thus unsurprising that courts have offered inconsistent approaches to product hopping. They have paid varying levels of attention to the regulatory structure, offered a simplistic analysis of consumer choice, adopted an underinclusive antitrust standard based on coercion, and focused on whether the brand firm removed the original drug from the market.

Entering this morass, we offer a new framework that courts, government enforcers, plaintiffs, and manufacturers can employ to analyze product hopping. This rigorous and balanced framework is the first to incorporate the economic characteristics of the pharmaceutical industry. For starters, it defines a "product hop" to include only those instances in which the brand manufacturer (1) reformulates the product in a way that makes the generic non-substitutable and (2) encourages doctors to write prescriptions for the reformulated product rather than the original. The test also offers two safe harbors, which are more deferential than current caselaw, to ensure that the vast majority of reformulations will not be subject to antitrust scrutiny.

The analysis then examines whether a brand's product hop passes the "no-economic-sense" test. In other words, would the reformulation make economic sense for the brand if it did not have the effect of impairing generic competition? Merely introducing new products would pass the test. Encouraging doctors to write prescriptions for the reformulated rather than the original product—"cannibalizing" the brand's own sales—might not. Imposing antitrust liability on behavior that does not make business sense other than through its impairment of generic competi-

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tion offers a conservative approach and minimizes "false positives" in which courts erroneously find liability. Showing just how far the courts have veered from justified economic analysis, the test would recommend a different analysis than that used in each of the five product-hopping cases that have been litigated to date, and a different outcome in two of them.

By carefully considering the regulatory environment, practicalities of prescription drug markets, manufacturers' desire for clear-cut rules, and consumers' needs for a rule that promotes price competition without deterring valued innovations, the framework promises to improve and standardize the antitrust analysis of product hopping.

INTRODUCTION

One of the most misunderstood and anticompetitive business behaviors in today's economy is "product hopping." A brand-name pharmaceutical company switches from one version of a drug (say, capsule) to another (say, tablet). The concern with this conduct is that some of these switches can significantly decrease consumer welfare, impairing competition from generic drugs to an extent that greatly exceeds any gains from the "improved" branded product.

The antitrust analysis of product hopping is nuanced. It implicates the intersection of antitrust law, patent law, the Hatch-Waxman Act, and state drug product selection laws. In fact, the behavior is even more complex because it involves uniquely complicated markets characterized by buyers (insurance companies, patients) who are different from the decisionmakers (physicians).

It thus should not be a surprise that courts have offered inconsistent approaches to product hopping. Some have emphasized the regulatory structure while others have ignored it. Some have offered a simplistic analysis of consumer choice, while others have adopted an underinclusive test based on coercion. Nearly all have focused on whether the brand firm removed the original drug from the market (a "hard switch") or left it on the market (a "soft switch").

Entering this morass, we offer a new framework that courts, government enforcers, plaintiffs, and manufacturers can employ to analyze product hopping. The framework, which is balanced and rigorous, is the first to incorporate the characteristics of the pharmaceutical industry. For starters, it defines a "product hop" to include only those instances in which the brand manufacturer:

(1) reformulates the product in a way that makes the generic non-substitutable; and

(2) encourages doctors to write prescriptions for the reformulated product rather than the original.

This definition excludes many product reformulations, such as those in which the brand manufacturer does not "cannibalize"[1] sales of the original

1 "Cannibalize" is an industry term loosely defined as the brand manufacturer's marketing against its own original product to encourage doctors to switch their prescriptions to the reformulated product. *See* Steve D. Shadowen et al., *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 RUTGERS L.J. 1, 44–45 (2009).

product. It also avoids targeting brand reformulations designed to improve the product by competing with other brands or growing the market, reserving its focus for the switching of the market in order to stifle generic competition.

Where the brand's conduct does not satisfy both elements of a product hop, it is not subject to antitrust scrutiny. And when the conduct does meet both elements, our framework offers two stages of analysis. First, we propose two safe harbors that are more deferential than current caselaw and that ensure that the vast majority of reformulations will not face antitrust review.

And second, for reformulations that are product hops and are outside the safe harbors, the framework examines whether the hop passes the "no-economic-sense" test. In other words, would the product hop make economic sense for the brand if the hop did not have the effect of impairing generic competition? Merely introducing new products would pass the test (indeed, would not even constitute a product hop). Encouraging doctors to write prescriptions for the reformulated rather than the original product—cannibalizing the brand's own sales—might not. Imposing antitrust liability on behavior that does not make business sense—other than through its impairment of generic competition—offers a conservative approach and minimizes "false positives" in which courts erroneously find liability. In fact, our framework offers manufacturers three opportunities to sidestep antitrust liability: (1) avoid our definition of "product hop"; (2) be covered by one of the safe harbors; or (3) undertake conduct that makes economic sense. Showing just how far the courts have veered from justified economic analysis, the test would recommend a different analysis than that used in each of the five product-hopping cases that have been litigated to date, and a different outcome in two of them.

By carefully considering the regulatory environment, realities of prescription drug markets, manufacturers' desire for clear-cut rules, and consumers' needs for a rule that promotes price competition without deterring valued innovations, the framework promises to improve the antitrust analysis of product hopping.

Part I offers a background on product hopping. Section A categorizes various types of reformulations. Sections B and C address the relevant regulations: the Hatch-Waxman Act and state substitution laws. Section D then focuses on the crucial element of timing, explaining how generic entry before a brand reformulates a drug dramatically reduces price.

Part II highlights the market failure that is unique to the pharmaceutical industry. Section A describes the "price disconnect" that distinguishes prescription drugs from other products and that separates the consumer's price/quality determination that is unified in other markets. Section B analyzes drug patents, emphasizing the limited role of the patent system and, in particular, the lack of a requirement of a medical improvement over earlier versions. Part C then provides several indicia of market failure based on medical evidence, the price of patented drugs in Mexico, U.S. prices before prescriptions were required, and lower prices in countries that have solved

the price disconnect. Given the absence of these measures in the United States, Part D highlights the importance of antitrust law.

Part III examines the five judicial analyses of product hopping. Section A begins with *TriCor*, in which the court offered a nuanced analysis, albeit one that some later courts limited to "hard switches," i.e., those in which the brand withdraws the original product from the market. Section B covers the *Walgreens* case, which offered a simplistic analysis of consumer choice in the context of a "soft switch" in which the brand did not withdraw the original product from the market. The first two product-hopping decisions, *TriCor* and *Walgreens*, framed the analysis for later decisions, with some courts assuming that hard switches could violate the antitrust laws but soft switches could not.

The *Suboxone* case addressed in Section C revealed aspects of both hard and soft switches, with the court offering a nuanced understanding of the regulatory regime. The *Doryx* case covered in Section D, in contrast, is an outlier that neglected the regime altogether. Section E then focuses on *Namenda*, which considered the regulatory regime in the context of hard switches, offering an underinclusive framework based on coercion. While the courts generally have considered the regulatory regime, Section F discusses the recent work of scholars that have paid less attention to this important issue.

Part IV then presents a new framework for courts to analyze the antitrust implications of product hopping. Section A begins with two safe harbors that brand firms can use if they implement the product hop (1) outside a "Generic Window" in which generic entry is expected or (2) after a generic version of the original drug has entered the market. If the product hop occurs during one of these windows, it will be immune from antitrust liability.

For product hops subject to antitrust scrutiny, Section B introduces a test based on whether the hop would make business sense for the brand manufacturer if it did not have the effect of impairing generic competition. Courts and commentators have advocated a no-economic-sense test in other areas, but the test remarkably has not been employed in a setting tailor-made for it. If a brand acquires or maintains monopoly power by engaging in product hopping that fails the no-economic-sense test, courts should find it liable for illegal monopolization since the behavior makes no sense other than by stifling generic competition.

Through the application of the no-economic-sense test, we show the errors of courts that have treated as outcome-determinative the distinction between hard and soft switches. In particular, a brand might be anticompetitively undertaking actions that make no economic sense not only when it makes a hard switch and withdraws the original product from the market, but also when it makes a soft switch, leaving the original drug on the market but reformulating the product and "cannibalizing" it (switching sales to the new version), for example by denigrating, misrepresenting features of, increasing the price of, or pulling the marketing and promotion from, its original product.

Part V then applies the new framework to the five product-hopping cases presented in Part III. It supports the conclusions of potential liability in *TriCor*, *Suboxone*, and *Namenda*, albeit on the different ground of the no-economic-sense test. And it suggests a different outcome from that in the *Walgreens* and *Doryx* cases on the ground, again, that the product hop lacked economic sense except for its impairment of generic competition. The fact that judicial analysis would be so different under the defendant-friendly no-economic-sense test shows just how far the courts have veered from justified economic analysis.

I. PRODUCT HOPPING

Product hopping, which is also known as "evergreening" or "line extension," refers to "a drug company's reformulation of its product"[2] and encouragement of doctors to prescribe the reformulated, rather than original, product. Under our definition, a brand manufacturer engages in a "product hop" by combining two actions:

(1) reformulating the product in a way that makes a generic version of the original product not substitutable; and

(2) encouraging doctors to write prescriptions for the reformulated rather than the original product, i.e., switching the prescription base from the original to the reformulated product.

This definition of product hopping does not include any instance in which the manufacturer promotes the original and reformulated products equally and without encouraging doctors to switch to the reformulated product. For example, brands often, without reducing their promotion of the original version, introduce modestly adjusted versions of their products to fill out a product line or satisfy demand for a particular formulation or delivery mechanism. In contrast, our definition of a product hop is limited to the brand's switch of the prescription base to a reformulated product for which the generic is not substitutable. Limiting potential antitrust liability to instances in which the brand switches the prescription base is crucial: our test does not target rational brand efforts to *expand* the prescription base by competing with other branded products or growing the market. The test instead identifies and targets a brand's efforts to *migrate* the base in order to impair generic competition.[3]

2 Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 FLA. L. REV. 1009, 1016 (2010).

3 The generic-impairing product switches are particularly concerning given the "price disconnect" between buyers and decisionmakers discussed below. *See infra* Section II.A and text preceding Section IV.A. From a policy and regulatory perspective, the act of switching the prescription base raises anticompetitive concerns in threatening the generic-promoting goals of the Hatch-Waxman Act and state drug product substitution laws, *see infra* Sections I.B, I.C, through a switch to a reformulation for which a generic cannot be substituted. And that conduct lacks any innovation-based justifications because the brand does not build up the prescription base by competing with other brands or expanding the market, but merely leverages already-gained power solely by blocking generic entry.

There are several types of reformulations, which Section A catalogs. Sections B and C introduce the foundations of the regulatory regime: the Hatch-Waxman Act and state substitution laws. Section D then focuses on a crucial element of pharmaceutical competition: the timing of the brand's reformulation in relation to generic entry.

A. Forms of Product Hopping

Product hopping occurs through one (or more than one) of several types of reformulations. One category involves new forms, which consist of switches from a capsule, tablet, injectable, solution, suspension, or syrup to another form, such as any of the above, as well as extended-release capsules or tablets, orally dissolving tablets, and chewable tablets.[4] For example, the makers of antidepressant Prozac and cholesterol treatment TriCor switched from capsule to tablet form, while anxiety-treating Buspar was switched from tablet to capsule.[5]

A second type of reformulation involves changing molecule parts (known as "moieties") by adding or removing compounds. More technically, a manufacturer can switch from a mix of two enantiomers (one of a pair of chemical compounds that has a mirror image[6]) to a single enantiomer. For example, and foreshadowing the change discussed below from heartburn-treating Prilosec to Nexium, a manufacturer can "switch from a chemical compound that is an equal mixture of each enantiomer, only one of which contains the active ingredient, to a compound that includes only the enantiomer that contains the active ingredient."[7] Chemical changes also explain the switches from allergy medication Claritin to Clarinex, antidepressant Celexa to Lexapro, and heartburn medication Prevacid to Kapidex.[8]

A third category of reformulation involves a combination of two or more drug compositions that had previously been marketed separately.[9] Combinations have involved migraine-treatment Treximet (combining Imitrex and Naproxen Sodium) and high-blood-pressure medications Azor (Norvasc and Benicar), Caduet (Norvasc and Lipitor), and Exforge (Norvasc and Diovan).[10]

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4 Shadowen et al., *supra* note 1, at 24.

5 *Id.* at 37.

6 *Enantiomer*, MERRIAM-WEBSTER, http://www.merriam-webster.com/dictionary/enantiomer (last visited Oct. 22, 2016).

7 Shadowen et al., *supra* note 1, at 24; *see also id.* at 25 (also including changes to molecules already on the market resulting in "new esters, new salts, or other non-covalent derivatives"); *infra* Section III.B.

8 Shadowen et al., *supra* note 1, at 38.

9 *Id.* at 25.

10 *Id.* at 38–41.

B. Hatch-Waxman Act

A crucial element of the regulatory framework forming the backdrop of product hopping is the Hatch-Waxman Act, enacted by Congress in 1984 to increase generic competition and foster innovation in the pharmaceutical industry.[11]

The Act promoted generic competition by creating a new process for obtaining U.S. Food and Drug Administration (FDA) approval, encouraging generics to challenge invalid or noninfringed patents by introducing a 180-day period of marketing exclusivity for the first generic to do so, and resuscitating a defense that allowed generics to experiment on a brand drug during the patent term.[12] The drafters of the Act sought to ensure the provision of "low-cost, generic drugs for millions of Americans"[13] and recognized that generic competition would save consumers, as well as the federal government, millions of dollars each year.[14]

One central goal of the Act was to expedite generic competition.[15] Generic drugs are very similar to patented brand drugs, having the same active ingredients, dosage, administration, performance, and safety.[16] Despite this equivalence, however, generic manufacturers were required, before the Act, to demonstrate safety and effectiveness by engaging in lengthy and expensive trials. They could not begin the process during the patent term since the FDA approval process took several years[17] and the required tests constituted infringement.[18] Generics thus waited until the end of the term to begin these activities. As a result, they were not able to enter the market until two or three years after the patent's expiration. At the time of the Hatch-Waxman Act, there were roughly 150 drugs for which the patent term had lapsed but there was no generic on the market.[19]

In the Act, Congress encouraged competition through several mechanisms. First, it allowed generics to experiment on the drug during the patent

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11 Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 28, 35 U.S.C.).

12 Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 42–43 (2009).

13 130 CONG. REC. 24,410, 24,427 (1984) (statement of Rep. Waxman).

14 *Id.* at 24,456 (statement of Rep. Minish).

15 For an overview of the mechanisms employed to carry out the other primary goal, fostering innovation, see Carrier, *supra* note 12, at 43–45 (discussing patent term extensions, non-patent market exclusivity, and an automatic 30-month stay of FDA approval of generics).

16 *Generic Drugs: Questions and Answers*, FOOD & DRUG ADMIN., http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm (last updated Jan. 7, 2015).

17 CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 38 (1998).

18 *Id.* at 3.

19 *See* H.R. REP. NO. 98-857, pt. 1, at 17 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2650.

term.[20] Along these lines, the legislature exempted from infringement the manufacturing, use, or sale of a patented invention for uses "reasonably related to the development and submission of information" under a federal law regulating drugs' manufacture, use, or sale.[21]

Second, the Act provided 180 days of marketing exclusivity to the first generic to challenge a brand's patent or claim that it did not infringe the patent.[22] This exclusivity "was reserved for the first generic firm—known as a 'Paragraph IV filer'—that sought to enter during the patent term."[23] During the 180-day period, which begins after the drug's first commercial marketing, the FDA is not able to approve other generic applications for the same product.[24]

Third, and most relevant for our purposes, Congress created a new process for generics to obtain FDA approval. Before the Act, generic firms that offered identical products to approved drugs were required to prove safety and efficacy.[25] In fact, one reason that generics decided not to bring drugs to the market after the expiration of a patent was the time and expense involved in replicating clinical studies.[26] The Act created a new type of drug application, called an Abbreviated New Drug Application (ANDA), through which generics could rely on brands' safety and effectiveness studies, thereby avoiding the need to engage in lengthy and expensive preclinical or clinical studies.[27]

In short, faced with the problem of insufficient generic entry and high drug prices, Congress enacted legislation that introduced several industry-shaping mechanisms to encourage generic entry.

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20 35 U.S.C. § 271(e)(1) (2012).

21 *Id.* For an elaboration on this discussion, see Carrier, *supra* note 2, at 1013, from which this passage draws.

22 21 U.S.C. § 355(j)(5)(B)(iv) (2012). Three other patent certifications apply if the drug is not patented, the patent has expired, or the generic agrees it will not seek approval until the patent expires. 21 U.S.C. § 355(j)(2)(A)(vii).

23 21 U.S.C. § 355(j)(5)(B)(iv).

24 Carrier, *supra* note 2, at 1014; *see also* FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 7 (2002) [hereinafter FTC, GENERIC DRUG STUDY], https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf. Until amended in 2003, the Hatch-Waxman Act included as a second trigger for the 180-day period a court decision finding invalidity or lack of infringement. Colleen Kelly, Note, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD & DRUG L.J. 417, 439–40 (2011).

25 Elizabeth Stotland Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 ANTITRUST L.J. 585, 588 (2003).

26 *See id.*

27 FTC, GENERIC DRUG STUDY, *supra* note 24, at 5. For an elaboration on this discussion, see Carrier, *supra* note 2, at 1013, from which this passage draws.

C. State Drug Product Selection Laws

States have also made it easier for generics to reach the market through their enactment of drug product selection (DPS) laws. Such laws, in effect in all fifty states today, are designed to lower consumer prices.[28] The laws allow (and in some cases require) pharmacists—absent a doctor's contrary instructions—to fill prescriptions for brand-name drugs with generic versions.[29]

States enacted DPS laws to address the price disconnect in the industry, described in detail below,[30] between doctors, who prescribe a drug but are not directly responsive to drug pricing, and insurers and consumers, who pay but do not directly select a prescribed drug.[31] In particular, the laws ensure an important role for pharmacists, who are more price-sensitive than doctors.[32] Doctors are subject to "a vast array of drug promotion, which includes detailing (sales calls to doctor's offices), direct mailings, free drug samples, medical journal advertising, sponsored continuing medical education programs, and media advertising."[33] Pharmacists, in contrast, make greater margins on generics and recommend them to consumers,[34] competing with other pharmacies on price.[35]

The DPS laws "typically allow pharmacists to substitute generic versions of brand drugs only if they are 'AB-rated' by the FDA."[36] This is solely a safety regulation, unconcerned with and unresponsive to the requirement's effect on competition. For a generic drug to receive an AB rating, it must be "therapeutically equivalent" to the brand drug, which means that it "has the same active ingredient, form, dosage, strength, and safety and efficacy profile."[37] The drug also must be "bioequivalent," which means "the rate and extent of absorption in the body is roughly equivalent to the brand drug."[38]

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28 *See, e.g.*, Norman V. Carroll et al., *The Effects of Differences in State Drug Product Selection Laws on Pharmacists' Substitution Behavior*, 25 MED. CARE 1069 (1987).

29 Carrier, *supra* note 2, at 1017.

30 *See infra* Section II.A.

31 BUREAU OF CONSUMER PROT., DRUG PRODUCT SELECTION: STAFF REPORT TO THE FEDERAL TRADE COMMISSION 2–3 (1979); *see also In re* Schering-Plough Corp., 136 F.T.C. 956, 985 (2003) ("The underlying premise of these [DPS] laws . . . is that generic competition has the potential to lower prices," and "these regulations need to be accepted as real market factors in an antitrust analysis.").

32 ALISON MASSON & ROBERT L. STEINER, GENERIC SUBSTITUTION AND PRESCRIPTION DRUG PRICES: ECONOMIC EFFECTS OF STATE DRUG PRODUCT SELECTION LAWS 7 (1985).

33 STUART O. SCHWEITZER, PHARMACEUTICAL ECONOMICS AND POLICY 87–93 (2d ed. 2007). For an elaboration on this discussion, see Carrier, *supra* note 2, at 1017, from which this passage draws.

34 Shadowen et al., *supra* note 1, at 16.

35 MASSON & STEINER, *supra* note 32, at 7; *see generally* Carrier, *supra* note 2, at 1017–18.

36 Carrier, *supra* note 2, at 1018.

37 *Orange Book Preface: Approved Drug Products with Therapeutic Equivalence Evaluations*, CTR. FOR DRUG EVALUATION & RESEARCH, FOOD & DRUG ADMIN., http://www.fda.gov/drugs/developmentapprovalprocess/ucm079068.htm (36th ed. last updated June 10, 2016).

38 *See id.* For an elaboration on this discussion, see Carrier, *supra* note 2, at 1018, from which this passage draws.

Product-hopping schemes exploit this regulation. By making minor changes to the original product—for example, switching from a capsule to a tablet, or from a 10-mg to a 12-mg dose—the brand can prevent the generic from obtaining the AB rating the generic needs to be substituted for the brand. After the brand's reformulation, the generic cannot be substituted for the new version. To become substitutable it must start the FDA approval process all over again. And while the generic may eventually obtain an AB rating to the reformulated product, such a showing likely will not occur for years as the generic reformulates its product, seeks FDA approval, and typically files a Paragraph-IV certification, which tends to be "followed by the brand firm's automatic 'thirty month stay' of FDA approval and additional delays from patent litigation."[39] All of these delays prevent the effective operation of the DPS laws, removing the role of pharmacists and depriving consumers of the practical opportunity to consider a lower-priced generic version of the drug.

D. Timing of Generic Entry

A seminal event in the lifecycle of a prescription drug is generic entry. When multiple generics enter the market, the price falls to a fraction of the brand price.[40] Brand firms thus have every incentive to delay the entry of generic competition as long as possible. The dramatic effects of generic entry explain the crucial role played by the Hatch-Waxman Act and state DPS laws. And they shed light on the essential characteristic, in the product-hopping context, of the timing of generic entry.

Put simply, the brand firm will be much more successful in forestalling generic competition if it can switch the market to the reformulated drug *before* a generic of the original product enters the market.[41] Without a generic on the market, the brand's heavy promotion and marketing artillery can convince doctors to prescribe the reformulated drug. If the brand successfully switches the market to the reformulated product before the generic enters, the generic entry is of no practical significance: there are few or no prescriptions for the original product for which the generic can be substituted.[42]

Several examples demonstrate the crucial role of timing, in particular the brand's recognition of its dramatically higher success if it can switch the

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39 Carrier, *supra* note 2, at 1018.

40 *Generic Competition and Drug Prices*, FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm (last updated May 13, 2015); *see generally* Fiona Scott Morton & Margaret Kyle, *Markets for Pharmaceutical Products*, *in* 2 HANDBOOK OF HEALTH ECONOMICS 763, 792–93 (Mark V. Pauly et al. eds., 2012) (summarizing recent studies on generic penetration rates and prices).

41 *See* Shadowen et al., *supra* note 1, at 51 (explaining how introduction of reformulated product before generic entry ensures that not only will there be almost no competition on price but also that there will be almost no competition on quality).

42 For a discussion of why managed care organizations are not able to solve the problem, see *infra* note 113.

market to the reformulated drug before a generic version of the original drug enters the market. In the *TriCor* case, discussed below,[43] the brand firm predicted that it would sell more than *ten times* as many tablets if it was able to switch doctors to the reformulated product before the generic version of the original product entered the market.[44] Another example involved a confidential analysis of a product for which projected sales would be *three times* higher if the reformulation (replacing a twice-daily version with a once-a-day version) occurred two years before the generic of the original product entered the market.[45] Another brand firm acknowledged that "its reformulation was 'a gimmick' and that switching the market before generic entry was the 'cardinal' determinant of success."[46]

Similar testimony in a different case referred to a "[t]otal [d]isaster" if the reformulated product was introduced after the generic of the original product entered the market.[47] The brand's internal documents in the hearing in the *Namenda* case, discussed below,[48] revealed that "if we do the hard switch and . . . convert patients and caregivers to once-a-day therapy versus twice a day, it's very difficult for the generics then to reverse-commute back."[49] And a recent empirical review of product hops concluded that "after a patient is on the new drug and the old drug has gone generic, the new brand did not lose share," which was true "regardless of clinical differentiation."[50]

The European Commission (EC) also recognized the importance of timing in its Pharmaceutical Sector Inquiry Report, which addressed obstacles blocking generic entry.[51] The EC concluded that brands would suffer reduced prices and sales if generics entered the market earlier than, or at the same time as, the reformulated product.[52] Brands thus viewed it as "of [the] utmost importance . . . to bring the follow-on product on the market before the first product effectively loses exclusivity."[53] And the brand firm is able to facilitate such a switch by "channeling . . . demand from the first product to the follow-on product" and by "delay[ing] or prevent[ing] generic entry for the sensitive period of the product switch."[54] For 13 of the 22 second-generation products mentioned in the report, the reformulated product was

43 *See infra* Section III.A.

44 Shadowen et al., *supra* note 1, at 52.

45 *Id.* at 53.

46 *Id.* (footnote omitted).

47 Meijer, Inc. v. Barr Pharm., Inc., 572 F. Supp. 2d 38, 43 (D.D.C. 2008).

48 *See infra* Section III.E.

49 New York *ex rel.* Schneiderman v. Actavis PLC (*Namenda*), 787 F.3d 638, 656 (2d Cir. 2015).

50 Aaron Gal, Why Does Lifecycle Management Still Work? 3 (2013).

51 European Comm'n, Pharmaceutical Sector Inquiry Final Report ¶ 3 (2009), http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf.

52 *Id.* ¶ 1010.

53 *Id.*

54 *Id.* ¶ 1011.

launched before the first lost its exclusivity,[55] with an average lead time of 17 months.[56]

Suggesting a reason for this timing, the report included multiple telling comments from drug companies. One explained that "the switch rate is dramatically reduced" if generics enter at the time of, or before, the introduction of the second-generation product.[57] Along similar lines, another brand firm conceded that "each patient that is not switched quickly enough" to the second-generation product is "forever lost to the generics."[58] On the other side, as a third brand firm admitted: "Once the patient is switched to [the new product] the physician does not have to, cannot and will not switch him to a generic, and . . . more important: the pharmacist cannot substitute!!"[59]

In short, the timing of a product hop is a crucial factor in a brand's ability to switch the market to a reformulated drug. It is therefore critical to incorporate timing into an appropriate antitrust analysis of product hopping.[60]

Moreover, the outsized importance of timing provides evidence that the high prices in many prescription drug markets result not from valuable innovations, but from market failure. If these markets were competitive, it would make little difference that the generic of the original product beat the reformulated brand product to the market, or vice-versa. A competitive market would make the same adjustment in either circumstance, probably with a modest first-mover or incumbent advantage. The fact that beating the generic to the market results in a three- or ten-fold increase in sales strongly suggests that these markets have quite significant imperfections. An appropriate antitrust analysis must also take this unique industry characteristic into account.

We now explore additional evidence of that market failure.

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55 *Id.* ¶ 1030 fig.138.

56 *Id.* ¶ 1031.

57 *Id.* ¶ 1025.

58 *Id.* ¶ 1028.

59 *Id.*; *see also* Abuse of a Dominant Position by Reckitt Benckiser Healthcare (UK) Ltd. & Reckitt Benckiser Grp., PLC, Case CE/8931/08, ¶ 2.194 (Office of Fair Trading Apr. 12, 2011) (Eng.), https://assets.publishing.service.gov.uk/media/555de4bbe5274a7084000156/rb-decision.pdf (quoting numerous documents in which brand insisted that "we must implement [the product hop] . . . before a generic name is granted"); Case T–321/05, AstraZeneca v. European Comm'n, 2010 E.C.R. II-2830, 3108 ("Astra intended to launch Losec MUPS before generic omeprazole products entered the market in large volumes and drove prices down to lower levels."). For an elaboration on this discussion, see Carrier, *supra* note 2, at 1021.

60 One commentator has suggested that whether patients will switch back after a generic becomes available is an empirical question "that has not yet been tested." Daniel A. Crane, *Provigil: A Commentary*, 3 HASTINGS SCI. & TECH. L.J. 453, 454 (2011). But the European Commission's final report and a comprehensive product-hopping article, Shadowen et al., *supra* note 1, were published two years earlier and extensively quoted industry sources on the issue. The *Namenda* litigation has also now revealed additional data establishing that substantial percentages of patients will not switch back to the original drug. *See infra* Section III.E.

II. Market Failure

Understanding market failure in the pharmaceutical industry is important in determining the appropriate role for antitrust law. As we discuss in Section A, a "price disconnect" distinguishes prescription drugs from other products, separating the price/quality determination that is unified in other markets. Section B focuses on pharmaceutical patents, highlighting the limited and incomplete role played by the patent system. Section C then provides several indicia of market failure based on medical evidence, the price of patented drugs in Mexico (where a prescription is not required), U.S. prices before prescriptions were required, post-patent prices in the United States, and lower prices in countries that have addressed the disconnect. Given that the United States has not utilized the means employed in other countries to respond to the disconnect, Section D highlights the importance of antitrust law.

A. The Price Disconnect

Many prescription drug markets in the United States fail to deliver innovative drugs at reasonable prices because the markets suffer from a market failure. Fundamentally, these markets are characterized by a *price disconnect*: the doctor who prescribes the product does not pay for it, and the consumer (or her insurer) who pays for it does not choose it. In these markets, consumers do not make the fundamental trade-off between price and quality, and it is this balancing or trading-off that makes markets function well.

In well-functioning markets, large numbers of consumers are personally knowledgeable about the comparative quality and attributes of competing products, and those same consumers are themselves responsible for paying for the products. Being both knowledgeable and responsible for paying, consumers decide whether the quality and attributes of a particular product make it worth paying a higher price than for other products in the market. Competition for the dollars of knowledgeable, paying consumers keeps prices at competitive levels.[61]

In a competitive market with knowledgeable and price-sensitive consumers, a firm can reap a price premium above the competitive level *only if, and only to the extent that*, it provides a product with characteristics that those consumers value. For example, if Product A is sold at a monopoly price of $50, and a competitor introduces Product B, which is the same quality and has essentially the same attributes as Product A, but with some relatively modest "new and improved" aspects, the price should fall to, say, $25 for Product A

61 *See, e.g.*, Paul A. Samuelson & William D. Nordhaus, Economics 80 (16th ed. 1998) (asserting that choice and utility theory are founded on "the fundamental premise that people tend to choose those goods and services they value most highly" (emphasis omitted)); *see also* Fed. Trade Comm'n, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, ch. 1 at 3 (2003) http://www.ftc.gov/os/2003/10/innovationrpt.pdf (arguing that increased consumer welfare results from "the optimum mix of products and services in terms of price, quality, and consumer choice").

and $30 for Product B. Competitive entry drives down the price of the products to the extent of their overlapping quality and attributes, while Product B can command a price premium only for its "new and improved" aspects. Competition allows consumers to reap the full benefit of both price competition and innovation.

Prescription drug markets are different. Consumers are not knowledgeable buyers of prescription drugs. State drug-safety laws prevent consumers from buying the drugs without a permission slip—a prescription—from their doctors. But the doctor who chooses which product the consumer will buy does not herself have to pay for it. So the person who chooses does not pay, and the person who pays does not choose. *No one* makes the price/quality decision or trade-off that ensures that manufacturers sell products at competitive prices.[62]

The price disconnect makes product hopping a viable competition-impairment strategy in prescription drug markets. This is shown with a simple, stylized example. Assume that a brand manufacturer competes in an ordinary, not-price-disconnected market. Assume further that the brand currently makes $200 million in annual sales of the product; that the research and development (R&D) costs of redesigning the product are $20 million; and that redesigning the product in fact would not improve it and therefore would not result in any sales above $200 million. The manufacturer would not redesign the product because the redesign would: (1) not increase sales; (2) not impair competition; and (3) cost $20 million, resulting in a net loss.

Now assume the same facts, except that the redesign *would* significantly impair competition from generics, preventing them from taking $160 million of the $200 million in existing sales. In this situation, the manufacturer has a strong incentive to redesign the product even though it is in fact not an improvement that would entice consumers to buy more or pay more. If the manufacturer redesigns the product, the R&D costs are an investment not in improving consumer welfare, but in impairing competition.

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62 The "price disconnect" market failure in prescription drug markets has been recognized in the economics literature since at least the early 1960s. *See, e.g.*, STAFF OF S. COMM. ON THE JUDICIARY SUBCOMM. ON ANTITRUST & MONOPOLY, 87TH CONG., REP. ON ADMINISTERED PRICES: DRUGS 3 (Comm. Print 1961) [hereinafter ADMINISTERED PRICES]; RONALD S. BOND & DAVID F. LEAN, FED. TRADE COMM'N, STAFF REPORT ON SALES, PROMOTION, AND PRODUCT DIFFERENTIATION IN TWO PRESCRIPTION DRUG MARKETS 75 (1977); BUREAU OF CONSUMER PROT., supra note 31, at 2–3; MASSON & STEINER, *supra* note 32, at 5; Shadowen et al., *supra* note 1, at 9 n.31 (summarizing economics literature). And it was introduced in the legal literature in the late 2000s. *See, e.g.*, Carrier, supra note 2, at 1011; Bengt Domeij, *Anticompetitive Marketing in the Context of Pharmaceutical Switching in Europe*, *in* JOSEF DREXL & NARI LEE, PHARMACEUTICAL INNOVATION, COMPETITION AND PATENT LAW 273, 282 (2013); Richard Gilbert, *Holding Innovation to an Antitrust Standard*, 3 COMPETITION POL'Y INT'L 47, 66 (2007); Shadowen et al., *supra* note 1, at 9. Although some courts have ignored the price disconnect, the Second Circuit recognized it in the *Namenda* decision discussed below. New York *ex rel.* Schneiderman v. Actavis PLC (*Namenda*), 787 F.3d 638, 645–46 (2d Cir. 2015); *see infra* Section III.E.

B. Drug Patents' Role

There is a general misperception that the high prices of prescription drugs in the United States are the natural (and earned) result of patents. The government grants a patent on an innovative product, so the argument goes, and high prices and profits are the inventor's just reward for developing that product.

Antitrust scrutiny of prescription drug product hops is needed, however, because high prices and profits might be the result not of valued innovations, but of the exploitation of market failures. The granting of a patent by the U.S. Patent and Trademark Office (PTO) certainly does not guarantee, or even suggest, that the reformulated product is superior in any way to existing products. The PTO requires only that the product be "novel[]"[63] and "non-obvious,"[64] not that it be an improvement. The Federal Circuit has explained that "[f]inding that an invention is an 'improvement' is not a prerequisite to patentability," as "[i]t is possible for an invention to be less effective than existing devices but nevertheless meet the statutory criteria for patentability."[65] Under this standard, the PTO routinely grants patents on minor differences in existing chemical entities, such as different crystalline forms of a chemical, or different formulations that do not necessarily improve the product in any meaningful way.[66] Likewise, before approving a new product for marketing, the FDA requires that the product be superior only to a placebo, not to existing products.[67]

In competitive markets, patents do not always, or even usually, create the ability to charge supracompetitive prices.[68] Patent law simply prevents others from using or making the exact same (or very similar) invention. Competitors can offer consumers similar products that perform the same function in an analogous way, and this competition is typically sufficient to keep market prices at or near the competitive level.

This competition point is crucial. Society grants patents to inventors as an inducement for them to innovate and bring valuable new products to the market. But in an otherwise competitive market, a patent will allow the man-

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63 35 U.S.C. § 102(a) (2012).

64 *Id.* § 103.

65 Custom Accessories, Inc. v. Jeffrey-Allan Indus., 807 F.2d 955, 960 n.12 (Fed. Cir. 1986); *see also* Giles S. Rich, *Principles of Patentability*, 28 GEO. WASH. L. REV. 393, 393 (1960) (discussing "the unsound notion that to be patentable an invention must be better than the prior art").

66 *See, e.g.*, Forest Labs., Inc. v. Ivax Pharm., Inc., 501 F.3d 1263 (Fed. Cir. 2007) (upholding patent on enantiomers); Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348 (Fed. Cir. 2007) (upholding a patent on a particular salt); AstraZeneca AB v. Mut. Pharm. Co., 384 F.3d 1333 (Fed. Cir. 2004) (upholding a formulation patent).

67 *See generally* Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 TEX. L. REV. 685, 709 (2009) (noting that the FDA "has neither the mandate nor the power to take competition concerns into account in approving particular pharmaceutical products"); Jeanne Whalen, *Glaxo Strategy Threatened by FDA Delays*, WALL ST. J., June 17, 2008, at B3.

68 *See, e.g.*, Ill. Tool Works, Inc. v. Indep. Ink, Inc., 547 U.S. 28 (2006).

ufacturer to price the product above the competitive level *only if and to the extent that the patented technology reflects a real, valuable innovation* for which knowledgeable, price-sensitive consumers are willing to pay a premium.[69]

The vast majority of products protected by patents or other IP rights command little or no premium price in the market, precisely because most markets are otherwise competitive.[70] While some consumers strongly prefer one brand over the other—indeed, wouldn't want the other brand if it were given away for free—most consumers would not pay a price premium for one over the other.[71] The result is that consumers are able to obtain many patented products at competitive prices despite the manufacturers' extensive IP rights.

These same principles would apply in prescription drug markets if they were otherwise competitive. The additional profits arising from a pharmaceutical patent would reflect the additional consumer value created by the invention covered by the patent. As in the example above, the entry of a new competing pill that provided the same medical benefits as an existing pill would drive the market price down toward the competitive level, and the new pill could command a premium over that competitive price only if and to the extent that it had some patented attribute for which a substantial number of knowledgeable and price-sensitive consumers were willing to pay a premium. For example, if the new product were in capsule form while the existing competitor were a tablet, the new entry would drive the market price down, and the new entrant would enjoy a price premium, only if and to the extent that consumers who paid out of their own pockets were willing to pay a price premium for the patented capsule (e.g., if it was substantially easier to swallow).

Of course, the key here is the important qualification "in an otherwise competitive market." Given the price disconnect, there is no *a priori* reason to think that the high prices of many prescription drugs reflect an efficient reward that society intentionally granted to inventors in exchange for valuable innovations. Those prices instead might well reflect a market failure that society unintentionally created as a by-product of drug-safety regulations—the prescription requirement.

C. Evidence of Market Failure

Determining whether the high prices in prescription drug markets are the result of valuable innovations or market failure is vitally important. If the

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69 *See* Arjun Jayadev & Joseph E. Stiglitz, *Two Ideas to Increase Innovation and Reduce Pharmaceutical Costs and Prices*, 28 HEALTH AFF. 165 (2008); Panos Kanavos & Uwe Reinhardt, *Reference Pricing for Drugs: Is It Compatible with U.S. Health Care?*, 22 HEALTH AFF. 16, 21 (2003); Joseph E. Stiglitz, *Economic Foundations of Intellectual Property Rights*, 57 DUKE L.J. 1693, 1707 (2008).

70 *See, e.g.*, *Ill. Tool Works*, 547 U.S. at 28; Christopher R. Leslie, *Patent Tying, Price Discrimination, and Innovation*, 77 ANTITRUST L.J. 811, 823 (2011).

71 *See, e.g.*, Mark A. Lemley & Mark P. McKenna, *Is Pepsi Really a Substitute for Coke? Market Definition in Antitrust and IP*, 100 GEO. L.J. 2055 (2012).

high prices are the consequence of innovation in an otherwise competitive market, society should accept those prices as the presumably efficient cost of rewarding inventors for valuable new products. But if the high prices result from market failure, society should not blindly accept them but should try to prevent manufacturers from exploiting the market failure.

The available evidence indicates that the high prices in many drug categories result from market failure rather than valuable innovations. This includes medical evidence—that many drugs perform essentially the same function in the same way—as well as an array of economic evidence, including data from circumstances where prescription drugs are patented but the price disconnect does not exist. Without the price disconnect, drug patents often do not result in high returns for the inventor.[72]

1. Medical Evidence

In a recent five-year period, 67% of the "new" drugs approved by the FDA were "me-too" drugs—drugs that are slight chemical variants of their predecessor and that produce essentially the same medical results in patients.[73] With four or five me-too branded drugs available, in a competitive market the price on all of these drugs should be competed down to the equilibrium level. But that is not what happens. Instead, the entry of the second and third competitors, and even the fourth and fifth, rarely results in competitive prices. The industry's profit pie does not get substantially smaller; it just gets split among more manufacturers. Doctors might prescribe one of the me-too drugs rather than another, but consumers pay supracompetitive prices regardless of which prescription they get. It is only competition from generic drugs that typically causes the average price of the molecule to drop toward competitive levels, and the generic competition has

72 The market failure caused by the price disconnect in the United States is exacerbated by the shielding of consumers from direct responsibility to pay for prescription drugs. As a result of private, employer-sponsored, and government insurance, by 2010 consumers directly paid only 8% of the total costs of prescription drugs. Morton & Kyle, *supra* note 40, at 788. This compares to 70% in 1980. *Id.* The consumer-patient today is removed in large part from the economics of the prescription decision. The physician mainly decides what drug is used, and the third-party insurer, whether private or public, pays most of the bill.

73 Our analysis of FDA data shows that from 2011 through 2015, the FDA approved 548 NDAs, only 182 (33%) of which were for New Molecular Entities. Of those 182 NMEs, the FDA gave priority review (which is reserved for drugs that treat a serious condition and provide a significant improvement in safety or effectiveness) to only 90. Thus, just 16% of NDA approvals were for truly innovative drugs. Previous analyses came to similar conclusions. *See, e.g.*, MARCIA ANGELL, THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT 53–56 (2005) (analyzing data for the period from 1998 to 2002). Our figures might overstate the rate of innovation for standard prescription drugs, because we include data for biologics.

that effect only for its AB-rated branded counterpart, not for other branded drugs in the therapeutic class.[74]

Perhaps the most infamous example is presented by the GERD/heartburn therapeutic class. This consists of "proton pump inhibitors" (PPIs), including Prilosec, Prevacid, Protonix, Aciphex, and Nexium, which ease the symptoms of chronic indigestion. In the early 2000s, this class "feature[d] competition among five branded products, all of which treat[ed] essentially the same conditions and did so equally effectively—they were all "me too" versions of Prilosec."[75] The entry of multiple, nearly identical branded competitors did not cause the price of PPIs to fall substantially. Instead, the net prices (after including rebates and discounts) remained high, with each of the competitors making sales in the hundreds of millions of dollars annually.[76] As demonstrated by the prices charged by generic versions of the drugs, the brands were sold at net prices more than 25 times their marginal costs of production.[77]

A market consisting of "five close functional substitutes could not yield margins anywhere near that magnitude if consumers made the relevant price/quality choices."[78] The astronomically high price of me-too drugs in crowded therapeutic classes is strong evidence that the prices result from market failure, not from valued innovations.

2. Prices of Patented Drugs in Mexico

The prices of drugs that are patented but not subject to a price disconnect provide further data to determine whether high drug prices result from valuable innovations or market failure. In these circumstances, high prices could potentially reflect innovations valued by consumers in a competitive market. On the other hand, lower prices would provide further evidence that patented "innovations" do not command a price premium in the

74 Transcript of Record at 123–26, *In re* Nexium (Esomeprazole) Antitrust Litig., 309 F.R.D. 107 (D. Mass. 2015) (No. 12-md-02409) (testimony of Richard Fante) (on file with authors); *id.* at 79–84 (testimony of Dr. Meredith Rosenthal) (on file with authors); *id.* at 88–92 (testimony of Linda Palczuk) (on file with authors).

75 Shadowen et al., *supra* note 1, at 69; *see, e.g.*, STANLEY IP ET AL., AGENCY FOR HEALTHCARE RES. & QUALITY, PUB. NO. 06-EHC003-EF, COMPARATIVE EFFECTIVENESS OF MANAGEMENT STRATEGIES FOR GASTROESOPHAGEAL REFLUX DISEASE 35 (2005), http://effectivehealthcare.ahrq.gov/reports/final.cfm (finding no differences in effectiveness of equal doses of omeprazole, esomeprazole, lansoprazole, pentoprazole, and rabeoprazole); AGENCY FOR HEALTHCARE RES. & QUALITY, Pub. No. 06-EHC003-A, *Comparing Health Care Choices: Gastroesophageal Reflux Disease (GERD)* (2005), http://effectivehealthcare.ahrq.gov/repfiles/consumer.gastro.pdf ("Studies show that, overall, each PPI works about as well as another for relieving symptoms."); *See also generally* ANGELL, *supra* note 72, at 74–93 (explaining "me-too" drugs and using PPIs as an example).

76 Transcript of Record at 70–74, *In re Nexium*, 309 F.R.D. 107 (No. 12-md-02409) (testimony of Dr. Meredith Rosenthal).

77 *Id.* at 83–84. Accounting data have shown that brands' profit margins, even including R&D and marketing in the costs, are 70%. *Id.* at 86.

78 Shadowen et al., *supra* note 1, at 70.

absence of the price disconnect. It is the market failure, not valued innovation, that is generating the monopoly power.

Prescription drug markets in Mexico provide just such an experiment. For the most part, major prescription drugs patented in the United States also are patented in Mexico.[79] Until 2010, however, many patented drugs that require a prescription in the United States did not require a prescription in Mexico (or pharmacies routinely dispensed the drugs without requiring prescriptions).[80] For these drugs, in the United States there were patents and prescriptions (and thus a price disconnect), but in Mexico there were patents and no prescriptions (and no price disconnect). In Mexico, consumers simply walked into a pharmacy, chose for themselves which patented drug to buy, and paid for it out of their own pockets.[81]

Studies of comparative prices of brand, on-patent pharmaceuticals in the two countries consistently found during the relevant time period that prices in Mexico were substantially lower.[82] For example, a study comparing prices in El Paso, Texas, and its sister city, Ciudad Juarez, Mexico, found, after controlling for exchange rates, that retail prices were on average 29% lower in Juarez.[83] The study noted that consumers could buy these patented drugs

79 ELÍAS MIZRAHI ALVO, CEPAL DE MEX., SERIE ESTUDIOS Y PERSPECTIVAS NO. 121, REGULACIÓN Y COMPETENCIA EN EL MERCADO DE MEDICAMENTOS: EXPERIENCIAS RELEVANTES PARA AMÉRICA LATINA 8, 38 (2010).

80 THOMAS M. FULLERTON JR. & OSVALDO MIRANDA, UNIV. TEX. EL PASO, TECH. REP. TX10-1, ARE BRAND NAME MEDICINE PRICES REALLY LOWER IN CIUDAD JUAREZ? 9 (2010); José A. Pagán et al., *Self-Medication and Health Insurance Coverage in Mexico*, 75 HEALTH POL'Y 170, 170–71 (2006); Peter Temin, *Technology, Regulation, and Market Structure in the Modern Pharmaceutical Industry*, 10 BELL J. ECON. 429, 434 (1979); Pierre Moïse & Elizabeth Docteur, *Pharmaceutical Pricing and Reimbursement Policies in Mexico* 43–44 (Org. for Econ. Cooperation & Dev. Health Working Paper No. 25, 2007). Beginning in 2010, Mexico required prescriptions for large numbers of medicines. *See* COMISIÓN FEDERAL PARA LA PROTECCIÓN CONTRA RIESGOS SANITARIOS, Guía para el Cumplimiento del "Acuerdo por el que se Determinan los Lineamientos a los que estará Sujeta la Venta y Dispensación de Antibióticos" (2010) (guide issued by Mexican government to pharmacies outlining the requirements of Article 226 of Mexico's Public Health Code, which took effect on August 25, 2010). Many pharmacies, however, countered that measure by having on-site doctors who would write prescriptions for a nominal fee. *See* Nuria Homedes & Antonio Ugalde, *Mexican Pharmacies: Benefits and Risks for Border Residents in the United States of America and Mexico*, 33 REV. PANAM SALUD PUBLICA 196, 201–02 (2013).

81 *See, e.g.*, ERNESTO ENRIQUEZ RUBIO ET AL., HACIA UNA POLÍTICA FARMACÉUTICA INTEGRAL PARA MÉXICO 79 (2005) (noting that, even for drugs requiring a prescription, 43% of purchases were made without one). Before 2010, various government plans paid for approximately 40% of prescription drugs in Mexico. *See* David J. Cantor, *Prescription Drug Price Comparisons: The United States, Canada, and Mexico*, *in* THE PHARMACEUTICAL INDUSTRY: ACCESS AND OUTLOOK 45, 47 (Ethan N. Parvis ed., 2002). We do not include the prices of those drugs in our analysis.

82 *See, e.g.*, Patricia M. Danzon & Michael F. Furukawa, *Prices and Availability of Pharmaceuticals: Evidence from Nine Countries*, HEALTH AFF. ONLINE, Oct. 29, 2003, at W3-521, W3-527 Ex. 4.

83 FULLERTON & MIRANDA, *supra* note 80, at 8–9, 14 tbl.3; Temin, *supra* note 80, at 434.

without a prescription in Mexico but required a prescription in the United States.[84]

The Mexican experience provides additional evidence that, holding patents constant, prices are consistently and substantially higher when prescriptions are required. This again strongly suggests that market failure, not valuable innovation, causes supracompetitive drug prices.[85]

3. Non-Prescription Prices in the United States

Another example of market failure is provided by drug prices in the United States before the law required prescriptions.

In 1938, the Federal Food, Drug, and Cosmetic Act (FDCA) created for the first time a distinction between prescription and over-the-counter drugs.[86] A leading historian of the industry discerned the beginnings of the price disconnect:

> As the number of prescription drugs increased . . . the marketing of drugs was directed more and more at the medical profession. These new "customers" had a peculiar characteristic; they did not pay for the drugs they ordered. In fact, they often did not even know how much these drugs cost. As a result, the demand for prescription drugs was more inelastic than it would have been without the FDA's regulation on prescription sales.[87]

In 1951, the FDA began routinely designating drugs as "for prescription use only."[88] The manufacturers quickly took advantage of this safety-based interposition of a doctor between the consumer and the product choice. In 1954, the brands formed a trade association, the National Pharmaceutical

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84 FULLERTON & MIRANDA, *supra* note 80, at 9.

85 To be clear, we do not suggest that prescriptions are undesirable from a safety perspective, but instead that they create a price disconnect between doctor and payor.

86 Temin, *supra* note 80, at 434.

87 *Id.*; *see also* DONALD C. KING, MARKETING PRESCRIPTION DRUGS 10 (1968) ("[I]n the purchase of prescription drugs, the consumer is unable to protect himself against the element of monopoly inherent in trademarking by choosing from among a number of competing brands."); Peter Temin, *The Origin of Compulsory Drug Prescriptions*, 22 J.L. & ECON. 91 (1979).

88 From 1906 to 1938, the FDA had closely regulated some narcotics and had required certain information in product labels, though consumers were free to choose whatever pharmaceutical concoctions they desired. Temin, *supra* note 87, at 91. But in 1937, more than 100 people died from taking Massengill's Elixir of Sulfanilamide, which had been manufactured with an untested, and poisonous, solvent. *See id.* at 94–95. In response to public outcry, Congress passed the FDCA, which revised the original 1906 Act. *See id.* at 91–94. In addition to requiring new drugs to prove their safety prior to marketing, the Act required drugs to have expanded labels with adequate directions for safe use. From 1938 to 1951, the FDA used this provision of the FDCA to extend its regulatory reach by ruling that some drugs could not be labeled for safe use because consumers lacked sufficient expertise to comprehend the label and that those drugs could be sold only through a doctor's prescription. *See generally* Temin, *supra* note 87. The 1951 Durham-Humphrey Amendment to the FDCA extended the FDA's right to designate pharmaceuticals "for prescription use only." *See id.* Today, there are thousands of pharmaceuticals that can be purchased only after obtaining a doctor's prescription.

Council (NPC), whose first concerted effort was to lobby state boards of pharmacy to tighten their substitution laws.[89]

Those laws had previously allowed pharmacists in some circumstances to substitute among brands of the same type of prescription drug, prohibiting only substitution of one *type* of drug for another.[90] For example, a pharmacist receiving a prescription for Eli Lilly's erythromycin could substitute Pfizer's oleandomycin, which had a different chemical structure but performed essentially the same antibiotic function. The pre-1954 substitution laws merely prevented the pharmacist who received a prescription for an antibiotic such as erythromycin from substituting an aspirin.[91]

Under intense NPC lobbying, 44 state boards of pharmacy had by 1959 changed their substitution laws to prohibit substitution of one manufacturer's brand for another's.[92] The manufacturers simultaneously began intensifying their marketing to doctors, encouraging them to write prescriptions for a particular branded drug rather than for a drug class.[93] These changes "combined to prestructure a more favorable context for high profitability."[94] Congressional hearings from 1957 to 1963 examined high drug prices and led to the conclusion that the new state restrictions on substitution heightened the price disconnect and monopoly power. The Senate Report discussed the disconnect and its economic effects:

> Regardless of how well intentioned the physician may be, another party can never be expected to be as interested in price as the individual who has to spend his own money. Once the physician has written his prescription (usually in terms of a brand name), the consumer is limited to the product prescribed under that brand name; he cannot "shop around" for the same product under a different (or no) brand name at a lower price. Hence in [prescription] drugs the ability of the ordinary consumer to protect himself against the monopoly element inherent in trademarks by being able to choose from a number of competing brands is nonexistent. The consumer is "captive" to a degree not present in any other industry.[95]

The constriction in state substitution laws, together with the manufacturers' "remarkable success in persuading physicians to prescribe by trade names rather than generic names," resulted in "the opportunity for price competition disappear[ing]."[96] This was true "regardless of whether the drugs are patented or non-patented."[97]

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89 *See* HOWARD ALDRICH, ORGANIZATIONS AND ENVIRONMENTS 146 (2008).

90 Paul M. Hirsch, *Organizational Effectiveness and the Institutional Environment*, 20 ADMIN. SCI. Q. 327, 332–33 (1975).

91 ADMINISTERED PRICES, *supra* note 62, at 235.

92 *Id.* at 236.

93 Hirsch, *supra* note 90, at 336; *see generally* ADMINISTERED PRICES, *supra* note 62, at 235–38.

94 Hirsch, *supra* note 90, at 336.

95 ADMINISTERED PRICES, *supra* note 62, at 3.

96 *Id.* at 223.

97 *Id.*

Not surprisingly, economic historians have traced the rise of "Big Pharma" and the industry's outsized profits to exactly this time period in which regulations were introduced requiring a prescription and limiting substitutability.[98] By "restrict[ing] the sale of some drugs (including almost all of the new drugs) to prescription sales," the FDA "reduc[ed] sharply the elasticity of demand."[99]

4. Post-Patent Prices in the United States

Just as history shows that the price disconnect, not patents, sharply reduced cross-price elasticity, so too does history show that prices remain inelastic when patents expire but the price disconnect remains.

In 1984, Congress enacted the Hatch-Waxman Act to streamline the entry of generic drugs.[100] The legislature's fundamental premise in enacting the statute was that, even after patents had expired, competition among branded pharmaceuticals was insufficient to drive prices to competitive levels. Congress understood that only competition from generic drugs could bring about competitive prices.[101]

Due to then-applicable FDA requirements that generic manufacturers duplicate the brand's clinical studies, as of 1983 only 35% of branded drugs that were *off-patent* faced generic competition.[102] The fundamental economic premise upon which Congress enacted the Hatch-Waxman Act was that, even after patents expired, *brands were continuing to sell at supracompetitive levels and only generic competition could generate competitive prices.*[103] In Senator Hatch's words, the Act was designed to "significantly lower the price of off-

98 *See, e.g.*, ALFRED D. CHANDLER, JR., SHAPING THE INDUSTRIAL CENTURY: THE REMARKABLE STORY OF THE EVOLUTION OF THE MODERN CHEMICAL AND PHARMACEUTICAL INDUSTRIES 179–80 (2005); KING, *supra* note 87, at 21 tbl.5 (industry sales, in dollars, nearly quadrupled from 1946 to 1960); TOM MAHONEY, THE MERCHANTS OF LIFE: AN ACCOUNT OF THE AMERICAN PHARMACEUTICAL INDUSTRY 4 (1959) ("As late as 1939 no ethical drug manufacturer in America had a sales volume as large as a department store like Macy's in New York or Hudson's in Detroit."); Temin, *supra* note 80, at 443–44.

99 Temin, *supra* note 80, at 443–44.

100 Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 28, 35 U.S.C.).

101 Richard E. Caves et al., *Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry*, 1991 BROOKINGS PAPERS ON ECON. ACTIVITY: MICROECONOMICS 1, 10.

102 *Id.*; Carrier, *supra* note 12, at 49; *see generally* H.R. REP. NO. 98-857, pt. 1, at 17 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2650.

103 *See, e.g.*, H.R. REP. NO. 98-857, pt. 1, at 17 ("Currently, there are approximately 150 drugs approved after 1962 that are off patent and for which there is no generic equivalent . . . . The availability of generic versions of pioneer drugs approved after 1962 would save American consumers $920 million over the next 12 years."); *id.* pt. 2, at 4, *as reprinted in* 1984 U.S.C.C.A.N. 2686, 2688 ("The FDA rules on generic drug approval for drugs approved after 1962 have had serious anti-competitive effects. The net result of these rules has been the practical extension of the monopoly position of the patent holder beyond the expiration of the patent. This is so because of the inability of generics to obtain approval for these post-1962 drugs without enormous expenditures of money for duplicative tests."). Generic competition usually erodes the market power of only the

patent drugs, by many times in some cases, through increased generic competition."[104]

In short, the entire premise of Hatch-Waxman's generic-encouraging provisions is that the market fails to generate adequate price competition among branded alternatives, even when the brand drugs are off patent. Once again, the price disconnect, not patents, permits supracompetitive prices. Generic competition is necessary precisely because the price disconnect creates a significant market failure.

5. Prices When the Disconnect Is Solved

Finally, many jurisdictions outside the United States require prescriptions but have taken effective action to reconnect the price/quality decision. The success of these price-reconnection techniques in delivering competitive prices again points to the price disconnect, not valuable innovations, as the culprit in generating supracompetitive prices in the United States.[105]

Some nations reunite the drug choice and payment obligation by having the payor—often a state agency—participate in drug selection by imposing a formulary or determining reimbursement levels under state-run insurance plans. Other nations reunite choice and payment by giving the doctor a financial stake in the product selection, for example by requiring a prescription "budget" and giving the doctor a financial incentive to stay within it.[106] Recognizing that the price disconnect is itself the result of government regulation—the requirement that the consumer get a prescription—other nations directly regulate the price of prescription drugs.[107]

All of these techniques have been successful in bringing more competitive prices to consumers. Although methodological issues complicate international price comparisons, one conclusion is beyond dispute: the prices of branded prescription drugs in the United States significantly exceed those in other developed nations.[108] By contrast, when there is no price disconnect—for example, for generic prescription drugs and over-the-counter drugs—the

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generic's AB-rated counterpart, not other drugs in the therapeutic class. *See supra* note 74 and *infra* notes 106–07 and accompanying text.

104 130 CONG. REC. 15791, 15847 (1984) (statement of Sen. Hatch).

105 *See* Jayadev & Stiglitz, *supra* note 69; Steve D. Shadowen et al., *Bringing Market Discipline to Pharmaceutical Product Reformulations*, 41 INT'L REV. OF INTELL. PROP. & COMPETITION L. 698 (2011) (including a detailed survey of international price-disconnect remedies).

106 Shadowen et al., *supra* note 105, at 718–20.

107 *Id.* at 716–17.

108 *See, e.g.*, MCKINSEY GLOBAL INST., ACCOUNTING FOR THE COST OF HEALTH CARE IN THE UNITED STATES (2008); DAVID A. SQUIRES, THE U.S. HEALTH SYSTEM IN PERSPECTIVE: A COMPARISON OF TWELVE INDUSTRIALIZED NATIONS 6–7 (2011); Patricia M. Danzon & Michael F. Furukawa, *International Prices and Availability of Pharmaceuticals in 2005*, 27 HEALTH AFF. 221, 227–29 (2008); Richard G. Frank, *Prescription-Drug Prices*, 351 NEW ENG. J. MED. 1375 (2004); Marcio Machado et al., *International Drug Price Comparisons: Quality Assessment*, 29 REV. PANAM SALUD PUBLICA 46, 49 (2011).

United States has among the most competitive prices among developed nations.[109]

D. Market Failure's Relevance to Antitrust Analysis

To date, the United States has resisted the regulatory remedies that other developed nations have applied to the price-disconnect market failure. Instead, the United States has relied exclusively on two more market-oriented remedies: generic drugs and antitrust law.

As noted above, the Hatch-Waxman Act provides a pathway for the FDA to approve the marketing of generic drugs. The Act has effectively promoted price competition in limited circumstances. Generic drugs offer substantial price competition, but *only to the specific branded drug for which the prescription was written*, and *only after the patent for that specific drug is no longer in effect.* In a crowded class of me-too drugs, the entry of a generic version of Brand A will quickly cause most of the consumers of Brand A to switch to the generic. But the price disconnect almost always prevents that generic entry from generating competitive prices for Brands B, C, D, or E.[110]

In other words, generic competition may prevent the specific brand counterpart from extending its monopoly power beyond the expiration of its patents. But the price disconnect prevents generic competition from generating competitive prices within the therapeutic category. Price competition exists within only one slice of the therapeutic-category pie, with consumers unlucky enough to have doctors prescribing other branded drugs in the class continuing to pay supracompetitive prices. This is unsurprising given that this was the limited, stated purpose of the Hatch-Waxman Act.[111]

Through product reformulations, brand firms can disable even this limited, generic-drug-based, partial remedy to the price disconnect. U.S. courts have recently begun subjecting these reformulations to antitrust scrutiny. Although such scrutiny cannot solve the price-disconnect problem within a therapeutic class, it can help prevent manufacturers from extending their market power even after their patents are no longer effective.[112]

The importance of antitrust's role in this setting should be apparent. These markets suffer from a market failure resulting from the price disconnect. This market failure has prompted other developed nations to imple-

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109 CHRIS L. PETERSON & RACHEL BURTON, CONG. RESEARCH SERV., RL34175, U.S. HEALTH CARE SPENDING: COMPARISON WITH OTHER OECD COUNTRIES 22–24 (2007); Danzon & Furukawa, *supra* note 108, at 229–30.

110 *See generally* E.M. KOLASSA, THE STRATEGIC PRICING OF PHARMACEUTICALS 232 (2009) ("Generics, in general, devastate the sales *only* of the originator brand . . . . There is a misconception that the entrance of a generic into a market will affect the shares and use of other products in the category as well. We have not found this to be true in most cases."); *see also supra* note 74 (citing testimony from *Nexium* antitrust litigation).

111 *See supra* Section I.B.

112 Preventing this extension of market power (often after the brand has received nonpatent exclusivities and a 30-month stay) would promote a central purpose of the Hatch-Waxman Act: facilitating price competition.

ment comprehensive regulatory remedies including direct price regulation, state-run formularies, and financial incentives for prescribing doctors. The United States has responded with a market-based solution—the promotion of generic drugs—that solves only one small part of the problem. When manufacturers try to disable even that modest remedy, the United States again forgoes any comprehensive regulatory solution, but instead relies solely on the ad hoc application of antitrust law.[113]

Fortunately, antitrust law is able to consider the regulatory regime, in this case, the Hatch-Waxman Act, state DPS laws, and the price disconnect. In *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*, the Supreme Court made clear that courts must take "careful account" of "the pervasive federal and state regulation characteristic of the industry"[114] and must "recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies."[115] In an important case discussed below,[116] the *Namenda* court relied on this principle in rejecting the argument that "antitrust law is not a vehicle for enforcing the 'spirit' of drug laws."[117] And the *Namenda* court specifically recognized that "what Defendants call 'free riding' . . . is authorized by law; is the explicit goal of state substitution laws; and furthers the goals of the Hatch-Waxman Act by promoting drug competition and by preventing the 'practical extension of [brand drug manufacturers'] monopoly . . . beyond the expiration of the[ir] patent[s]."[118]

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113 Economic and structural hurdles prevent managed care organizations (MCOs) from defeating product-hopping schemes. *See generally* GAL, *supra* note 50, at 1 (discussing how a survey of benefit managers revealed that "the top two reasons [that MCOs cannot defeat product hops] are (i) pharma companies' resources and ingenuity in addressing formulary restrictions and (ii) the symbiotic relationship between pharma and managed care (blocking drug A would lead to lower rebate on drug B)"). Importantly, a collective action problem prevents individual MCOs from countering product-hopping schemes. *See, e.g.*, *id.* at 6 ("The US payor system is fragmented—a well motivated, organized pharma company with a portfolio of drugs can effectively overcome payor tools or at least make them so costly to implement that the payors are forced to the negotiation table."); Shadowen et al., *supra* note 1, at 21 ("An individual MCO's success in discouraging doctors from writing scripts for the new product is . . . dependent on the action of its competitors. Paradoxically, those competitors' incentive is to do nothing and instead free-ride on others' efforts.").

114 540 U.S. 398, 411–12 (2004) (quoting United States v. Citizens & S. Nat'l Bank, 422 U.S. 86, 91 (1975)).

115 *Id.* (quoting Concord v. Bos. Edison Co., 915 F.2d 17, 22 (1st Cir. 1990)).

116 *See infra* Section III.E.

117 New York *ex rel.* Schneiderman v. Actavis PLC (*Namenda*), 787 F.3d 638, 658 (2d Cir. 2015).

118 *Id.* at 657–58 (second, third, fourth, and fifth alterations in original) (citation omitted) (citing FTC v. Actavis, Inc., 133 S. Ct. 2223, 2228 (2013)) (quoting H.R. REP. NO. 98-857, pt. 2, at 4 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2686, 2688); *see also Actavis*, 133 S. Ct. at 2228 (recognizing Hatch-Waxman Act's bestowal on generics of ability to "piggyback" on brand's approval efforts, which speed "'the introduction of low-cost generic drugs to market' . . . thereby furthering drug competition" (quoting Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 132 S. Ct. 1670, 1676 (2012))).

If any industry requires a specialized, nuanced analysis, it is the pharmaceutical industry. There is market failure, generic drugs can remedy one small part of the problem, product reformulations can disable even that partial remedy, and antitrust law is the only available means in the United States of policing reformulations. We now turn to courts' analyses of these issues, which have garnered mixed results in considering the regulatory regime and understanding the competitive consequences of product hopping.

III. JUDICIAL AND ACADEMIC ANALYSIS

Given the complexity of the relevant economics and market structure, it is not a surprise that judicial analysis of product hopping has varied widely. Just as important, the timing of the cases has shaped the development of the law. In particular, the factual settings of the first two cases set the stage for the analysis in later cases.

Section A begins with *TriCor*, in which the court offered a nuanced analysis, albeit one that some later courts restricted to "hard switches" (in which the brand firm removes the old product from the market). Section B discusses the *Walgreens* case, which addressed a "soft switch" (in which the brand leaves the original product on the market) and offered a simplistic analysis of consumer choice.

The *Suboxone* case, addressed in Section C, revealed aspects of both hard and soft switches, with the court offering a nuanced understanding of the regulatory regime. The *Mylan* case addressed in Section D, in contrast, is an outlier that completely neglected the regime. The *Namenda* opinion, addressed in Section E, understood the regulatory regime in the context of hard switches, but overemphasized the distinction between hard and soft switches and introduced a new, underinclusive framework based on coercion. While the courts generally have considered the regulatory regime, Section F discusses the recent work of scholars who have paid less attention to this context.

A. TriCor: *Hard Switch, Nuanced Analysis*

In *Abbott Laboratories v. Teva Pharmaceuticals USA, Inc.* (*TriCor*), the Delaware district court provided the first analysis of product hopping.[119] It considered Abbott's series of changes to its billion-dollar cholesterol and triglycerides drug, TriCor. Abbott marginally lowered the drug's strength, switched from a capsule to a tablet, stopped selling capsules, bought back existing supplies of capsules from pharmacies, and changed the code for capsules in the national drug database to "obsolete."[120] After the generics developed equivalents for the reformulated tablets, Abbott again transitioned to a new (marginally lower-strength) tablet, stopped selling the original tablets, and again changed the database code to "obsolete."[121] In removing the old

119 432 F. Supp. 2d 408 (D. Del. 2006).

120 *Id.* at 415–16.

121 *Id.* at 418.

drugs from the market, Abbott engaged in what has since been deemed a "hard switch."

Because of the "nature of the pharmaceutical drug market," the court applied the Rule of Reason.[122] The defendants' proposed standard of per se legality "presuppose[d] an open market where the merits of any new product [could] be tested by unfettered consumer choice."[123] But in this case the complaint alleged a price disconnect, and in addition the defendants "allegedly prevented such a choice by removing the old formulations from the market while introducing new formulations."[124] Both circumstances justified "an inquiry into the effect of Defendants' formulation changes."[125]

The court did not require the plaintiffs "to prove that the new formulations were absolutely no better than the prior version or that the only purpose of the innovation was to eliminate [generic competition]."[126] Rather, "if Plaintiffs show anticompetitive harm from the formulation changes, that harm will be weighed against any benefits presented by Defendants."[127]

The court also found it irrelevant that the reformulation did not completely bar the generics from entering the market, but only prevented automatic substitution at the pharmacy counter.[128] The analysis asks not whether exclusionary conduct bars competitors "from all means of distribution," but only whether it precludes access to the "cost-efficient ones."[129] While generics "may be able to market their own branded versions of the old TriCor formulations, they cannot provide generic substitutes for the current TriCor formulation, which is alleged to be their cost-efficient means of competing in the pharmaceutical drug market."[130] Such an opportunity "has allegedly been prevented entirely by Defendants' allegedly manipulative and unjustifiable formulation changes," and "[s]uch a restriction on competition, if proven, is sufficient to support an antitrust claim."[131]

In short, in the first judicial treatment of product hopping, the court offered a thoughtful approach that considered the realities of pharmaceutical markets—in particular, the existence of the price disconnect and the importance of generic substitution—and relied on the Rule of Reason in balancing the anticompetitive and procompetitive effects of product hopping. Some later courts, however, limited the reach of the ruling by cabining its reasoning to the "hard switch" scenario.

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122 *Id.* at 422.

123 *Id.*

124 *Id.*

125 *Id.* (citing HERBERT HOVENKAMP ET AL., IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW §§ 12.5, 15.3c1 (2015)).

126 *Id.*

127 *Id.* (citing United States v. Microsoft Corp., 253 F.3d 34, 59, 66–67 (D.C. Cir. 2001)).

128 *See id.* at 423 (citing United States v. Dentsply Int'l, Inc., 399 F.3d 181, 191 (3d Cir. 2005)).

129 *Id.* (quoting *Microsoft Corp.*, 253 F.3d at 64).

130 *Id.*

131 *Id.*

B. Walgreens*: Soft Switch, Simplistic Choice*

In particular, such a course was shaped by the second case, *Walgreen Co. v. AstraZeneca Pharmaceuticals* (*Walgreens*), which involved AstraZeneca's conversion from heartburn drug Prilosec to Nexium.[132] The plaintiffs alleged that there was "almost no difference" between the drugs and there was "no pharmacodynamic reason" the two forms would have different effects in the body.[133] The plaintiffs also alleged that AstraZeneca "aggressively promoted and 'detailed' Nexium to doctors" while stopping its promotion and detailing of Prilosec.[134] And they claimed that AstraZeneca was able to switch the market (to a drug receiving patent protection for an additional thirteen years) only through "distortion and misdirection in marketing, promoting and detailing Nexium."[135]

Unlike the court in *TriCor*, the District of Columbia court ignored the plaintiffs' detailed allegations of the price disconnect in pharmaceutical markets. The court granted AstraZeneca's motion to dismiss, concluding that "there is no allegation that AstraZeneca eliminated any consumer choices."[136] But that conclusion rested on three factual assertions, all of which required the court to ignore the price disconnect. The court asserted as facts that:

> [1] AstraZeneca added choices . . . [by] introduc[ing] a new drug to compete with already-established drugs . . .[;]
>
> [2] [D]etermin[ations of] which product among several is superior . . . are left to the marketplace[; and]
>
> [3] New products are not capable of affecting competitors' market share unless consumers prefer the new product.[137]

Each of those factual assertions contradicted plaintiffs' allegations regarding the price disconnect and its effects. In a price-disconnected market, switching doctors' prescriptions from an original branded product (facing impending generic competition) to a reformulated product (not facing generic competition)—what the court called "add[ing] choices"—significantly impairs consumers' ability to choose a generic product. The "added choice" of the reformulated product is actually the means by which consumers' real choice is eliminated. Moreover, the question is not which product among several is superior, but rather which product offers the consumer the *best trade-off between price and quality*, a determination that "the marketplace" cannot make in a price-disconnected market. In fact, the switching of the market from the original to the reformulated version certainly *is* capable of affecting competitors' market shares despite consumers' preferences. The court's contrary assertion ignored not only the plaintiffs' detailed allegations,

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132 534 F. Supp. 2d 146 (D.D.C. 2008).
133 *Id.* at 149.
134 *Id.* (footnote omitted).
135 *Id.* at 148–49.
136 *Id.* at 151.
137 *Id.*

but also the economic rationale of fifty state DPS statutes and the Hatch-Waxman Act.[138] None of those statutes would be necessary if consumers in fact revealed their preferences through price/quality choices.

In addressing a soft switch, the court confronted a different scenario than that in *TriCor*. But the divide between hard and soft switches did not need to be as stark as the court made it. The die was cast, however, when the court articulated an analysis of consumer choice that, even if it would make sense in non-pharmaceutical markets where consumers make the price/quality tradeoff, does not capture the realities of drug markets.

C. Suboxone*: Hard/Soft Switch, Nuanced Analysis*

A third court considered elements of both hard and soft switches in a nuanced analysis of the regulatory regime. In *In re Suboxone Antitrust Litigation*,[139] the Eastern District of Pennsylvania court considered allegations that Reckitt switched the market from opioid dependence-treating Suboxone tablets to sublingual film. Reckitt allegedly promoted Suboxone film to physicians, disparaged Suboxone tablets, warned of false safety concerns, publicly announced the removal of tablets for these fabricated safety reasons but did not remove the tablets until six months later, and raised the price of tablets in relation to film even though film was more expensive to manufacture and package.[140]

The court began its analysis by noting that "[b]ecause ordinarily innovation will also inflict harm upon competitors, 'courts should not condemn a product change . . . unless they are relatively confident that the conduct in question is anticompetitive.'"[141] But "when the introduction of a new product by a monopolist prevents consumer choice, greater scrutiny is appropriate,"[142] with the test (similar to *TriCor*) for whether conduct is exclusionary based "not [on] total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit."[143]

The court found that the conduct at issue "seems to fall somewhere between that alleged in" *Walgreens* and *TriCor*.[144] The behavior was more concerning than that in *Walgreens* because Reckitt removed tablets from the market, but less concerning than that in *TriCor* because Reckitt did not buy back tablets or label an old product "obsolete."[145] The court made clear that "simply introducing a new product on the market, whether it is a superior

138 *See id.* The district court acknowledged the price disconnect only inadvertently, alternately identifying patients and doctors as the "consumers" who supposedly did not suffer the "elimination of consumer choice." *Id.* at 151–52.

139 64 F. Supp. 3d 665 (E.D. Pa. 2014).

140 *Id.* at 674.

141 *Id.* at 679–80 (second alteration in original) (quoting Abbott Labs. v. Teva Pharm. USA, Inc. (*TriCor*), 432 F. Supp. 2d 408, 421 (D. Del. 2006)).

142 *Id.* at 680 (quoting *TriCor*, 432 F. Supp. 2d at 421).

143 *Id.* (quoting United States v. Dentsply Int'l, Inc., 399 F.3d 181, 191 (3d Cir. 2005)).

144 *Id.* at 681.

145 *Id.*

product or not, does not, by itself, constitute exclusionary conduct."[146] Rather, "[t]he key question is whether the defendant combined the introduction of a new product with some other wrongful conduct, such that the comprehensive effect is likely to stymie competition, prevent consumer choice and reduce the market's ambit."[147] Crucially, "[t]his analysis must be undertaken with the somewhat unique characteristics of the pharmaceutical market in mind."[148]

Applying this analysis, the court found that "the facts presented sufficiently allege that the disparagement of Suboxone tablets took place alongside 'coercive' measures," as "[t]he threatened removal of the tablets from the market in conjunction with the alleged fabricated safety concerns could plausibly coerce patients and doctors to switch from tablet to film."[149] The court recognized that "Plaintiffs have plausibly alleged that various market forces unique to the pharmaceutical industry make generic substitution the cost-efficient means of competing for companies selling generic pharmaceuticals."[150] In particular, the court noted that the "disconnect" that "exists between the person paying for the prescription and the person selecting the appropriate treatment" led to "the ordinary market forces that would allow consumers to consider price when selecting a product [being] derailed."[151] A patient would not be able to "simply request to receive a generic from his or her pharmacist because the film and the generic tablets are not [bioequivalent] and thus may not be substituted."[152] The court noted but did not rely on the dichotomy between hard and soft switches, instead conducting an analysis rooted in the regulatory framework and ultimately concluding that the plaintiffs "plausibly pleaded exclusionary conduct."[153]

D. Doryx*: Ignored Regulatory Regime*

While the *Suboxone* court grounded its decision in the regulatory framework, the Third Circuit in *Mylan Pharmaceuticals v. Warner Chilcott* (*Doryx*)[154] did not. In that case, Warner Chilcott engaged in an array of behaviors that resembled those of Abbott in *TriCor*: it stopped selling capsule versions of acne-treating Doryx to wholesalers; removed Doryx capsules from its website; worked with retailers to "auto-reference" the Doryx tablet whenever a doctor filed a Doryx prescription; informed wholesalers, retailers, and dealers that "Doryx Capsules have been replaced by Doryx Tablets;" and bought back and

146 *Id.* at 682.
147 *Id.*
148 *Id.*
149 *Id.*
150 *Id.* at 683–84.
151 *Id.* at 684.
152 *Id.*
153 *Id.*
154 No. 15-2236, 2016 WL 5403626 (3d Cir. Sept. 28, 2016).

destroyed capsule inventory.[155] Despite allegations of hard switches and lack of economic sense, the court rejected Mylan's claims of anticompetitive conduct, finding that "Mylan was not foreclosed from the market."[156] Even though it found, "viewing the facts in the light most favorable to Mylan, that Defendants had indeed made the Doryx 'hops' primarily to 'delay generic market entry,'" it affirmed summary judgment for the Defendants.[157]

After concluding that the plaintiff—the competitor generic manufacturer—failed to adduce evidence of monopoly power,[158] the court indicated that it would have affirmed summary judgment on the alternative ground that the plaintiff failed to satisfy its initial burden of introducing evidence of anticompetitive conduct under the Rule of Reason.[159] But the court never explained what it considered to be an anticompetitive effect; nor did it consider whether a substantial reduction in the prescription base available for automatic generic substitution would count. Instead, in direct opposition to the Supreme Court's instruction that the relevant effect is on consumers, not competitors,[160] the court focused exclusively on the effect of Warner Chilcott's conduct on Mylan, the generic *competitor*, never even mentioning the effect on *consumers*.[161]

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155 *Id.* at *3.

156 *Id.* at *10.

157 *Id.* at *5 (quoting Mylan Pharm., Inc. v. Warner Chilcott, PLC (*Doryx*), No. 12-3824, 2015 WL 1736957, at *5 (E.D. Pa. Apr. 16, 2015)).

158 This Article does not address the monopoly-power element of the case. But just to mention some of the most glaring of the *Doryx* court's fundamental errors on this issue: (1) the court's conclusion that Warner Chilcott lacked monopoly power is inconsistent with the district court's finding that Warner Chilcott's "primary" purpose was to "delay generic market entry," *id.* (internal quotation marks omitted), as a manufacturer without monopoly power typically will not spend money to exclude a rival; (2) the court engaged in a muddled analysis of direct evidence of market power in the form of price-cost margins and output reductions; (3) the court acknowledged the existence of the price disconnect, *id.* at *2, but ignored its role in generating market power; (4) the court's crediting of anecdotal evidence that "some" and a "number" of managed care organizations "sought to" generate price competition among therapeutic alternatives, *id.* at *9 (quoting *Doryx*, 2015 WL 1736957, at *9 (internal quotation marks omitted)), did not address the relevant issue—the *actual effect* of these efforts on *marketwide* prices; (5) the court applied the wrong legal (and economic) standard for defining relevant antitrust markets, incorrectly holding that products are in the same market if there is "the existence of cross-elasticity" between them, *id.* at *10, when the proper standard is whether *sufficient* cross-elasticity exists between them *to constrain the price to the competitive level*; and (6) relatedly, the court failed to consider that its analysis succumbed to the *Cellophane* fallacy in its assumption that lost sales from price increases revealed a lack of monopoly power instead of a monopolist's inability to charge an infinite price.

159 *Id.*

160 *E.g.*, Harrison Aire, Inc. v. Aerostar Int'l, Inc., 423 F.3d 374, 385 (3d Cir. 2005) (noting that the Supreme Court in *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477 (1977), held that "antitrust laws protect consumers, not competitors").

161 *Doryx*, 2016 WL 5403626, at *11. We focus our analysis on only some of the most glaring of the court's fundamental mistakes, not addressing, for example, its mischaracterization of the facts and fundamental holding in *Namenda*. *See id.*

Regarding the product hops' effects on Mylan (and assuming this were an appropriate inquiry, which it is not), the court offered only a series of non-sequiturs, asserting that Warner Chilcott's conduct was not anticompetitive because:

(1) Mylan received a 180-day exclusivity period under the Hatch-Waxman Act[162] (although Mylan's sales at relatively high generic prices are irrelevant to whether Warner Chilcott substantially reduced the number of sales and profits that Mylan would have made absent the product hops);

(2) Mylan set its generic price higher than the brand price for a period of time[163] (although the court failed to explain the relevance of this fact and did not consider whether the product hop caused Mylan's pricing strategy—a generic unable to distribute its product through automatic substitution might well increase price for the sales it can make);

(3) Mylan made profits of $146.9 million on the sales of generic Doryx[164] (although that number is meaningless unless compared to the profits that Mylan would have made absent the product hops).[165]

Finally, the Court offered a hodge-podge potpourri for courts to decide other product-hopping cases, stating that courts should balance exceedingly broad policy goals, such as "encouraging innovation," "protect[ing] consumers," and "ensur[ing] fair competition."[166] Among the "non-exhaustive" factors that courts may consider is the need to be "wary" of "turning courts into tribunals over innovation sufficiency."[167] Presumably another factor to consider is the decisions of fifty states and Congress to promote generic competition. The court provided no guidance at all on how courts are to balance these objectives.

E. Namenda*: Robust Regulatory Analysis, Improper Coercion Focus*

The Second Circuit has offered another recent treatment. In *New York ex rel. Schneiderman v. Actavis PLC* (*Namenda*), the court upheld a preliminary injunction preventing brand firm Forest from withdrawing its original drug from the market.[168] As Forest's Alzheimer's drug Namenda IR (taken twice a day) neared the end of its patent term, it introduced Namenda XR (taken

162 *Id.*

163 *Id.*

164 *Id.*

165 The court also asserted that Warner Chilcott had "offered strong evidence" of procompetitive justifications but did not discuss evidence sufficient to defeat summary judgment such as whether Mylan could rebut those justifications, show that Warner Chilcott could have achieved those objectives in a less restrictive manner, or show that the conduct was anticompetitive on balance.

166 *Id.* at *12.

167 *Id.* While the court noted that Congress could have chosen to expressly make product hopping unlawful, *id.* at *12 n.88, it also could have enacted special antitrust rules for product hops or made them immune from antitrust scrutiny altogether. The court also implied, without citation to any facts, that the price disconnect generates market power only in the presence of "extreme [doctor] coercion" or other similar factors. *Id.* at *12.

168 787 F.3d 638 (2d Cir. 2015).

once a day), with a patent expiring fourteen years later.[169] Although it initially planned to keep IR on the market (the soft switch), it later implemented a plan to effectively withdraw IR from the market (the hard switch).[170]

The court found that "neither product withdrawal nor product improvement alone is anticompetitive," but "when a monopolist *combines* product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits and to impede competition, its actions are anticompetitive under the Sherman Act."[171] The court also rejected a defense based on "free riding" since "generic substitution by pharmacists following the end of Namenda IR's exclusivity period [ ] is authorized by law; is the explicit goal of state substitution laws;" and also "furthers the goals of the Hatch-Waxman Act by promoting drug competition and by preventing the 'practical extension of [the brand firm's] monopoly . . . beyond the expiration of the[ ] patent[ ].'"[172]

The court held that the defendants' justifications were pretextual, and that even if they were not, any benefits were "outweighed by the anticompetitive harms."[173] It found monopolization from the combination of "withdrawing a successful drug from the market" and "introducing a reformulated version of that drug," which forced patients to "switch to the new version" and "imped[ed] generic competition, without a legitimate business justification."[174] The court then upheld an injunction because of the irreparable harm from the "planned hard switch strategy."[175] The court required the defendants to continue making Namenda IR tablets available.[176]

While the court understood the regulatory framework, it applied a test based on coercion that was underinclusive in targeting antitrust harm. The court stated that

> [a]s long as Defendants sought to persuade patients and their doctors to switch from Namenda IR to Namenda XR while both were on the market (the soft switch) and with generic IR drugs on the horizon, patients and doctors could evaluate the products and their generics on the merits in furtherance of competitive objectives.[177]

The court focused on Forest's "forc[ing] patients to switch" from Namenda IR to Namenda XR, and cited the defendants' figures that a soft

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169 *Id.* at 642.

170 *Id.* at 658.

171 *Id.* at 653–54 (citations omitted).

172 *Id.* at 657–58 (second alteration in original) (citation omitted) (citing FTC v. Actavis, Inc., 133 S. Ct. 2223, 2228 (2013)) (quoting H.R. REP. No. 98-857, pt. 2, at 4 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2686, 2688).

173 *Id.* at 658.

174 *Id.* at 659.

175 *Id.* at 660–61 (quoting New York v. Actavis, PLC, No. 14-Civ.-7473, 2014 WL 7015198 (S.D.N.Y. Dec. 11, 2014)).

176 *Id.* at 649.

177 *Id.* at 654.

switch would convert only 30% of patients while a hard switch would convert 80 to 100%.[178] The court stated that "[h]ad Defendants allowed Namenda IR to remain available until generic entry, doctors and Alzheimer's patients could have decided whether the benefits of switching to once-daily Namenda XR would outweigh the benefits of adhering to twice-daily therapy using less-expensive generic IR (or perhaps lower-priced Namenda IR)," but "[b]y removing Namenda IR from the market prior to generic IR entry, Defendants sought to deprive consumers of that choice."[179]

While the court appreciated the regulatory regime, its coercion-based framework does not make room for potential soft-switch harms that arise from the unique nature of drug markets and that might not make economic sense.

F. Commentators: Abandonment of Antitrust Analysis

Though many of the courts could have benefited from further attention to the price-disconnect market failure, at least (with the exception of *Walgreens* and *Doryx*) they anticipated a nontrivial role for antitrust law. That is more than can be said for commentators Joshua D. Wright, a former Federal Trade Commissioner, and Judge Douglas H. Ginsburg, a Senior Judge on the U.S. Court of Appeals for the D.C. Circuit, in their joint comment to the Canadian Competition Bureau on its draft updated Intellectual Property Enforcement Guidelines.[180] In that comment, the authors offer a constricted approach to product hopping that would limit antitrust more than any of the judicial approaches described above.

Wright and Ginsburg "recommend against imposing a competition law sanction on product switching absent clear and convincing objective evidence that [the reformulated product] represents a sham innovation with zero or negative consumer welfare benefits."[181] The authors worry that "applying a standard competition law analysis is likely to deter innovation that would have benefitted consumers."[182] The given reason is that "innova-

178 *Id.*

179 *Id.* at 655.

180 Joshua D. Wright & Douglas H. Ginsburg, Comment on the Canadian Competition Bureau's Draft Updated Intellectual Property Enforcement Guidelines (Aug. 10, 2015), https://www.ftc.gov/system/files/documents/public_statements/734661/150810canadacomment.pdf. The Guidelines concluded that product switching could constitute an abuse of a dominant position based on factors such as the likely effect of a brand's conduct on a generic's ability to compete and whether the brand's purpose was "to delay or foreclose" generic supply. COMPETITION BUREAU CAN., ENFORCEMENT GUIDELINES: INTELLECTUAL PROPERTY, Ex. 9A, at 37–39 (2016). To the extent it is relevant, Carrier served as a consultant to the Bureau on the Guidelines.

181 Wright & Ginsburg, *supra* note 180, at 1.

182 *Id.* at 2. For a similar argument, see Dennis W. Carlton et al., A Critical Evaluation of the FTC's Theory of Product Hopping as a Way to Promote Competition 13–15 (July 8, 2016) (unpublished manuscript), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2808822.

tions, including even small changes in product design, can generate significant consumer benefits."[183]

The authors claim that "[c]ompetition law is not a suitable instrument for micromanaging product design and innovation" as it "requires competition agencies and courts to weigh the benefits to consumers from the innovation against any costs to consumers arising from the diminution of competition."[184] The agencies and courts are "ill-equipped" to make these determinations, and it is "unclear" whether such a balancing "can be done at all."[185]

The authors also contend that "product switching does not amount to exclusionary conduct because the generic company is still free to compete and is 'able to reach consumers through, *inter alia*, advertising, promotion, cost competition, or superior product development.'"[186]

The authors trust not the antitrust agencies but the "judgment [of] the value of product design changes levied by consumers in the market."[187] The apparent problem of applying antitrust law is that agencies and courts would be "substituting their judgment for the judgment made by consumers."[188] The authors claim that subjecting drug reformulations to antitrust scrutiny "most remarkably assumes that pharmaceutical markets are somehow so different from other product markets that producers are free to ignore consumer judgments about the value of product innovations."[189]

At least four problems undermine the authors' argument. First, no empirical or other evidence suggests that a well-structured antitrust analysis would deter innovation in this setting. Quite the contrary. A proper antitrust framework could subject to scrutiny only those reformulations that are temporally linked to the imminent introduction of the generic. Clear, bright lines could signal to brand companies that their reformulations would not be subject to *any* antitrust scrutiny unless they engage in certain suspect behavior. In essence, brand firms would "volunteer" for antitrust scrutiny by engaging in the identified conduct. The sole empirical analysis on this subject indicates that just 20% of reformulated drugs are temporally linked to the imminent introduction of the generic.[190] And the five cases litigated to date represent no more than 1% of all reformulations in the past twenty years.[191]

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183 Wright & Ginsburg, *supra* note 180, at 2.

184 *Id.*

185 *Id.*

186 *Id.* at 3 (quoting Mylan Pharm., Inc. v. Warner Chilcott, PLC (*Doryx*), No. 12-3824, 2015 WL 1736957, at *14 (E.D. Pa. Apr. 16, 2015)); *see also* Carlton et al., *supra* note 182, at 8–9.

187 Wright & Ginsburg, *supra* note 180, at 3.

188 *Id.* at 4.

189 *Id.*

190 Shadowen et al., *supra* note 1, at 26–27 (finding that 344 of 425 reformulations occurred outside the Generic Window).

191 *Id.*

The evidence makes clear that, for the subset of potentially anticompetitive reformulations, antitrust scrutiny is likely not to deter innovation, but to spur it. Brand firms often *withhold incremental innovations from the market* to use them later as part of a product hop.[192] For example, manufacturers in the *TriCor* case delayed seeking a new indication for the original product, reserving it exclusively for the reformulated product, even though "[t]he data necessary to get the new indication was available much earlier."[193] Similarly, in Warner-Lambert's admission of criminal liability for promoting off-label uses of seizure-treating Neurontin, it conceded that a "principal reason[ ] for not seeking FDA approval for those uses was that it wanted to reserve them for a later promotional campaign for its reformulated product."[194] And in *Namenda*, Forest waited until generic competition for twice-daily Namenda was imminent before introducing the once-daily version, even though "[a]ll other Alzheimer's disease treatments are administered once a day."[195] It is telling that Forest had obtained FDA approval to market the once-daily version three years earlier but had withheld it from the market until entry of the twice-daily generics was looming.[196]

More broadly, in *Namenda* the court found that the defendants "presented no evidence to support their argument that antitrust scrutiny of the pharmaceutical industry will meaningfully deter innovation."[197] The Second Circuit noted that "immunizing product hopping from antitrust scrutiny may deter significant innovation by encouraging manufacturers to focus on switching the market to trivial or minor product reformulations rather than investing in the research and development necessary to develop riskier, but medically significant innovations."[198] Any serious argument that antitrust scrutiny might deter innovation must contend with the substantial indications that the *absence* of scrutiny tempts brands to withhold innovations from the market and invest in trivial modifications. In short, industry realities undercut contrary, evidence-free pronouncements about adverse effects on innovation.[199]

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192 MARIBEL RIOS, THE OUTSOURCING ADVANTAGES IN FORMULATION DEVELOPMENT 40 (2005) (brands often "intentionally hold[ ] back a twice- or once-a-day formulation to use against generic competition later on").

193 Shadowen et al., *supra* note 105, at 710.

194 *Id.*

195 New York *ex rel.* Schneiderman v. Actavis PLC (*Namenda*), 787 F.3d 638, 647 (2d Cir. 2015).

196 *Id.*

197 *Id.* at 659.

198 *Id.*; *see also* C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. EMPIRICAL LEGAL STUD. 613, 615 (2011) ("Brand-name firms have sought increasing recourse to ancillary patents on chemical variants, alternative formulations, methods of use, and relatively minor aspects of the drug.").

199 Nor is it true, as Wright and Ginsburg assert, that an antitrust analysis would require agencies and courts to weigh the benefits and detriments to consumers. Wright & Ginsburg, *supra* note 180, at 2. As we develop in detail below, agencies and courts can and

Second, after assuming that antitrust scrutiny would harm innovation, Wright and Ginsburg double down by positing, without support, that these asserted effects outweigh product hopping's well-established negative price effects. On a blockbuster drug, a product hop can deprive consumers of $1 billion or more in cost savings, with little, no, or negative gain in product quality.[200] Wright and Ginsburg offer no empirical or even theoretical basis for believing that *in this industry*, where the gains from price competition are so enormous, any supposed positive innovation effects would outweigh the documented negative price effects.[201] Indeed, the fact that brands withhold innovations from the market to impair generic competition speaks volumes. Such delayed reformulations provide strong evidence that losses to consumers from impaired generic competition are greater than any gains from increased quality.[202]

Third, Wright and Ginsburg's assertion that, notwithstanding the product hop, generic firms are still able to reach "consumers"[203] is curious. As the *TriCor* and *Suboxone* courts explained, the law (and economics) is clear that conduct can harm consumers—that it can be condemned as exclusionary—if it substantially impairs competition while not preventing it altogether.[204] Wright and Ginsburg suggest that generics, like brands, can market their products through detailing and product innovation.[205] But again, this ignores the industry's regulatory structure and competitive dynamics. Typically, once the brand's patents are no longer effective, *no one*—neither the brand nor any generics—can profitably market the product on a basis other than price.[206]

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should apply a no-economic-sense test that judges product reformulations based on objective economic evidence of their value *to the manufacturer*.

200 On a brand drug with $1 billion in annual sales, the lost savings from impairing generic competition can easily be $765 million annually: generics take 90% of the unit sales, at an average price discount (with multiple generics in the market) of at least 85%. *See, e.g.*, John LaMattina, *Patent Expirations of Crestor and Zetia and the Impact on Other Cholesterol Drugs*, FORBES (Jan. 18, 2016), http://www.forbes.com/sites/johnlamattina/2016/01/18/patent-expirations-of-crestor-and-zetia-and-the-impact-on-other-cholesterol-drugs/#2b708f805c59.

201 Wright & Ginsburg, *supra* note 180.

202 If the value of the "innovation" to consumers were greater than the value to the manufacturer of impairing generic competition, the manufacturer would immediately introduce the innovation in order to reap the increased gains. *See, e.g.*, Natalie Mizik & Robert Jacobson, *Trading Off Between Value Creation and Value Appropriation: The Financial Implications of Shifts in Strategic Emphasis*, 67 J. MARKETING 63, 65 (2003).

203 Wright & Ginsburg, *supra* note 180, at 3.

204 *See In re* Suboxone, 64 F. Supp. 3d 665 (E.D. Pa. 2014); Abbott Labs. v. Teva Pharm. USA, Inc. (*TriCor*), 432 F. Supp. 2d 408, 416–18 (D. Del. 2006); *see also* Teva Pharm. USA, Inc. v. Abbott Labs. (*TriCor II*), 580 F. Supp. 2d 345 (D. Del. 2008).

205 *See also* Carlton et al., *supra* note 182, at 8–9.

206 This is why, when facing imminent generic competition, brands almost always stop promoting the product. Shadowen et al., *supra* note 1, at 15. To the extent Wright and Ginsburg suggest that generics are free to market their products based on price, they fail to

In this setting, costs incurred to encourage a doctor to write a prescription for one's product would be squandered because the pharmacist could fill the prescription with a competitor's AB-rated product.[207] As *Namenda* concluded, "additional expenditures by generics on marketing would be impractical and ineffective because a generic manufacturer promoting a product would have no way to ensure that a pharmacist would substitute its product, rather than one made by one of its generic competitors."[208]

The inability of generics to profitably market to doctors is desirable. If a generic could do so, this would reintroduce the price-disconnect failure. The generic-substitution regime is *designed* to render unprofitable active marketing of the product to doctors. Yet Wright and Ginsburg suggest that generics try to defeat product hops by engaging in the doctor-focused marketing that is the problem and that DPS laws intentionally render unprofitable.

Fourth, Wright and Ginsburg find it "remarkabl[e]" that scholars and courts conclude that the price disconnect substantially impairs these markets.[209] This is the crux of their analysis. Yet they provide neither empirical nor theoretical support for second-guessing the judgment of Congress in 1963 and 1984, the repeated conclusions of the FTC, and the unanimous judgment of all fifty states. The price disconnect is the economic premise around which all states and the federal government have for the past forty years built a robust generic-substitution regulatory regime.[210] And it is the bedrock principle around which respected industry scholars have based their work.[211] Yet Wright and Ginsburg try to wave it away based on their say-so and nothing else.

Having denied the existence of the price disconnect, Wright and Ginsburg do not address the question whether, given its existence and importance in these markets, the disconnect (as opposed to valued innovations) is a likely source of market power and sound basis for antitrust scrutiny. It is

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address the viability and strength of that competition in the face of substitutability at the pharmacy counter. Wright & Ginsburg, *supra* note 180, at 2.

207 Shadowen et al., *supra* note 1, at 15.

208 New York *ex rel.* Schneiderman v. Actavis PLC (*Namenda*), 787 F.3d 638, 656 (2d Cir. 2015).

209 Wright & Ginsburg, *supra* note 180, at 4.

210 *See also Namenda*, 787 F.3d at 657–58 (recognizing that "what Defendants call 'free riding' . . . is authorized by law; is the explicit goal of state substitution laws; and furthers the goals of the Hatch-Waxman Act by promoting drug competition and by preventing the 'practical extension of [brand drug manufacturers'] monopoly . . . beyond the expiration of the[ir] patent[s]" (second, third, fourth, and fifth alterations in original) (citations omitted) (citing FTC v. Actavis, Inc., 133 S. Ct. 2223, 2228 (2013)) (quoting H.R. REP. No. 98-857, pt. 2, at 4 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2686, 2688)); *see also Actavis*, 133 S. Ct. at 2228 (recognizing the Hatch-Waxman Act's bestowal on generics of the ability to "piggy-back" on brands' approval efforts, which speed "'the introduction of low-cost generic drugs to market' . . . thereby furthering drug competition" (quoting Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 132 S. Ct. 1670, 1676 (2012))).

211 *See* Shadowen et al., *supra* note 1, at 10 n.32 (collecting sources).

well-established that lesser market failures, such as strong network effects, are a basis for scrutiny.[212] Generic products are substitutable only if they are AB-rated to the brand, and, just as in network industries, this requirement of "compatibility" with the brand increases the opportunity and incentive for competition-impairing reformulations.[213] This premium on compatibility (as well as attention to the regulatory regime) fully justifies antitrust scrutiny in drug markets.[214]

In short, limiting antitrust scrutiny of product hopping to "sham innovations" is a recipe for anticompetitive behavior in complex markets that would have dramatic effects on consumers.[215]

IV. A New Product-Hopping Framework

As should be crystal clear, the pharmaceutical industry is unique in its complexity. Any antitrust analysis of product-hopping conduct must therefore, as the Supreme Court has explained, "be attuned to the particular structure and circumstances of the industry at issue."[216] With courts veering from simplistic "choice," to underinclusive coercion, to varied attention to the regulatory regime, it is time for a new antitrust framework for product hopping. This Part embarks on such a project.

Section A begins by offering two safe harbors for brand firms based on the timing of the reformulation. The first applies when the brand introduces a reformulation outside the temporal window in which generic entry is expected. The second applies when the brand introduces the reformulation after the generic version of the original product has entered the market. Section B then introduces a no-economic-sense test that has been applied elsewhere in antitrust law, which offers greater certainty for brand firms, and which results in a finding of monopolization when the brand engages in conduct that makes sense only by stifling generic competition.

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212 *See* IIIB Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 776c, at 297 (3d ed. 2008) (explaining that network effects justify antitrust scrutiny of Microsoft's product redesigns); *see also* John M. Newman, *Anticompetitive Product Design in the New Economy*, 39 Fla. St. U. L. Rev. 681 (2012) (arguing for antitrust scrutiny of computer code redesigns).

213 Shadowen et al., *supra* note 1, at 79–81.

214 *See, e.g.*, Hovenkamp et al., *supra* note 125, § 15.3 (pharmaceutical reformulations should be subjected to the same antitrust analysis as product redesigns in network industries); Jonathan Jacobson et al., *Predatory Innovation: An Analysis of* Allied Orthopedic v. Tyco *in the Context of Section 2 Jurisprudence*, 23 Loy. Consumer L. Rev. 1, 8 (2010) ("There are two scenarios where an exclusionary redesign may be especially harmful: (a) in the context of networked markets . . .; and (b) in pharmaceutical markets . . . .").

215 Like Wright and Ginsburg, Richard Gilbert worries about the effect on innovation of subjecting product-hopping to antitrust scrutiny. Gilbert, *supra* note 62, at 71. His analysis also implies that withholding a true innovation from the market reduces consumer welfare. *Id.* at 52. But he never puts the two concepts together by realizing that the *failure* to subject product hopping to antitrust scrutiny will impair innovation.

216 Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 411 (2004).

This Part focuses on the safe harbors and no-economic-sense test. But many reformulations will not even reach these stages. Our definition of product hopping requires:

(1) reformulating the product in a way that makes a generic version of the original product not substitutable; and

(2) encouraging doctors to write prescriptions for the reformulated product rather than the original product, i.e., switching the prescription base from the original to the reformulated product.

The second factor in particular distinguishes between the brand's expansion of the prescription base by taking away sales from other branded products or enticing new patients into the market, and switching the base solely to impair generic competition. The former, which will be satisfied by the mere introduction of a product (even one predicted to lose money) or the equal promotion of the old and reformulated products, will not raise antitrust concern. The other could, however, depending on the application of the safe harbors and no-economic-sense test.

The switching of the prescription base is particularly concerning in the pharmaceutical industry because of the price disconnect, as the doctor who prescribes the product does not pay, and the consumer (or her insurer) who pays does not choose. With no one making the fundamental judgment as to whether the "innovation" is worth the price, the brand manufacturer has an incentive and opportunity to make product redesigns with welfare-reducing intent and effect. The market cannot prevent the brand from switching the prescription base to a product that is not in fact worth the consumer savings that are lost from the impaired generic competition.

A. Safe Harbors

Brand firms often introduce new versions of existing drugs. The vast majority of these reformulations do not threaten competitive harm. For example, brands often, without reducing their promotion of the original version, introduce modestly-adjusted versions of their products to fill out a product line or satisfy demand for a particular formulation or delivery mechanism. We offer two safe harbors to ensure that antitrust liability is off the table for changes like these.

The first safe harbor immunizes reformulations made long enough before generic approval that they typically are not intended to impair generic competition. The second safe harbor exempts reformulations that are not likely to thwart generic competition because they are introduced after the generic version of the original drug has entered the market. The safe harbors ensure that brands have the certainty to engage in most of their anticipated reformulations without facing potential antitrust liability. And they offer a more deferential analysis than currently exists in the caselaw.

1. Outside Generic Window

The first safe harbor applies when a brand introduces a reformulated drug outside a "Generic Window" in which generic entry is expected. We propose immunity for the introduction of reformulations outside a four-year window, as these reformulations are less likely to have the purpose and effect of impairing generic competition.

Such a window would begin 18 months before the first generic application (Abbreviated New Drug Application or ANDA) is filed seeking approval to market a generic version of the original brand product. The rationale for granting a safe harbor for reformulations made prior to the 18-month period immediately before the ANDA filing is straightforward. Eighteen months is sufficient time for the generic firm to reformulate the generic product to match the new brand product and file an ANDA on the reformulated version. Thus, a reformulation implemented earlier than 18 months before the first ANDA is filed is unlikely to alter the competitive landscape. In such a case, no ANDA is about to be filed, and the reformulation is not temporally linked to generic entry.[217]

The rationale for denying a safe harbor once the ANDA is filed is also straightforward: the brand can get an automatic 30-month stay on approval of the generic.[218] The brand should not enjoy antitrust immunity for reformulations made while the generic is statutorily prohibited from entering the market. Reformulations made while the generic is prohibited from entering are likely to be aimed at delaying generic competition. The combination of the 18- and 30-month periods results in a four-year window. Outside this window, a brand's reformulation should be immune from antitrust scrutiny.

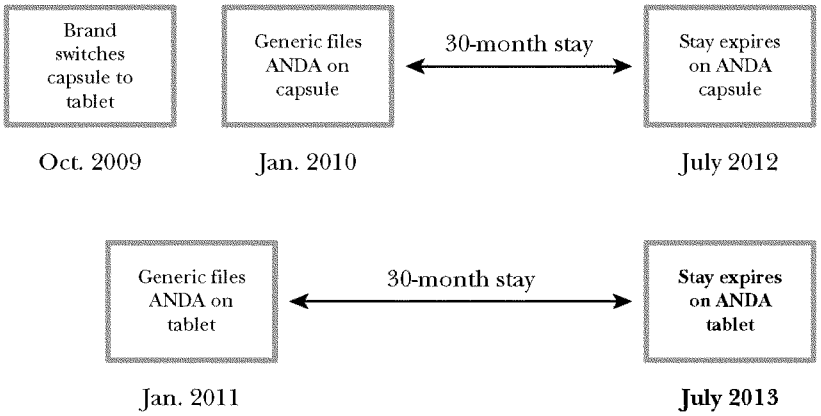
Two examples clarify. Assume that the brand reformulates from a capsule to a tablet and begins switching the market in October 2009—three months before the first ANDA is filed in January 2010 (see Figure 1). Assume further that the ANDA contains a Paragraph IV certification that the brand's *capsule* patent is invalid—a certification that elicits a patent lawsuit by the brand and an automatic 30-month stay, prohibiting generic entry until July 2012. A strong possibility in this case is that (1) the brand had anticipated the filing of the ANDA and timed the reformulation to impair the anticipated competition; (2) the generic's planning was so far advanced that it made sense to file the ANDA despite the reformulation; and (3) the reformulation could delay generic competition by prompting the generic firm to reformulate its product to match the new brand tablet, a process that could take, say, 15 months. In January 2011, the generic files a new ANDA, with a new Paragraph IV certification for the *tablet* product. The brand sues again, which results in an automatic stay that expires in July 2013—a one-year delay

217 The event that triggers the safe harbor is the brand's introduction on the market of the reformulated version. The event is not FDA approval of the reformulation because the brand could still, after approval, delay entering the market, even for years, to forestall generic entry.

218 Carrier, *supra* note 2, at 1018.

from July 2012, when the 30-month stay on the *capsule* product expired. This reformulation would not enjoy a safe harbor under our framework because the reformulation occurred within 18 months of the filing of the first ANDA.

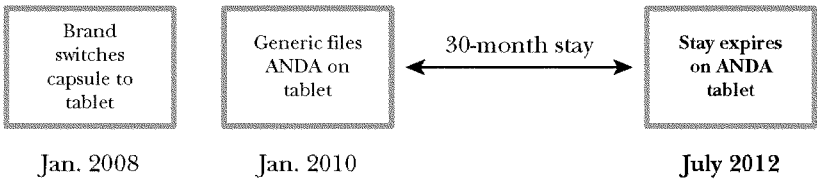
FIGURE 1



Now consider the same reformulation from a capsule to a tablet, but assume that the brand begins switching the market in January 2008—24 months before the first ANDA is filed in January 2010 (see Figure 2). This switch is not likely to alter the competitive terrain because the generic manufacturer has ample time to reformulate from a capsule to a tablet and get the ANDA and Paragraph IV certification for the *tablet* on file by January 2010. Because the generic has the time to file an ANDA directly on the brand's reformulated tablet, no delay beyond the original 30-month stay results from the reformulation. Under our framework, this reformulation enjoys a safe harbor because the reformulation occurred more than 18 months before the filing of the first ANDA.[219]

219 We offer a slightly different rule when the brand product enjoys five-year NCE exclusivity. *See* 21 U.S.C. § 355(j)(5)(F)(ii) (2012). In that setting, we would provide a safe harbor only for a reformulation that begins 30 months or less after the start of the NCE exclusivity period. The FDA is precluded from accepting for filing any ANDA for such a product until four years after the start of the NCE exclusivity period. To ensure that the generic manufacturer has 18 months to react to any reformulation and still be in as good a competitive posture as it would have been absent the reformulation, we would subject to antitrust scrutiny any reformulation that begins 30 months (18 months plus 12 months (representing the one-year period within the five-year exclusivity in which the generic can file an ANDA)) or less before the end of the five-year period.

FIGURE 2



In short, a reformulation that occurs within 18 months of the filing of the first ANDA often appears to have the purpose and effect of impairing generic competition. In contrast, a reformulation made more than 18 months before the first ANDA is filed likely had neither that purpose nor that effect. Historically, the vast majority of product reformulations have fallen outside this Generic Window and thus would enjoy the antitrust safe harbor under our proposal.[220] Procedurally, antitrust agencies could simply announce and apply this safe harbor. Private litigation is unlikely to ensue if the brand introduced the reformulated product outside the Generic Window because the reformulation typically will not have caused any damage. If any private litigation does ensue, the brand could point to the reformulation's timing and ask the court to give dispositive (or near-dispositive) weight to it in the no-economic-sense analysis we advocate below.

2. Reformulation After Generic Entry

One characteristic of the safe harbor for reformulations outside the Generic Window is that obtaining immunity is not within the brand's direct control. The safe harbor is tied to the filing of the ANDA, an event that the generic, not the brand, controls.

In contrast, the second safe harbor is entirely within the brand firm's control. We propose immunity for a reformulation introduced after a generic version of the original product has entered the market.[221] As noted in detail above, reformulations introduced after generic entry are far less effective in impairing generic competition. Generics make three to ten times more sales if the reformulation is introduced after (compared to before) generic entry.[222]

To be sure, quality competition between the reformulated brand and generic original products may not be ideal. The brand firm may have withdrawn all of its promotion and marketing from the original product. Or it may have switched all of its promotion and marketing to the reformulated product. But at least doctors, third-party payors, and consumers are gener-

220 Shadowen et al., *supra* note 1, at 2, 26.

221 Even the introduction of the generic *contemporaneously* with the brand results in significant sales to the generic. *See, e.g.*, Ernst R. Berndt et al., *Authorized Generic Drugs, Price Competition, and Consumers' Welfare*, 26 HEALTH AFF. 790, 797 (2007).

222 *See generally* Haiden A. Huskamp et al., *Generic Entry, Reformulations, and Promotion of SSRIs*, 26 PHARMACOECONOMICS 603, 604 (2008).

ally aware that a generic is on the market and the industry's generic-promoting mechanisms have a chance to work.[223] And because reformulations after generic entry have such a significantly reduced effect on generic competition, we offer a safe harbor, freeing the brand firm even from the task of showing that its conduct makes economic sense.[224]

On balance, we believe the antitrust agencies and courts should recognize this safe harbor to ensure that the brand has the ability, within its sole control, to completely avoid antitrust scrutiny. This guarantees that consumers will get the benefit of any innovations whose true purpose is to offer an improved product, not to impair generic competition.

B. No-Economic-Sense Test

The safe harbors introduced in the previous section provide far more protection for brands than is offered under the caselaw. In contrast, the no-economic-sense test we introduce in this section reaches more aggressively than some of the caselaw—specifically, *Walgreens* and *Doryx*—to deter anticompetitive conduct. The fact that a test so universally viewed as defendant-friendly leads to such different results shows how far those two cases

223 Devlin and Jacobs come to a similar result, but on erroneous grounds. *See* Alan Devlin & Michael Jacobs, *Anticompetitive Innovation and the Quality of Invention*, 27 BERKELEY TECH. L.J. 1 (2012). As we understand it, they would subject to antitrust scrutiny only those product hops in which the reformulated version enters before the generic of the original product has received FDA approval. *Id.* at 49. They would do so, however, based on the incorrect assertion that the FDA is prohibited from approving an ANDA if the brand firm has removed its product from the market. *Id.*

More fundamentally, Devlin and Jacobs wrongly assert that a product hop that does not prohibit a generic from gaining FDA approval "cannot exclude an equally or more efficient rival, [and therefore] fails to arouse the concern at the heart of Section Two jurisprudence." *Id.* at 50. Like Wright and Ginsburg, they fail to address, let alone satisfactorily include in their analysis, the price disconnect, which *does* substantially impair competition from equally efficient rivals. Also erroneous is their assertion that courts should not apply antitrust principles to drug markets because "antitrust rules are designed to operate in unregulated markets . . . ." *Id.* at 51. To the contrary, courts are *required* to apply antitrust principles to regulated markets and to take into account unique characteristics such as the price disconnect. *See also* FTC v. Actavis, Inc., 133 S. Ct. 2223, 2234, 2235 (2013) (noting the "general procompetitive thrust" of the Hatch-Waxman Act and holding that courts must apply antitrust law to prevent brands from manipulating the "unique regulatory framework" that "unintentionally . . . created special incentives" for anticompetitive conduct).

224 Carlton gives an example of a product hop in which the brand stops promoting the original product two years *after* introducing the reformulated product. Carlton et al., *supra* note 182, at 7. That example would almost certainly fall within one of our safe harbors and/or would pass the no-economic-sense test. Brand manufacturers engaged in a product hop designed to impair generic entry make the switch *before* the generics enter, and they achieve the switch by stopping promotion of the original product in favor of the reformulated product. So if a brand manufacturer has continued promoting the original product for two years after introducing the reformulated product, as in the Carlton example, it is doing something other than trying to impair generic competition.

veered from justified economic analysis. And while the no-economic-sense test leads to the same result in *TriCor*, *Suboxone*, and *Namenda*, the test keeps the antitrust analysis focused on economic realities rather than any artificial distinctions between "hard" and "soft" switches.

The no-economic-sense analysis asks whether conduct allegedly maintaining a monopoly by excluding nascent competition "likely would have been profitable if the nascent competition flourished and the monopoly was not maintained."[225] Applying the test requires a comparison of the conduct's gains (not including those from eliminating competition) and costs to the monopolist.[226] Conduct yielding a net negative payoff to the monopolist fails the test.[227] The test focuses on the conduct's "reasonably anticipated impact" (according to "objective economic considerations for a reasonable person") when undertaken rather than its actual impact.[228]

The no-economic-sense inquiry offers an economic test to determine whether the monopolist's sole motive was to impair competition. If a firm undertakes conduct that makes no economic sense, then its "anticompetitive intent" can be "unambiguously . . . inferred."[229] As one commentator has explained, the test's application "could not be simpler if . . . the conduct cannot possibly confer an economic benefit on the defendant other than by eliminating competition."[230] Even the "technological superiority" of a new product should not prevent a finding of exclusionary conduct since the "value to consumers of the new system relative to the preexisting system" may not be "greater than the required development costs."[231] In short, if a brand

225 Gregory J. Werden, *Identifying Exclusionary Conduct Under Section 2: The "No Economic Sense" Test*, 73 ANTITRUST L.J. 413, 415 (2006). For conduct allegedly creating a monopoly, the test asks "whether the conduct likely would have been profitable if the existing competitors were not excluded and monopoly was not created." *Id.*

226 *Id.* at 416.

227 *Id.*

228 *Id.*

229 A. Douglas Melamed, *Exclusive Dealing Agreements and Other Exclusionary Conduct—Are There Unifying Principles?*, 73 ANTITRUST L.J. 375, 393 (2006); *see also id.* at 391–92 (employing the "sacrifice test" because it is "widely used," but recognizing that both this test and the no-economic-sense test depend "not on the timeline, but rather on the nature of the conduct—on whether it would make no business or economic sense but for its likelihood of harming competition"); Shadowen et al., *supra* note 1, at 76 (explaining that conduct that is economically irrational absent reduced competition leads to the natural inference that the actor "was aware of and motivated solely to achieve that reduction").

230 Werden, *supra* note 225, at 415.

231 Janusz A. Ordover & Robert D. Willig, *An Economic Definition of Predation: Pricing and Product Innovation*, 91 YALE L.J. 8, 49 (1981); *see also* Spirit Airlines v. Nw. Airlines, 431 F.3d 917, 953 (6th Cir. 2005) (Moore, J., concurring) (involving predation claims based on the theory that "an incumbent seeks to retain monopolist control in the future by ceasing to engage in economically rational behavior in the present in an effort to drive potential rivals from the market"); ROBERT H. BORK, THE ANTITRUST PARADOX: A POLICY AT WAR WITH ITSELF 144 (1978) (laying out a test used to identify business practices that "would not be considered profit maximizing except for the expectation either that (1) rivals will be driven from the market, leaving the predator with a market share sufficient to command

acquires or maintains monopoly power by engaging in product hopping that fails the no-economic-sense test, courts should find it liable for illegal monopolization since the behavior makes no sense other than by stifling generic competition.

Our use of the no-economic-sense test avoids some of the recognized shortcomings of the profit-sacrifice test.[232] In particular, the profit-sacrifice test could punish short-term sacrifices such as investments in R&D or capital equipment even though they would lead to a higher profit in the long term.[233] The no-economic-sense test does not punish such investments "because they make economic sense apart from any tendency to eliminate competition and because they have no such tendency."[234] The test also avoids disputes about whether the manufacturer anticipated that it would recoup its sacrificed profits sometime in the future.[235] Some anticompetitive product hops could be profitable to the brand immediately, with no lost profits to be recouped later.

1. Virtues of the No-Economic-Sense Test

From the brand firm's perspective, the no-economic-sense test has three advantages as compared to existing caselaw. First, the test judges conduct *ex ante* rather than *ex post*. That is, the relevant inquiry under the no-economic-sense test is whether *at the time of the reformulation* the firm *projected* that the additional profits would justify the additional costs. The no-economic-sense test does not impose liability when the brand projects that the profits would exceed the costs but miscalculates because the costs were greater or the sales lower than reasonably projected. This is a significant advantage as the brand

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monopoly profits, or (2) rivals will be chastened sufficiently to abandon competitive behavior the predator finds inconvenient or threatening").

232 The profit-sacrifice analysis determines if conduct would be "unprofitable for the defendant but for the exclusion of rivals and resulting supra-competitive recoupment." Melamed, *supra* note 229, at 389; *see also* Ordover & Willig, supra note 231, at 9–10 ("[P]redatory behavior is a response to a rival that sacrifices part of the profit that could be earned under competitive circumstances, were the rival to remain viable, in order to induce exit and gain consequent additional monopoly profit." (footnotes omitted)).

233 Werden, *supra* note 225, at 424; *see also* Herbert Hovenkamp, *The Harvard and Chicago Schools and the Dominant Firm* 14 (Univ. Iowa Legal Studies Research Paper No. 07-19, 2010), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1014153 (noting that the profit-sacrifice test "does not adequately distinguish anticompetitive 'sacrifice' from procompetitive 'investment'").

234 Werden, *supra* note 225, at 424.

235 *See* Christopher R. Leslie, *Predatory Pricing and Recoupment*, 113 COLUM. L. REV. 1695, 1699 (2013) (describing "unnecessary and counterproductive" recoupment analysis); Steven C. Salop, *Exclusionary Conduct, Effect on Consumers, and the Flawed Profit-Sacrifice Standard*, 73 ANTITRUST L.J. 311, 319–20 (2006) (noting that the no-economic-sense test "is primarily different from the conventional profit-sacrifice standard because it does not require a showing that there is a period of time in which the defendant's profits are lower than they were before the exclusionary conduct was undertaken" and "[t]he reduction in profits can be conceptual rather than temporal").

can be fairly certain whether a given reformulation will avoid antitrust liability.

Second, and relatedly, the no-economic-sense test is based on objective economic evidence rather than ambiguous qualitative evidence of "intent." Emails, narratives in memoranda, and the like may provide some surrounding "flavor" as to whether a reformulation makes economic sense. But the foundation of the no-economic-sense test consists of the manufacturer's sales and costs projections: Did the brand project that its reformulation of the product and cannibalization of the prescription base would expand sales sufficiently to justify the additional costs? Such an inquiry promotes certainty in business planning.

Third, the no-economic-sense test offers an easier antitrust hurdle for the brand to clear, substantively, than the rule-of-reason standard, which considers anticompetitive effects and procompetitive justifications. As noted above, the no-economic-sense test is essentially an economic test to determine whether the brand's *sole* motive was to impair competition. The brand will clear the no-economic-sense hurdle with a mixed motive of impairing competition and offering an improved product, even if the former motive swamps the latter.

This can be seen with an example that applies both the no-economic-sense test and the Rule of Reason. Assume that a product hop (1) will cost $20 million in additional R&D; (2) will be valued by a small group of new purchasers (enticed away from other therapeutic alternatives), resulting in additional sales of $40 million; and (3) will impair generic competition at a cost to existing purchasers of $160 million. Under the Rule of Reason, this reformulation would likely be unlawful because the costs *to purchasers* far outweigh the benefits *to purchasers*. But under the no-economic-sense test, the reformulation would likely be lawful because the costs *to the manufacturer* are less than the benefits *to the manufacturer*.

Courts and agencies apply a no-economic-sense test when the type of conduct in which the manufacturer is engaged—here, designing products and bringing them to market—is *generally* the type of conduct that benefits consumers. So even if the conduct might not be welfare-enhancing when analyzed on a product-by-product basis, it may well be welfare-enhancing when viewed through a wider lens. Legal rules attempt to avoid deterring the type of conduct that generally results in welfare gains unless the evidence makes clear that the particular instance of the conduct is anticompetitive and should not be countenanced. In short, the no-economic-sense test imposes liability only when, *ex ante*, objective evidence shows that the brand's sole motive was to impair competition.[236]

236 Gilbert contends that a rule targeting "predatory innovation" could falsely condemn "[r]eally good" innovations that are costly to develop but that in the long run may "make old technologies obsolete." Gilbert, *supra* note 62, at 52. Under the test we propose, a manufacturer that projected that its design change would revolutionize the therapeutic class and thus take sales from other branded drugs in the class would easily clear our no-economic-sense threshold. In contrast, the design changes that would not pass are those

2. Support for the No-Economic-Sense Test

Many courts, most notably the Supreme Court, have endorsed and applied the no-economic-sense test.[237] In *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, the Court found that the defendant "was willing to sacrifice short-run benefits and consumer goodwill in exchange for a perceived long-run impact on its smaller rival."[238] And in *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*, the Court confirmed that the evidence in *Aspen Skiing* reflected "a willingness to forsake short-term profits to achieve an anticompetitive end."[239] Lower courts have offered similar approaches.[240]

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that the manufacturer projects will not take sales from other *branded* products in the class and thus whose only motivation is to impair competition from imminent *generic* competition. Gilbert worries about falsely condemning a breakthrough innovation that involves "a sacrifice of profit in the short run followed by elimination of rivals and higher prices (or lower consumer surplus) . . . ." *Id.* at 53. Our test accurately condemns only those design changes that make no economic sense and result in eliminating *only the generic competitor.*

Gilbert also goes awry in his treatment of the role of regulation in the antitrust analysis. He asserts that if the regulatory structure of the pharmaceutical industry generates competition concerns unique to the industry, the remedy is to change the regulations. *Id.* at 74; *see also* Carlton et al., *supra* note 182, at 11–13. We believe, and the courts have consistently held, that antitrust enforcers and courts must *take the existing regulatory structure as a given.* That means that courts must apply antitrust law unless the regulatory structure displaces it (and it is clear that in the pharmaceutical industry it does not). Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 411 (2004). Courts cannot get into the business of deciding whether competition from generic drugs—especially competition that is encouraged by comprehensive federal and state law—is bad for consumers. Nat'l Soc'y of Prof'l Eng'rs v. United States, 435 U.S. 679, 695 (1978); *see also generally* Dogan & Lemley, *supra* note 67, at 709, 717 (noting that "[t]he pharmaceutical industry presents a perfect storm for regulatory gaming" and that "[i]f a pharmaceutical company designs its products for the sole purpose of dragging out a regulatory process for years and thereby forestalling competition, it has engaged in exclusionary behavior that harms consumers").

237 Many of the courts' versions apply the related profit-sacrifice test, which offers an even more aggressive test that may not credit short-term profit sacrifice even for long-term economic gain. *See supra* notes 232–33 and accompanying text.

238 472 U.S. 585, 610–11 (1985).

239 540 U.S. 398, 409 (2004).

240 *See, e.g.*, Novell, Inc. v. Microsoft Corp., 731 F.3d 1064, 1075 (10th Cir. 2013) (stating that the test is satisfied when a "monopolist's conduct [is] irrational but for its anticompetitive effect" (citing *Trinko*, 540 U.S. at 407; *Aspen*, 472 U.S. at 597; IIIB AREEDA & HOVENKAMP, *supra* note 212, at 223; Werden, *supra* note 225, at 422–25)); Covad Commc'ns Co. v. Bell Atl. Corp., 398 F.3d 666, 676 (D.C. Cir. 2005) (considering a predatory practice to be "one in which a firm sacrifices short-term profits in order to drive out of the market or otherwise discipline a competitor" (citing Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp., 509 U.S. 209, 222–23 (1993))); Advanced Health-Care Servs., Inc. v. Radford Cmty. Hosp., 910 F.2d 139, 148 (4th Cir. 1990) (explaining that conduct is exclusionary if a monopolist made "a short-term sacrifice in order to further its exclusive, anticompetitive objectives" (citing SmithKLINE Corp. v. Eli Lilly & Co., 575 F.2d 1056, 1065 (3d Cir. 1978))); Ne. Tel. Co. v. AT&T, 651 F.2d 76, 94–95 (2d Cir. 1981) (finding a properly instructed jury could reasonably find that a monopolist designed the product to impede competition); Response of Carolina, Inc. v. Leasco Response, Inc., 537 F.2d 1307,

Commentators have advocated the test.[241] So have the leading antitrust treatises.[242] And the Department of Justice (DOJ) has advanced it in several important cases. For example, in *Trinko*, the agency asserted that "conduct is not exclusionary or predatory unless it would make no economic sense for the defendant but for its tendency to eliminate or lessen competition."[243] In *United States v. Microsoft Corp.*,[244] the DOJ contended that Microsoft's protection of its operating system monopoly was exclusionary because it "would not make economic sense unless it eliminated or softened competition."[245] In *American Airlines*,[246] the agency asserted that the defendant excluded rivals by

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1330 (5th Cir. 1976) (finding technological tying cases "limited to those instances where the technological factor tying the hardware to the software has been designed for the purpose of tying the products, rather than to achieve some technologically beneficial result"); ILC Peripherals Leasing Corp. v. IBM, 458 F. Supp. 423, 439 (N.D. Cal. 1978) (no liability where "there was no evidence that IBM was sacrificing present profits with the expectation of recouping its losses with subsequent price increases"); Abuse of a Dominant Position by Reckitt Benckiser Healthcare (UK) Ltd. & Reckitt Benckiser Grp., PLC, Case CE/8931/08, ¶¶ 6.34, 6.42 (Office of Fair Trading Apr. 12, 2011) (Eng.), https://assets.publishing.service.gov.uk/media/555de4bbe5274a7084000156/rb-decision.pdf (concluding that the product hop at issue would "result in a decrease in RB's profitability that would render the strategy commercially irrational in the absence of benefits derived from hindering the development of full generic competition").

241 *See, e.g.*, Susan A. Creighton & Jonathan M. Jacobson, *Twenty-Five Years of Access Denials*, 27 ANTITRUST 50, 54 (2012) (noting that, as applied to rival's access demands, rule "runs the least risk of reducing investment incentives while maintaining society's critical interest in preserving consumer welfare through competition"); Melamed, *supra* note 229, at 389 (offering test providing that "conduct is anticompetitive if, but only if, it makes no business sense or is unprofitable for the defendant but for the exclusion of rivals and resulting supracompetitive recoupment"); Werden, *supra* note 225, at 422–25 (articulating the "no economic sense" framework); *cf.* Henry N. Butler, *REMS-Restricted Drug Distribution Programs and the Antitrust Economics of Refusals to Deal with Potential Generic Competitors*, 67 FLA. L. REV. 977, 1023 (2015) ("[U]nder the profit-sacrifice test, conduct is anticompetitive only if the defendant has no legitimate business purpose for the conduct or it is unprofitable in the short run and makes business sense only if a rival is excluded, leaving the defendant with a supracompetitive recoupment in the long run."). For additional sources, see generally Shadowen et al., *supra* note 1, at 75–77.

242 *See generally* IIIA PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 773e, at 209–13 (2d ed. 2002) (explaining that refusal to deal is unlawful if irrational in the sense that the defendant sacrificed an opportunity to make a profitable sale only because of the adverse impact the refusal would have on rival); *see also generally* HOVENKAMP ET AL., *supra* note 125, § 12.3, at 13 ("If a design change makes no economic sense unless the exclusion of rivals is taken into account, it is reasonable to infer both that the purpose behind the design change was anticompetitive and, more importantly, that the anticompetitive effects of the design change predominated over any technological benefits.").

243 Brief for the United States and the FTC as Amici Curiae Supporting Petitioner at 15, Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398 (2004) (No. 02-682) (emphasis omitted).

244 253 F.3d 34 (D.C. Cir. 2001).

245 Brief for Appellees United States and the State Plaintiffs at 48, United States v. Microsoft Corp., 253 F.3d 34 (D.C. Cir. 2001) (Nos. 00-5212, 00-5213).

246 United States v. AMR Corp. (*American Airlines*), 335 F.3d 1109 (10th Cir. 2003).

adding "money-losing capacity" and that "distinguishing legitimate competition from unlawful predation requires a common-sense business inquiry" based on "whether the conduct would be profitable, apart from any exclusionary effects."[247] And in *United States v. Dentsply International, Inc.*,[248] the DOJ argued that "Dentsply's exclusionary policies made no economic sense but for their tendency to harm rivals, and so were predatory."[249]

* * *

Courts and commentators have offered the no-economic-sense test as a basis for antitrust liability in settings like predatory pricing and refusals to license, where the vast majority of conduct is likely to not present antitrust concern. In such a setting, satisfying the test has been treated as a necessary element of liability. Given the benefits of low prices and difficulties inherent in punishing refusals to license, courts have been hesitant before finding monopolization.

Similar considerations support applying the no-economic-sense test to product hops in prescription drug markets. Most innovation in most markets is beneficial to consumers. A lenient (to the monopolist) standard[250] is thus appropriate so as not to deter genuinely beneficial product redesigns. The no-economic-sense test also provides guidance to product developers, who can know with a high degree of precision whether the redesign will clear antitrust hurdles.

Given the unique aspects of the pharmaceutical industry, most notably the price disconnect, it is conceivable that application of the no-economic-sense test would not capture every switch that ultimately is anticompetitive. For example, and as discussed above,[251] a brand could avoid liability by engineering a switch that would allow it to enjoy modest profits but result in significant losses to consumers. Our conservative approach would allow the reformulation.

Stated differently, our no-economic-sense test (together with a rigorous two-factor threshold for product hops and two safe harbors) would lead to far more false negatives than false positives. In fact, the construction of the test ensures that there should be few if *any* false positives since the only firms subject to antitrust liability would be those that engage in behavior that literally does not make sense absent its impairment of generic competition. The test would allow false negatives to the extent firms engage in conduct that does not involve a lack of economic sense, but offers few innovations for consumers while preventing significant price reductions. We believe such a

247 Brief for Appellant at 2, 30, *American Airlines*, 335 F.3d 1109 (No. 01-3202) (public redacted version).

248 399 F.3d 181 (3d Cir. 2005).

249 Brief for the United States at 28, *Dentsply*, 339 F.3d 181 (No. 03-4097) (public redacted version).

250 *See infra* note 252 and accompanying text.

251 *See supra* subection IV.B.1.

tradeoff is justified based on the importance of innovation and business certainty.

C. No-Economic-Sense Versus Hard Switch/Soft Switch

Courts' and commentators' product-hopping analyses have veered far from justifiable economic analysis. The no-economic-sense test would lead to dramatically different analyses and results. Courts and commentators have drawn rigid distinctions between hard switches, viewed as anticompetitive because the brand removes the original drug from the market, and soft switches, viewed as not concerning because the original remains on the market. The lesson of this Section is that the no-economic-sense test is far superior to the hard switch/soft switch dichotomy for at least two reasons: (1) the fundamental conduct that impairs generic competition is the reformulation of the brand product and "cannibalization" of its sales *by any means* before the generic enters the market, and (2) the "choice" theory that underlies the dichotomy between hard and soft switches is not satisfactory.

First, it is not always, or even often, necessary for the brand to remove the original product from the market to substantially impair generic competition. What matters is whether the brand has successfully moved the prescription base from the original to the reformulated product before the generic enters the market. The essential exclusionary conduct is the reformulation of the product and cannibalization of the prescription sales base. The *particular* means used to cannibalize the sales is not critical to the anticompetitive effect. Some means may be more effective than others in moving the sales base, but it is the moving of the sales base, not the particular means, that causes the anticompetitive effect.

This can clearly be seen with an example. The brand in *TriCor* reformulated the product, cannibalized it, interfered with the generics' insurance coverage, drained the supply chain of the original product, and entirely removed it from the market.[252] The result was that the generics made only 2% of unit sales.[253] In *Walgreens*, the brand reformulated the product, cannibalized it, and interfered with the generics' insurance coverage, but did not remove the product from the market.[254] The result was that the generics made roughly 25% of unit sales.[255]

According to the well-established economics of the industry, absent the reformulations, the generics in both cases would have captured at least 85%

252 Abbott Labs. v. Teva Pharm. USA, Inc. (*TriCor*), 432 F. Supp. 2d 408, 416–18 (D. Del. 2006).

253 Transcript of Record at 534–35, Teva Pharm. USA, Inc. v. Abbott Labs. (*TriCor II*), 580 F. Supp. 2d 345 (D. Del. 2008) (No. 02-1512) (on file with authors).

254 First Amended Complaint & Demand for Jury Trial at 32–33, 36, Walgreen Co. v. AstraZeneca Pharm. L.P., 534 F. Supp. 2d 146 (D.D.C. 2008) (No. 1:06 CV 02084) [hereinafter Walgreens Complaint].

255 *Id.* ¶¶ 104–06. Several years after entry, the generics had captured just 7.4 million of Prilosec's 29.6 million pre-reformulation unit sales. *Id.* ¶ 106.

of unit sales.[256] With a product withdrawal in *Tricor*, they gained only 2%. But even without a product withdrawal in *Walgreens*, they gained only 25%. In this example, the product withdrawal was more effective in impairing generic competition, but the cannibalization without product withdrawal also inflicted massive losses on consumers—60% of additional unit sales should have been generic rather than branded, which would have saved consumers roughly $1.9 billion annually.[257] No difference in *anticompetitive effect*—in the nature or essential magnitude of losses—can differentiate "hard" from "soft" switches.

Second, despite broad statements to the contrary,[258] no differences in the *nature of the conduct*—in preserving or denying consumer "choice"—distinguish hard from soft switches. The court in *Namenda*, for example, suggested in dicta that consumers would have had the relevant "choice" if the brand had left the original product on the market.[259] The court asserted that withdrawal of the brand product "forced" doctors to write prescriptions for the reformulated rather than the original product.[260] But at the time doctors were forced to switch to the reformulated product, no generic was available, so the forced switch obviously did not prevent consumers from choosing a generic at that time. Their prescriptions were simply moved from one brand for which there was no generic to another brand for which there was no generic. Nor were consumers deprived of "choice" (in the sense in which the *Namenda* court apparently meant it) when the generics entered. Doctors at that time were perfectly free to write prescriptions for the original product and have them filled with the generic.[261]

The *Namenda* court's intuition was right. It correctly perceived that removing the brand product "forced" doctors to write prescriptions for the reformulated brand and that doctors would not move prescriptions back to the original product after the generics entered. But the court's dictum erred in failing to realize that doctors will not move prescriptions back to the original product *regardless of* the means the brand used to switch them to the

256 FED. TRADE COMM'N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 8 (2010) (generics take 90% of unit sales at an average 85% discount from the brand price).

257 Walgreens Complaint, *supra* note 254, ¶ 64. An average 80% discount on 60% of the $4 billion in pre-reformulation annual sales of branded Prilosec, *see id.* ¶ 42, equals annual lost savings to consumers of $1.9 billion. The evidence in *Namenda* showed that the brand projected that if it did not withdraw the original product, it could have switched only 30% of patients to the reformulated product, but by withdrawing the original product, it could switch between 80% and 100%. New York *ex rel.* Schneiderman v. Actavis PLC (*Namenda*), 787 F.3d 638, 654 (2d Cir. 2015). This evidence may have led the *Namenda* court to give near-dispositive significance to whether the brand witbdrew the product. *See id.* at 655. As we demonstrate in detail below, the court reached the correct conclusion but used an incorrect analysis. *See infra* Section V.A.

258 *See, e.g.*, *Namenda*, 787 F.3d at 654–55; HOVENKAMP ET AL., *supra* note 125, § 15.3.

259 *Namenda*, 787 F.3d at 655.

260 *Id.* at 654.

261 *Id.* at 654–55.

reformulated product. It is the timing of the reformulation in relation to generic entry—does the reformulated product beat the generic onto the market or not?—that determines whether consumers are able to make the relevant price/quality choice.

The *Namenda* court's dichotomy based on whether the brand removed the original product has a rhetorical appeal but reflects an insupportably narrow view of consumer "choice." What deprives consumers of the ability to make a price/quality trade-off is the combination of a price-disconnected market and the brand's reformulation and cannibalization of the original product's sales *by any means*. It is the absence of prescriptions for which the generics can automatically be substituted that deprives consumers of the relevant choice. Of crucial significance, the brand eliminated those prescriptions through its reformulation and cannibalization. The withdrawal of the original product is relevant only indirectly—solely to the extent it causes a reduced prescription base that limits substitution when the generics enter. It is the reduced prescription base that directly impairs generic substitution, and that reduced base can be caused by conduct other than withdrawal of the product.

Manufacturers engage in a variety of tactics to cannibalize the product before generic entry. In *TriCor*, Abbott bought back existing supplies of its capsules from pharmacies and changed the code for the capsules in the national drug database to "obsolete," each of which encouraged doctors to switch prescriptions to the reformulated product.[262] In *Doryx*, Warner Chilcott stopped selling capsules to wholesalers; removed capsules from its website; informed wholesalers, retailers, and doctors that "Doryx capsules have been replaced by Doryx tablets"; and destroyed and bought back some of the remaining capsules.[263] In *Suboxone*, Reckitt raised the price of its original tablets in relation to the reformulated film version, disparaged tablets, and warned of purported safety concerns.[264] The point is not that these tactics involved a lack of economic sense singly and in isolation. Some of them, such as buying back stock and creating artificial price differentials, might well lack economic sense even when viewed in isolation.

But these are mere tactics. The exclusionary conduct on which the competition analysis focuses is the reformulation and cannibalization of the product; in other words, switching the prescription base. The no-economic-sense test applies to *that* conduct. Withdrawing (or not) the product, creating an artificial price gap between the branded products, buying back stock, changing drug codes, etc., are merely tactics, i.e., particular means by which the brand engages in the suspect conduct of switching the prescription base.

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262 Abbott Labs. v. Teva Pharm. USA (*TriCor*), 432 F. Supp. 2d 408, 416 (D. Del. 2006).

263 Mylan Pharm., Inc. v. Warner Chilcott PLC (*Doryx*), No. 12–3824, 2015 WL 1736957, at *3 (E.D. Pa. Apr. 16, 2015).

264 End Payor Plaintiffs' Consolidated Amended Class Action Complaint ¶¶ 42–44, *In re* Suboxone Antitrust Litig., 64 F. Supp. 3d 665 (E.D. Pa. 2014) (No. 2:13-md-02445).

D. Applications

Part V below applies our framework to the five product-hopping cases litigated to date. But to provide more guidance to courts, the antitrust agencies, and companies themselves, it is worth highlighting three general points.

First, a brand's introduction of a new product, standing alone, will not violate our test. Indeed, it would not even constitute a product hop. To state the obvious, brands are allowed to introduce new products. In the presence of the price disconnect, antitrust concerns arise when the brand:

(1) reformulates the product in a way that prevents generic substitution and

(2) cannibalizes its own sales by switching the prescription base from the original to the reformulated product.[265]

These are the elements that, combined, require scrutiny under the no-economic-sense test.[266] As mentioned above,[267] our focus on the switching of the prescription base distinguishes between the expansion of the base by taking away sales from other branded products or enticing new patients into the market, and the switching of the base solely to impair generic competition. The concern with the latter conduct is particularly apparent in the pharmaceutical industry, which is plagued by the price disconnect, and where the conduct may even make the original drug *less desirable.*

Second, whether the reformulated product is patented is irrelevant to the no-economic-sense test. An example makes this clear. Assume that the brand manufacturer projects that (1) without a product hop, the original product will have annual sales (before the onset of generic competition) of $500 million; (2) R&D and other costs of switching to the reformulated product will be $80 million; (3) without a product hop, generics will quickly take 90% of the unit sales, leaving the brand with annual sales of only $50 million; and (4) with a product hop, annual sales of the reformulated product are likely to be $400 million (and sales of the original product will be $0).

Given this set of facts, application of the no-economic-sense test is straightforward. The brand manufacturer could be tempted to make the product hop. Without the hop, the brand would make $50 million in annual sales. With the hop, it would make $400 million in sales, at a cost of only $80

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265 As mentioned earlier, *see supra* note 3, the switching of the prescription base raises anticompetitive concern in threatening the generic-promoting goals of the Hatch-Waxman Act and state drug product substitution laws, through a switch to a reformulation for which a generic cannot be substituted. And that conduct lacks any innovation-based justifications because the brand does not build up the prescription base by competing with other brands or expanding the market, but merely leverages already-gained power solely by blocking generic entry.

266 Companies outside the pharmaceutical industry introduce new-generation products even when there is economic life remaining in the old, and the mere introduction of new products in the drug industry does not cause concern. But competition concerns arise when, in the presence of the price disconnect, the brand combines product reformulation with switching the prescription base.

267 *See supra* text preceding Section IV.A.

million. But the hop fails the no-economic-sense test because, absent the effect of impairing generic competition, it would not make economic sense. The brand would be spending $80 million to move from a product with *$500 million* in annual sales to a product with *$400 million* in annual sales. The only reason the brand gains anything is that it impairs generic competition.

This analysis holds true regardless of whether the reformulated product is patented. For example, the reformulated product might not be patented. Product hops can fail the no-economic-sense test when the reformulated product is unpatented. A product hop to an unpatented product can buy the brand two years or more of life without generics, as the generics reformulate their products and are required to start the lengthy FDA-approval process all over again. In granting approval of the brand's reformulated product, the FDA does not determine whether the reformulated product is an improvement, let alone one that is worth the cost of lost generic savings.[268] We therefore apply an objective, economic test to pinpoint product hops where it is crystal clear that the "improvement" not only is not worth the cost to consumers, but also is not even worth the cost to the manufacturer.

On the other hand, the reformulated product in the example could be protected by a patent. Our framework would apply the no-economic-sense test in a similar manner. For starters, the mere act of obtaining a patent is not even subject to the test since it does not involve encouraging doctors to write prescriptions for the reformulated, instead of original, drug. And regarding the broader course of conduct involving a patented reformulation, as demonstrated in detail in Section II.B, patent law does not require that the product be an improvement and in fact allows patents on "less effective" products.[269] That is why the PTO routinely grants patents on minor differences in existing chemical entities such as different crystalline forms of a chemical or different formulations that do not necessarily improve the product in any meaningful way.[270] Our framework thus appropriately does not depend on whether the PTO issued any applicable patents. Again, we apply an objective, economic test. Patent law provides no reason to do otherwise.[271]

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268 The FDA requires only that the product is superior to a placebo, not to existing products. *See generally* Dogan & Lemley, *supra* note 67 (explaining that the FDA "has neither the mandate nor the power to take competition concerns into account in approving particular pharmaceutical products"); Jeanne Whalen, *Glaxo Strategy Threatened by FDA Delays*, WALL ST. J., June 17, 2008, at B3.

269 Custom Accessories v. Jeffrey-Allan Indus., 807 F.2d 955, 960 n.12 (Fed. Cir. 1986); *see also* Rich, *supra* note 65, at 393 (discussing "the unsound notion that to be patentable an invention must be better than the prior art").

270 *See, e.g.*, Forest Labs. v. Ivax Pharm., 501 F.3d 1263 (Fed. Cir. 2007) (upholding patent on enantiomer); Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348 (Fed. Cir. 2007) (patent on particular salt); AstraZeneca AB v. Mutual Pharm., 384 F.3d 1333 (Fed. Cir. 2004) (upholding a formulation patent).

271 In addition to patent and FDA law not requiring that the new product is an improvement, the price disconnect prevents the market from determining whether the product is an improvement worth the cost of lost savings from generic competition. Anti-

Third, we emphasize again that our framework applies the no-economic-sense test to the product hop itself—to reformulating and cannibalizing the original product—not to any particular cannibalization tactics. For instance, assume that, in our example above, the brand's documents show that, given the decision to switch to a reformulated product, withdrawing the original product from the market would increase the combined sales of the original and reformulated products from $350 million to $400 million by eliminating confusion in the marketplace. Under our framework, this is not relevant because we apply the test to the product hop, not to the cannibalization tactic of withdrawing the original product. This example illustrates why: withdrawing the original product increases sales only compared to not withdrawing it. Withdrawal increases sales from $350 million to $400 million *given the decision to cannibalize.* But the no-economic-sense test applies to the product hop itself—reformulation and cannibalization—which *decreased* sales from $500 million to $400 million.

On the other hand, a product hop with a hard switch might well pass the no-economic-sense test. Change the fourth assumption in our example above: the brand manufacturer projects that sales of the reformulated product will be $600 million annually, rather than $400 million as the example originally posited. The product hop, even with a hard switch, passes the no-economic-sense test because the projected increase of $100 million in annual sales is greater than the $80 million in R&D costs.

The no-economic-sense test does not apply to individual cannibalization tactics (even to the one that some courts have thought dispositive—withdrawal of the original product from the market). Instead, it applies to the product hop itself—reformulating and cannibalizing the original product.

V. The Cases: A Second Look

Applying the new product-hopping framework to the five cases would lead to markedly different results. Two of the cases would come out the other way, and all would employ a new analysis. For starters, neither safe harbor would protect the brand in any of the five cases. Each brand implemented the reformulation within 18 months of the filing of the first ANDA, and none waited to launch the reformulated product until after generic entry. Consequently, each of the five cases would be resolved by applying the no-economic-sense test.

The big picture is that the plaintiffs alleged in each case that the brand projected that, compared to the sales it was enjoying with the original product, it would not make any additional sales by switching to the new formulation. That is, the "new and improved" version would not entice patients away from other therapeutic choices and would not allow the brand to increase the product's price. In fact, in each case, plaintiffs alleged that the switch to the new product was costly to the brand, usually in the form of *lost* unit sales

trust law must play a role because no other element of the regulatory regime is available to analyze the conduct.

(as doctors reacted to the reformulation by switching to a different therapeutic alternative), and additional R&D, marketing, and licensing costs. The brand made these investments not to improve products and make new sales, but *solely* to impair generic competition.

It is not surprising that each reformulation fails the no-economic-sense test, at least based on plaintiffs' allegations, because plaintiffs presumably bring the most egregious cases first. A detailed review of each case illustrates how the no-economic-sense test can be applied to product reformulations in the pharmaceutical industry.

A. TriCor*: No Economic Sense*

In *TriCor*, Abbott's conduct made no economic sense, except as a generic-impairment strategy. TriCor was a successful drug, with its original capsule form garnering sales of $200 million in 2001.[272] But after the FDA approved the tablet formulation in September 2001, Abbott encouraged doctors to write prescriptions only for the reformulated product by, in part, "prevent[ing] pharmacies from filling TriCor prescriptions with a generic capsule formulation."[273] Plaintiffs alleged that Abbott did not project that it would make any additional sales or profits.[274] Yet Abbott incurred substantial costs to accomplish the switch,[275] including costs for additional R&D and marketing, new royalty payments, buying back existing supplies of capsules from pharmacies, and forgoing a new indication for the original product. Absent the impairment of generic competition, the reformulation and cannibalization made no sense since Abbott incurred all of these costs despite in-house projections showing no new sales or profits.

Abbott's tactics in the cannibalization included withdrawing the original products, changing the drug product codes to "obsolete" in national databases, and buying back supplies of the original product.[276] Considered separately, the first two of those tactics might or might not make economic sense, while the third almost certainly does not. As noted above, however, it is the reformulation and cannibalization (by whatever means) that is subject to the no-economic-sense test, not the particular cannibalization tactics. And such conduct doesn't make sense here because Abbott did not project any increased sales, but incurred substantial costs to make the hop. Abbott's reformulation and cannibalization did not make sense absent the effect on generic competition.

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272 Amended Complaint ¶ 40, Teva Pharm. USA, Inc. v. Abbott Labs. (*TriCor II*), 580 F. Supp. 2d 345 (D. Del. 2008) (No. 1:05-cv-00340).

273 Abbott Labs. v. Teva Pharm. USA, Inc. (*TriCor*), 432 F. Supp. 2d 408, 416 (D. Del. 2006).

274 Amended Complaint ¶ 63, *supra* note 272; Class Action Complaint ¶¶ 93–94, *TriCor II*, 580 F. Supp. 2d 345 (No. 1:05-cv-00340).

275 Amended Complaint ¶¶ 61–65, *supra* note 272.

276 *TriCor*, 432 F. Supp. 2d at 416.

B. Walgreens*: No Economic Sense*

The *Walgreens* court dismissed the plaintiffs' complaint, but the allegations reveal conduct that does not make economic sense. Prilosec produced an astounding $4 billion in revenues in 1999.[277] Despite this success, and the fact that it was AstraZeneca's most profitable drug,[278] AstraZeneca stopped its promotion and detailing of the drug after it introduced Nexium.[279]

Plaintiffs alleged that AstraZeneca marketers, lawyers, and scientists charged with "finding a solution to the impending patent expiration of the company's best-selling drug"[280] conceded that "of the dozens of potential actions that they considered to replace the anticipated lost Prilosec sales, launching and switching prescriptions to Nexium was the worst for consumers."[281] The company's then-chief executive officer purportedly admitted that "[i]f we had left it to R&D, Nexium would not have been developed," but "[t]he project was driven by the marketing people."[282]

These broad allegations were bolstered by detailed, direct averments of lack of economic sense. Plaintiffs alleged that AstraZeneca expected (accurately, as it turned out) that switching the market from Prilosec to Nexium would cause a loss of sales.[283] During the shift from Prilosec to Nexium between 2000 and 2002, AstraZeneca's unit sales increased only 11%, far less than the increase of more than 30% enjoyed by prescriptions for other drugs in the therapeutic class.[284]

This is not surprising, because, according to plaintiffs, there was "no pharmacodynamic reason why a dose of (S)-omeprazole would interact with" the body any differently than an equal dose of omeprazole.[285] Confirming this lack of innovation, the plaintiffs alleged that "[t]he FDA Medical Officer who reviewed the entire set of clinical studies . . . concluded that '*superiority* of NEXIUM over omeprazole *was not demonstrated*,'"[286] with the review finding that "[t]here are no studies which demonstrate that [Nexium] is superior to [Prilosec], clinically or even statistically."[287] Similarly, the administrator of the Federal Centers for Medicare & Medicaid Services told attendees at a physicians convention: "You should be embarrassed if you prescribe Nexium," as "Nexium is Prilosec. . . . It is the same drug. It is a mirror com-

277 Walgreen Co. v. AstraZeneca Pharm., 534 F. Supp. 2d 146, 148 (D.D.C. 2008).

278 *Consumers Sue AstraZeneca over Nexium Ad Campaign*, CONSUMER AFF. (Oct. 19, 2004), http://www.consumeraffairs.com/news04/nexium_suit.html.

279 *Walgreens*, 534 F. Supp. 2d at 149; Walgreens Complaint, *supra* note 254, ¶ 62.

280 Walgreens Complaint, *supra* note 254, ¶ 45.

281 *Id.* ¶ 47.

282 *Id.* ¶ 67.

283 *Id.* ¶ 65–66.

284 *Id.* ¶ 65.

285 *Id.* ¶ 54.

286 *Id.* ¶ 85.

287 *Id.* (second and third alterations in original).

pound," and "Nexium is a game that is being played on the people who pay for drugs."[288]

To obtain *reduced* unit sales, AstraZeneca allegedly incurred "enormous out-of-pocket expenses" of "billions of dollars" to cover

> the costs of research and development to produce and obtain FDA approval for Nexium, incremental detailing and marketing expenses, stocking allowances paid to retailers to induce them to carry Nexium, and returned goods allowances paid to wholesalers and other direct purchasers in connection with the return of unused shipments of Prilosec.[289]

This conduct made economic sense for AstraZeneca only because it impaired generic competition.

Regarding the specific tactics used to cannibalize the product, AstraZeneca allegedly "stopped making positive product claims about Prilosec and, instead, began making negative (and false) claims," in the process "attempt[ing] to weaken the competitive position" of Prilosec in favor of its reformulated Nexium.[290] In general, AstraZeneca allegedly "used distortion and misdirection in marketing, promoting, and detailing Nexium."[291]

Assuming the facts to be true (which the court should have done on a motion to dismiss), the case thus could easily have survived based on the conduct's lack of economic sense. In this industry, the price disconnect prevents consumers from making the relevant price/cost trade-off. Monopolists therefore have an increased incentive and ability to make welfare-reducing switches from original to reformulated products. The complaint in this case alleged not only that the product hop reduced consumer welfare, but also that its sole purpose was to impair generic competition.

C. Suboxone*: No Economic Sense*

The third case also could have been decided on grounds of an absence of economic sense. Plaintiffs alleged that Reckitt projected that the reformu-

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288 *Id.* ¶ 94 (alteration in original).

289 *Id.* ¶ 66.

290 *Id.* ¶ 62.

291 Walgreen Co. v. AstraZeneca Pharm., 534 F. Supp. 2d 146, 149 (D.D.C. 2008). For example, plaintiffs alleged that AstraZeneca falsely told doctors

> that "Nexium is the first [proton pump inhibitor][or PPI] to demonstrate a significant clinical advantage over other PPIs;" that Nexium has "significantly greater healing and symptom resolution rates for . . . patients;" that Nexium has a "clinical advantage" over Prilosec; that the alleged clinical advantage "is demonstrated in longer term maintenance therapy, as well as in the initial healing stage;" that "more Nexium patients are symptom free;" that Prilosec has a "higher number of treatment failures;" that "Nexium has been shown to have a clinical advantage over omeprazole;" that "Nexium has a greater clinical advantage for more severe patients;" that Nexium is "a better PPI;" and that Nexium is "expected to positively affect other associated outcomes such as patient satisfaction, [quality of life] and productivity."

Walgreens Complaint, *supra* note 254, ¶ 91 (first and fourth alterations in original).

lated sublingual film would not generate any additional sales or profits as compared to the original tablets.[292] In fact, Reckitt predicted that it would make "as much as 30% fewer" unit sales of the reformulated drug.[293] The *sole* benefit that Reckitt expected to gain from the switch from tablets to film came *exclusively* from destroying generic substitutability.[294]

Absent the effect of impairing generic competition, the switch made no economic sense because it was very costly to Reckitt. The company raised the price of its original tablets in relation to the reformulated film version[295] even though the film was more expensive to manufacture and package.[296] Plaintiffs alleged that Reckitt increased the price of tablets by 15% while leaving the price of film unchanged, which resulted in the price of tablets rising 27% above the price of film.[297]

Further revealing an absence of economic sense, plaintiffs alleged that Reckitt "incurred substantial . . . costs to develop and manufacture Suboxone film and switch prescriptions from the tablets to the film" that took the forms of

> developing the film product and gaining FDA approval to market it . . .[;] pay[ing] a substantial royalty to a third-party manufacturer that supplies the film technology to Reckitt . . .[; and] pa[ying] tens or hundreds of millions of dollars more for its sales force to get doctors to prescribe the film rather than the tablets.[298]

As a result, Reckitt's North American business "experience[d] substantially reduced profit margins and net revenue in 2011 and 2012."[299]

In fact, based on plaintiffs' allegations, Reckitt conceded an absence of economic sense in its 2010 "Annual Business Review," which stated that Reckitt's "rapid[ ] conver[sion of] Suboxone tablets to . . . sublingual film" would lead to "a short-term dilutive impact on net revenue and operating profit" but "much better protects the medium and long-term earnings stream from the Suboxone franchise in the US."[300]

Reckitt's cannibalization tactics allegedly included disparaging the tablets to physicians and "warn[ing] of false safety concerns."[301] In particular, Reckitt claimed that the absence of unit dose packaging raised the risk of pediatric exposure.[302] Plaintiffs also alleged that Reckitt "directed its sales force to tell doctors that the film was more difficult than the tablets for

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292 End Payor Plaintiffs' Consolidated Amended Class Action Complaint ¶ 40, *In re* Suboxone Antitrust Litig., 64 F. Supp. 3d 665 (E.D. Pa. 2014) (No. 2:13-md-02445) [hereinafter Suboxone Complaint].

293 *Id.* ¶ 37.

294 *Id.* ¶ 39.

295 *Id.* ¶ 42.

296 *Id.* ¶ 38.

297 *Id.* ¶ 42.

298 *Id.* ¶ 38.

299 *Id.*

300 *Id.* ¶ 40.

301 *In re* Suboxone Antitrust Litig., 64 F. Supp. 3d 665, 674 (E.D. Pa. 2014).

302 *Id.* at 683.

patients or others to abuse by crushing and then ingesting in order to 'get high,'" even though "Suboxone film is far easier than the tablets for patients or others to dissolve and inappropriately inject or otherwise ingest."[303] These purported safety concerns did not seem so concerning given that Reckitt waited six months after publicly announcing its removal of tablets, until the FDA approved generic entry, before actually removing them.[304]

Absent the effect on generic competition, Reckitt's reformulation and cannibalization does not make sense.

D. Doryx*: No Economic Sense*

The *Doryx* case provides another example of lack of economic sense. Based on data from the first quarter of the year, Doryx capsules were profitable, garnering $50 to $60 million in revenues in 2003 and 2004.[305] According to plaintiffs, Warner Chilcott projected that the product switches would not garner any additional sales or profits.[306]

Plaintiffs additionally alleged that Warner Chilcott incurred additional costs

> to change Doryx's dosage form from capsules to tablets, to add a score to 75 and 100 mg Doryx tablets, to change Doryx's labeling to include applesauce dosing, to introduce a 150 mg Doryx tablet, and to launch promotional campaigns to shift demand from Doryx capsules to tablets (and discontinue capsules), and then from Doryx 75 and 100 mg tablets to the 150 mg tablet (and discontinue unscored 75 and 100 mg tablets).[307]

Moreover, the reformulated version was "more costly and difficult for the defendants to manufacture than the existing capsule formulation, and even required a reformulation of the delayed-release enteric coating on the pellets of doxycycline hyclate that comprise Doryx capsules so that they could withstand the compression force required to manufacture a tablet."[308] Given that Warner Chilcott did not expect any of these added costs to result in any increased sales or profits, these costs made sense only as investments in impairing competition.

Regarding the tactics of cannibalization, Warner Chilcott stopped selling capsules to wholesalers and removed capsules from the website.[309] It

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303 Suboxone Complaint, *supra* note 292, ¶ 44.

304 *See id.* ¶ 45.

305 *See Galen Holdings PLC Results for the First Quarter Ended 31 December 2003*, PR NEWSWIRE (Feb. 10, 2004), http://www.prnewswire.com/news-releases/galen-holdings-plc-results-for-the-first-quarter-ended-31-december-2003-58942652.html (identifying $13.8 million revenues in first quarter of 2003 and $15.7 million in the first quarter of 2004).

306 *See* Direct Purchaser Class Plaintiffs' Consolidated Amended Class Action Complaint ¶ 80, Mylan Pharm. Inc. v. Warner Chilcott PLC, 2013 WL 5692880 (E.D. Pa. June 12, 2013) (No. 2:12-cv-03824).

307 *Id.*

308 *Id.* ¶ 57.

309 Mylan Pharm. Inc. v. Warner Chilcott PLC (*Doryx*), 2016 WL 5403626, at *3 (3d Cir. Sept. 28, 2016).

ensured that retailers would "auto-reference" the tablet whenever doctors filled prescriptions.[310] And it further reduced demand for the product by informing wholesalers, retailers, and doctors that "Doryx Capsules have been replaced by Doryx Tablets,"[311] and destroying and buying back some of the remaining capsules.[312] Whether or not these specific tactics made economic sense when viewed individually and in isolation, the reformulation and cannibalization, through whatever tactics they were achieved, reveal a lack of economic sense.

E. Namenda*: No Economic Sense*

The *Namenda* case provides the final example of a manufacturer's conduct that made no economic sense (absent the effect of impairing competition). Namenda was one of Forest's best-selling drugs, generating roughly $1.5 billion in annual sales in 2012 and 2013.[313] Plaintiffs pointed in the complaint to Forest's documents, which revealed that its product-hopping strategy would produce a significant reduction in profits resulting from "patients who, in response to the lack of availability of Namenda IR, decide not to switch to Namenda XR."[314] The documents treated this loss as a "disruption," and projections estimated "as much as '20% franchise disruption' if [Forest] withdraws Namenda IR from the market prior to generic entry."[315] Providing a hornbook application of the no-economic-sense test, one Forest presentation included sales projections that showed that under any potential scenario, it would "lose tens if not hundreds of millions of dollars in the short term if it withdraws Namenda IR from the market."[316]

The *Namenda* court noted that "in deciding to take [the original product] off the market, Defendants were willing to give up profits they would have made selling IR—Forest's best-selling drug,"[317] revealing a "willingness to forsake short-term profits to achieve an anticompetitive end" and demonstrating anticompetitive behavior.[318] But the court appears to have applied such a test only to the discrete conduct of withdrawing the old product from the market, rather than, as we urge, to the manufacturer's overall conduct of reformulating the product and cannibalizing its sales (by whatever means).

Forest's cannibalization tactics included a cessation of active marketing of IR when it brought the reformulated version to the market.[319] In addition, Forest announced that it would discontinue Namenda and published

310 *Id.*
311 *Id.*
312 *Id.*
313 New York *ex rel.* Schneiderman v. Actavis PLC (*Namenda*), 787 F.3d 638, 647 (2d Cir. 2015).
314 Complaint ¶ 101, *Namenda*, 787 F.3d 638 (No. 14-cv-7473).
315 *Id.*
316 *Id.*
317 *Namenda*, 787 F.3d at 659.
318 *Id.* (quoting *In re* Adderall XR Antitrust Litig., 754 F.3d 128, 135 (2d Cir. 2014)).
319 *Id.* at 648.

letters on its website urging healthcare providers and caregivers to "discuss switching to Namenda XR" with their patients.[320] Finally, Forest sought to convert the largest customer base of Medicare patients to the reformulated version "by sending a letter to the Centers for Medicare & Medicaid Services requesting that the agency remove IR from the formulary list, so that Medicare health plans would not cover it."[321] Absent the effect on generic competition, Forrest's product hop did not make economic sense.

* * *

In short, application of the no-economic-sense test would lead to a different outcome in two of the cases and a different analysis in all of them. Such a framework conservatively recommends liability only when behavior literally makes no sense other than through its stifling of generic competition. At the same time, it focuses on the low-hanging fruit of straightforward economic analysis rather than getting bogged down in the tempting, but far-from-compelling, tangent of hard versus soft switches. The no-economic-sense test is widely recognized as favorable to defendants, but applying it leads to more rigorous outcomes in two of five cases and different reasoning in all five. This dissonance shows just how far the caselaw has veered from justifiable economic analysis.

Conclusion

Judicial and scholarly treatment of product hopping has varied. It has paid various levels of attention to the regulatory framework. And it has overemphasized the distinction between hard and soft switches, and offered a simplistic and unsustainable analysis of "coercion" and "choice."

This Article introduces a more justifiable framework for the antitrust analysis of product hopping that is based on the economics of the pharmaceutical industry. Most generally, it offers three ways for a brand manufacturer to avoid antitrust liability. First, it defines product hopping so that scrutiny is limited to reformulations involving the switching of the prescription base. This articulation limits antitrust scrutiny to hops designed to impair generic competition rather than reformulations designed to compete with other brands or grow the market.

Second, it introduces two safe harbors that ensure that the vast majority of reformulations are not subject to antitrust scrutiny, providing brand firms with more certainty and predictability than they receive under existing caselaw. Third, it provides a no-economic-sense test—a simple framework that avoids a complex, open-ended analysis and that minimizes false positives. Imposing antitrust liability on behavior that does not make economic sense other than through its impairment of generic competition provides a justifiable framework.

320 *Id.*

321 *Id.*

Under the no-economic-sense framework, merely introducing new products would pass the test—indeed, it would not even constitute a product hop. But when the brand combines a reformulation that destroys generic substitutability with cannibalizing the original product's sales, the framework would not treat as dispositive the distinction between hard and soft switches. Removing the original product from the market is just one of many cannibalization tactics. Our framework applies the no-economic-sense test not to specific cannibalization tactics, but to the product hop itself—reformulating the product and cannibalizing its sales (by whatever means). A soft switch might fail the no-economic-sense test, and a hard switch might pass it. As in every application of the no-economic-sense test in other industries and circumstances, each case will depend on the brand's *ex ante* projections of sales and costs.

Product hopping presents some of the most nuanced issues in antitrust and IP law. The consequences for consumers and the industry are significant, and courts' analyses of these issues have varied. This Article offers a conservative framework rooted in the economics of the pharmaceutical industry that courts, government enforcers, plaintiffs, and manufacturers can use to distinguish between investments in innovation and investments in impairing generic competition.

GIPC
GLOBAL INNOVATION POLICY CENTER

April 29, 2021

The Honorable David Cicilline
Chairman
Subcommittee on Antitrust,
Commercial, and Administrative Law
Washington, DC 20515

The Honorable Ken Buck
Ranking Member
Subcommittee on Antitrust,
Commercial, and Administrative Law
Washington, DC 20515

Re: Subcommittee Hearing entitled, "Treating the Problem: Addressing Anticompetitive Conduct and Consolidation in Health Care Markets"

Dear Chairman Cicilline and Ranking Member Buck:

The U.S. Chamber of Commerce appreciates the committee's interest in examining issues related to competition in the health care sector, and we look forward to working with you to improve the strength and effectiveness of our health care markets to better serve the American people.

Given the full committee's oversight of intellectual property (IP) issues and historically strong support for our domestic IP system and related policies, we hope the committee will give due attention to the critical role IP has played in American innovation, especially in the biopharma sector.

The industry's response to the COVID-19 crisis has produced effective vaccines and treatments in record time. America's innovation ecosystem –underpinned by our strong IP framework – enabled the U.S. response to the COVID-19 crisis and supported the development and access to life-saving vaccines, treatments, and medical devices that have saved countless lives throughout the world.

Some have argued that IP policies may need to be revisited in response to the current pandemic; we believe the facts show otherwise. In fact, the numerous collaborations that have led to vaccines and treatments being developed in less than a year were a direct result of our IP system. Witness, Pfizer-BioNTech; Moderna and the U.S. government; and many others. These partnerships between government, academia, and the private sector, which are central to the success of America's multi-stakeholder innovation ecosystem in normal times, gained new visibility and reached unprecedented levels during the pandemic. Such collaborations are enabled by predictable, reliable intellectual property rights that provide a legal and commercial basis for contractual arrangements—such as the nearly 300 and counting industry-to-industry licensing deals that are accelerating vaccine production around the world.

The committee will hear from witnesses who have previously put forth the unsupported premise that our patent system contributes to a lack of competition and access to products. Concerns are likely to be expressed about perceived abuses of the patent system, with terms such as "product-hopping" being used to support this mistaken premise. Again, we believe the facts support the exact opposite conclusion. Our domestic patent system ensures that America is the leader in the "innovation economy," which plays a foundational role in the development of new vaccines and treatments and affords the American people the broadest access of any country in the world to these products.

As the world is confronted with numerous COVID-19 virus variants and potential future threats, it is more important than ever that we can respond with new formulations to combat the emerging strains to end this pandemic. Unfortunately, efforts to prescriptively legislate "product-hopping" could limit the ability of the biopharma sector to respond to these new threats. The Chamber fully supports responding to abuse in the marketplace. It is important to note that "product-hopping" can already be found to be unlawful under existing antitrust law and companies have been held liable where such practices lack pro-competitive justifications.

Efforts to expand the law are likely to harm existing research programs that may otherwise lead to future innovations. For example, in coming years there may be generic/biosimilar applications filed for patents related to new vaccines and therapeutics to deal with COVID-19 variants or other threats. Existing manufacturers should not be exposed to antitrust liability if they invest in research programs that changes a vaccine or therapeutic formulation to target a new variant or change the delivery method for such revised or new vaccines or therapeutics, where additive innovations bring real value to patients. Helpful improvements such as enhancing the effectiveness of a vaccine by making it longer lasting and requiring fewer "booster" shots could be deemed as "product-hopping" under various legislative proposals.

Surely, these are not the types of outcome Congress would wish to incur, but they will be the unintended consequence of legislative solutions that overreach the perceived problems they are intended to address.

Those who look beyond antitrust law take a different view seek to limit access to our patent system in a discriminatory manner, seeking different rules for the biopharma sector than other industry sectors. One need only consider the many patents issued on successive generations of cell phone models or other tech industry products to appreciate the essential role "follow-on" patents play in bringing new, innovative products to market.

As the world celebrates "World IP Day" this week, the comments of four former directors of the United States Patent and Trademark Office (USPTO) at an event celebrating World IP Day deserve the committee's attention. All four past USPTO directors, from both Democrat and Republican administrations, stated it is their belief that America remains the leader in innovation and enjoys a strong competitive position in the global marketplace as a direct result of the strength of our domestic IP system, with an emphasis on the critical role of our patent system. All expressed concerns about efforts to weaken our patent framework and how that could undermine the innovation ecosystem it supports and connects.

We urge the full committee to fully explore the evidence that supports maintaining our strong IP system and to reject efforts to weaken the patent policies that allow America to remain the world's leader in innovation.

Thank you for your consideration of these issues. We look forward to working with you and members of the committee going forward.

Sincerely,

Patrick Kilbride

cc: Members of the Committee on the Judiciary

action
FOR HEALTH

May 5, 2021

The Hon. Jerrold L. Nadler
Chairman
House Committee on the Judiciary
U.S. House of Representatives
2132 Rayburn House Office Building
Washington, DC 20515

The Hon. Jim D. Jordan
Ranking Member
House Committee on the Judiciary
U.S. House of Representatives
2056 Rayburn House Office Building
Washington, DC 20515

Re: Statement for the record, "Treating the Problem: Addressing Anticompetitive Conduct and Consolidation in Health Care Markets"

Dear Chairman Nadler and Ranking Member Jordan:

Thank you for this opportunity to submit these comments regarding the Subcommittee on Antitrust, Commercial, and Administrative Law's recent hearing on healthcare competition. We are grateful for your leadership on this issue. Additionally, we applaud Chairman Cicilline and Ranking Member Buck's interest in focusing on the problem of consolidation, especially the monopolistic practices of hospitals and health insurance plans.

Action for Health[1] is a national, non-profit patient advocacy organization. In all our work, we attempt to educate policymakers like yourself, the media, and concerned citizens about critical healthcare issues. One of our main focuses currently is ensuring fair regulatory outcomes for the No Surprises Act, legislation enacted last year[2] that eliminates surprise medical bills for patients and constructs an independent dispute resolution (IDR) process for physicians and health insurers to settle out-of-network (OON) payment disputes. In fact, **equitable implementation of this law is the best way to stem the tide of consolidation in healthcare markets**. If the No Surprises Act is implemented to the advantage of health insurers, independent physicians will not be compensated fairly and will always lose their cases brought to an IDR arbitrator. These physicians will then have to become employed by hospitals, where costs are exponentially higher and administrative pressure leads to lower quality care.

Throughout our research and advocacy efforts, we spend considerable time analyzing the anticompetitive conduct of healthcare system actors. As such, we hope these comments are helpful to you and the Committee as you pursue your timely and important work on this subject.

[1] Action for Health, www.action4health.org.
[2] H.R. 133, Consolidated Appropriations Act, 2021, (P.L. 116-260), December 27, 2020, accessed: https://www.congress.gov/bill/116th-congress/house-bill/133/text.

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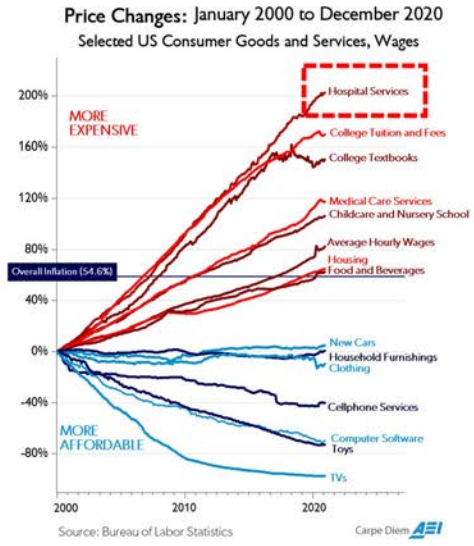
Introduction

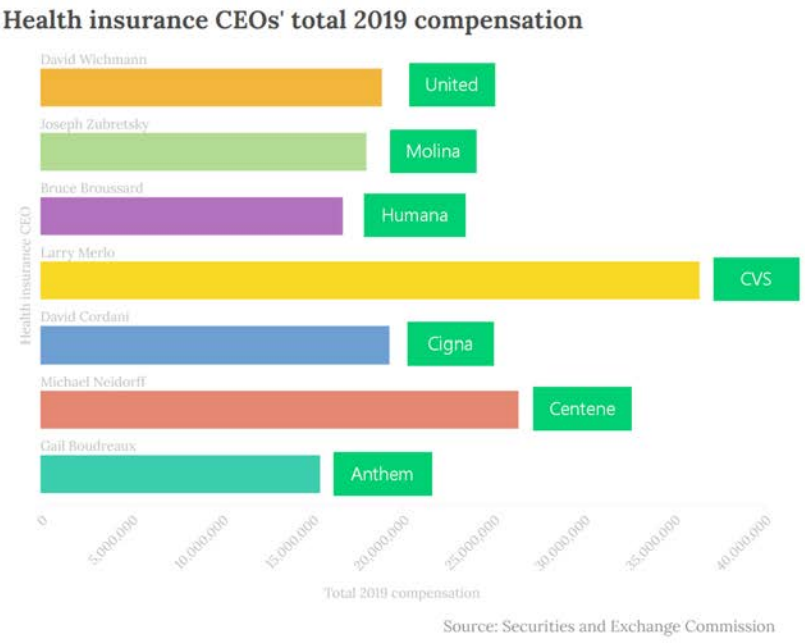
Healthcare costs in our country have soared because giant hospital systems and health insurers have exerted outsized regional and national dominance. Indeed, **the true impediment to improved quality and lower cost is hospital-insurance monopolies.** Establishing fairer rules and checking these actors' power would help everyone, especially patients. Moreover, independent doctors should be making healthcare decisions, rather than administrators and executives.

The CEOs of large hospitals and health insurance companies alike have aggressively pushed for more consolidation. This anticompetitive behavior not only drives up costs and increases their own profits and salaries, but also stifles competition, innovation, and quality improvements. This chart, often cited, captures just how extraordinarily hospital costs have risen over the past 20 years.[3]



[3] Mark J. Perry, "Chart of the day... or century?", American Enterprise Institute, January 17, 2021, accessed: https://www.aei.org/carpe-diem/chart-of-the-day-or-century-5.

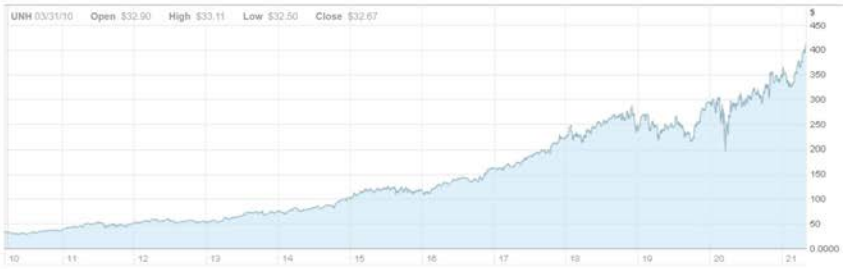
Speaking of salaries, total compensation for the nation's seven largest health insurance company chief executives continues to skyrocket.[4] To be clear, we are not opposed to executives earning large sums for stellar performance, nor do we advocate setting rates for renumeration. But for these CEOs to be earning these astronomical salaries on the backs of patients who are crushed by ever-increasing premiums and fewer choices due to insurers narrowing their coverage networks is wholly unacceptable.



[4] Paige Minemyer, "CVS' Merlo was the top paid health insurance CEO in 2019. Here's a look at what other payer CEOs earned", Fierce Healthcare, April 27, 2020, accessed: https://www.fiercehealthcare.com/payer/here-s-what-top-health-plan-ceos-earned-2019.

Perhaps even more egregious is the compensation supposed non-profit hospitals pay their CEOs. As a *Forbes* column highlighted, "...These hospitals add billions of dollars annually to their bottom line, lavishly compensate their CEOs, and spend millions of dollars, which are generated by patient fees, lobbying government to defend the status quo."[5] An eye-opening oversight report of the country's 82 largest non-profit hospitals really homes in on this extravagant pay. Of these largest hospitals, 13 of them compensated their top earner between $5 million and $21.6 million per year.[6] Without a doubt, while these non-profit hospital CEOs are getting wealthier, patients "are getting healthcare poorer."[7]

Additionally, concerning profits, it is worth noting the sheer financial fortune health insurers' anticompetitive practices have produced. For example, back when the Affordable Care Act (ACA) was passed in March 2010, UnitedHealth's share price was roughly $32 per the chart below.[8] Fast forward 11 years, and, as of this writing, UnitedHealth's stock is now worth $412 per share. In such a relatively short timeframe, **UnitedHealth's stock has appreciated %1,188.**



Source: Merrill Lynch

[5] Adam Andrzejewski, "Top U.S. 'Non-Profit' Hospitals & CEOs Are Racking Up Huge Profits", Forbes, June 26, 2019, accessed: https://www.forbes.com/sites/adamandrzejewski/2019/06/26/top-u-s-non-profit-hospitals-ceos-are-racking-up-huge-profits/?sh=f45665e19dfb.
[6] Open the Books, "Top 82 U.S. Non-Profit Hospitals: Quantifying Government Payments and Financial Assets", June 2019, accessed: https://www.openthebooks.com/top-82-us-non-profit-hospitals-quantifying-government-payments-and-financial-assets--open-the-books-oversight-report.
[7] Andrzejewski, Ibid.
[8] Merrill Lynch, UnitedHealth Group Incorporated (NYSE:UNH), Security Profile, May 4, 2021.

Physicians are rightfully standing up to these anticompetitive practices, as well. As the *New York Times* reported last month, "UnitedHealthcare, one of the nation's largest health insurers, is being sued in two states by a large group of anesthesiologists who are accusing the company of stifling competition by forcing the doctors out of its network and by using its enormous clout to pressure hospitals and surgeons to stop referring patients to them."[9]

Finally, last year's skewed and inequitable disbursement of Covid-19 provider relief funds has further exacerbated these consolidation and anticompetitive challenges. Approximately three months into the pandemic, the nation's two largest hospital operators had already received a combined $7.3 billion in aid.[10] Even earlier, in May 2020, four major hospital operators – all of whom are publicly-traded companies with significant access to capital – disclosed that they had already received between $195 and $700 million in federal aid.[11] Small hospitals and independent medical groups received next to nothing.

Healthcare decisions made between the nation's approximately one million physicians and the nation's 330 million patients have essentially been taken over by the large health system CEOs and their peers at the largest health insurance companies. There can be no real healthcare reform, cost reduction, or quality improvement without real reform of non-profit hospitals and insurance companies to allow for a functioning healthcare marketplace. Therefore, we are offering three (3) sets of recommendations, covering hospital reform, insurance reform, and government reform. It is hoped that the Congress in general, and your Committee specifically, thoroughly explores these recommendations. If implemented, they would reverse the trends of anticompetition and consolidation in our healthcare markets.

Hospital Reform

Large hospital systems are the only ones with any bargaining power with the dominant health insurance plans. **Together, hospitals and insurers are acting to lower in-network rates and force independent physicians out of business.** Thousands of doctors have been forced out of business by insurers. Conversely, not a single insurance plan has been forced out of business by physicians.

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[9] Reed Abelson, "Doctors Accuse UnitedHealthcare of Stifling Competition", New York Times, April 1, 2021, accessed: https://www.nytimes.com/2021/04/01/health/unitedhealthcare-lawsuit.html.
[10] Chad Terhune,, "Billions in COVID relief go to biggest hospital chains as smaller rivals await aid", Reuters, June 9, 2020, https://www.reuters.com/article/us-health-coronavirus-hospital-billions/billions-in-covid-relief-go-to-biggest-hospital-chains-as-smaller-rivals-await-aid-idUSKBN23G1GI.
[11] Ayla Ellison,, "14 health systems receiving biggest CARES Act payments", Becker's Hospital Review, May 8, 2020, https://www.beckershospitalreview.com/finance/14-health-systems-receiving-biggest-cares-act-payments.html.

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Health insurance companies agree to pay hospitals exorbitant in-network rates for hospital services in return for the hospital agreeing to put all its doctors in-network and "accepting" miniscule fees for the doctors' professional services. Hospitals then "true-up" physicians by paying them a much larger fee for their services than would be warranted from their in-network contracts. Hospitals kick back a large part of the large in-network fee for hospital technical services. As a result, all hospital physicians are often in-network, and many independent physicians are OON. In effect, the only option for many independent doctors is to refuse insurers' artificially low rates and remain OON.

Recommendations

Administration

- A non-profit hospital should make at least 50% of its emergencies (through emergency call) available to voluntary physicians on staff at that hospital.

Compensation

- A non-profit hospital should pay its employed physicians based approximately on the value of the insurance contracts for which it signs its physicians. For example, a physician's compensation for clinical services should be based on that physician's collections or expected collections minus overhead expenses (e.g., malpractice insurance, health insurance, secretarial salaries, and billing, marketing, and administrative costs). Non-clinical payments should also be made at fair market value. States would routinely check random physician compensation arrangements to confirm that they follow these provisions. Importantly, an exception can be made for physicians who work in hospitals in underserved communities where patients are primarily uninsured or covered only by Medicaid.

- Compensation, including bonuses and long-term incentive plans, for hospital administrators should not be tied in to increased hospital revenue, increase hospital profits, or increased hospital volume.

- Non-profit hospital public payments – such as through tax exempt charitable donations, other tax exemptions, or other government subsidies or payments – should not be used to pay for physician or administrator compensation.

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Credentialing

- A non-profit hospital should offer credentialing to any qualified voluntary provider (physician, physician's assistant, or nurse practitioner), provided the provider will pay for the cost of credentialing. Any provider who is denied prompt credentialing by a hospital may appeal to the applicable state for relief. The loser will bear the process' cost. This provision would not apply to physicians who are full-time employees of other hospitals.

- A non-profit hospital that has volume requirements for credentialing should allow for comparable case experiences to be used for such requirements.

Human Resources

- Any provider who believes that an unjust decision had been made against him or her in a hospital quality assurance committee or other care oversight committee may appeal the decision to the applicable state for relief. Any provider who has been subject to disciplinary action or termination from a hospital may appeal the decision to the applicable state for relief. The loser will bear the cost of the process.

- A non-profit hospital should be prohibited from creating or enforcing restrictive covenants against any providers or other employees. Additionally, a non-profit hospital should be prohibited from creating or enforcing gag orders against providers or employees who allege misconduct by the hospital.

- Non-profit hospitals should not be permitted to reward, pay, or pressure their employed physicians to refer to that hospital's services, or to the services of other physicians employed by that hospital. Similarly, these hospitals should not be permitted to threaten or punish physicians who choose not to refer patients to the services of that hospital or other physicians employed by that hospital.

Ownership

- It is high time that regulations from 2010 prohibiting new physician-owned hospitals (POH) from participating in Medicare or Medicaid be amended. Furthermore, anyone, including physicians, should be permitted to own a hospital.

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Health Insurance Reform

Private insurance company profits are tied to overall premiums. Due to regulations embedded in the ACA, these profits are capped at 20% of premiums. The higher the premiums, the higher their profits. For those health insurers that are publicly traded companies, they have a fiduciary responsibility to their shareholders to maximize their profits. Therefore, given the ACA cap, these insurers must continually raise their premiums year-over-year.

The health insurer business model is frankly straight forward: offer as few plans and providers in a region as possible. This consolidation leads to higher costs. Physicians and hospitals rely on private insurers to make up for Medicare and Medicaid. Unfortunately, health insurers can choose to deny contracts for any physician or hospital. Put simply, there are no real negotiations between insurers and independent doctors regarding in-network rates.

Insurers sign millions of essentially phony contracts with hospitals for their physician services, which insurers know will not be the basis for those doctors' compensation. As such, in-network rates are generally not market rates.

Recommendations

Competition

- Health insurance companies should not be permitted to coordinate any marketing, coverage, or other business activities with other insurers.

Contracting

- Insurers should agree to sign contracts with any competent provider or hospital, at no less than 10% of the median local contracted rate.

- Removal by an insurer of any competent provider or hospital from their network should be prohibited.

- Insurers should not be able to require that all physicians of a given group sign contracts in order to sign contracts with one or more such physicians.

- Health insurance companies should not be allowed to execute contracts with hospitals for physicians or other providers that are not based on what the hospital intends to ultimately compensate that physician or provider. The insurer should confirm with the

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hospital that it does not intend to kick back hospital collections or profits to offset the values of the rates agreed to with said insurer.

- The creation of "anti-assignment" provisions in insurance company contracts should be prohibited.

- Insurers should lower their payments for hospital ("technical") services and increase their payments for physician services. This way, contracted rates accurately reflect what hospitals and physicians are being paid for their services.

Ownership

- Anyone should be permitted to own or create a health insurance product. Such product should also not be unduly denied or delayed by the federal or state governments.

Payments

- Health insurers that claim a "claw back" is due to them may bring their case to an appropriate judicial proceeding. They should be prohibited, however, from withdrawing payments from those due for different patients or different services.

- At the signed request of a patient, his or her health insurer should send payments directly to the physician or hospital.

Referrals

- If a patient requires the services of a specialist and asks for an in-network specialist from their health insurer, the insurer must promptly provide the name of such a qualified and available regional provider. If that provider is determined to be unqualified or unavailable to provide such a service, the patient should be permitted to find an appropriate OON provider at no additional cost to the patient.

Reimbursement

- At the request of a patient or a treating physician (including a non-participating physician, if the patient has signed a waiver to this effect), the health insurer should promptly provide in writing exact data about its intended reimbursement benefits.

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Federal Government Reform

Last week, the Centers for Medicare and Medicaid (CMS) finalized a host of regulations that will impact the price of and access to 2022 ACA exchange plans for patients. While this is a step in the right direction, robust reform of Medicare and Medicaid has eluded the Congress for many years.

Recommendations

Equity

- Any entity or provider that provides a medical service in a given area should be paid the same for Medicare or Medicaid for providing that service.

Fee Schedules

- The Medicare and Medicaid fee schedules for hospitals and physicians should be recalibrated (i.e., hospital payments lowered and physician payments increased). This will more accurately reflect what hospitals are actually paying physicians for their services.

Subsidies

- If "extra clinical payments" are being made for "medical teaching" or "medical research", then any entity (e.g., large hospital, small hospital, or independent medical group) must be equally eligible to participate and receive such funding.

- Government subsidies (state and federal) that are made available to large hospitals should be equally available to small hospitals and to independent medical groups.

Conclusion

If large hospital systems and health insurance companies continue to use their unfair negotiating position to squeeze independent physicians, quality of care will ultimately suffer. Fewer independent physicians mean hospital and insurance concerns – and notably, their profits – will govern medical care.

This is much more than just dollars and cents. According to a survey by the Physicians Foundation and Merritt Hawkins, only 31.4% of physicians identified as independent practice

owners or partners in 2018. In 2012, independent physicians made up 48.5% of all doctors.[12] Physicians and other providers are already under siege from insurers. The effects of the Covid-19 pandemic on physicians' ability to work only made matters much worse.

In sum, the forced consolidation of medical practices will result in fewer physicians, higher costs, and poor quality of patient care.

Thank you again for this opportunity to provide you our comments on the current state of competition and consolidation in our nation's healthcare markets. Much more work remains, but we are confident there are solutions readily available, such as the recommendations provided herein, to address these problems. If we can be of any help to you or your staffs, please do not hesitate to contact me directly at (202) 823-2333.

Sincerely,

Christopher G. Sheeron
President
Action for Health

Cc: The Hon. David N. Cicilline
Chairman
Subcommittee on Antitrust, Commercial and Administrative Law

The Hon. Ken R. Buck
Ranking Member
Subcommittee on Antitrust, Commercial and Administrative Law

[12] Physicians Foundation, "2018 Survey of America's Physicians, Practice Patterns, and Perspectives", September 2018, p. 23, accessed: https://physiciansfoundation.org/wp-content/uploads/2018/09/physicians-survey-results-final-2018.pdf.

QUESTIONS AND ANSWERS FOR THE RECORD

Representative Eric Swalwell

House Committee on the Judiciary

Subcommittee on Antitrust, Administrative, and Commercial Law
Thursday, April 29, 2021; 1:00 p.m.

Hearing: Treating the Problem: Addressing Anticompetitive Conduct and Consolidation in Health Care Markets

Question for Pressor Robin Feldman, Leemore Dafny, and Michael Carrier

I represent Veeva Systems, a cloud computing company in the healthcare space. It has alleged, in a lawsuit as well as communications with my office and the Federal Trade Commission (FTC), certain antitrust abuses in the healthcare industry. Specifically, it complains that one company, IQVIA, which maintains an enormous database of global sales and reference data on doctors and prescriptions of pharmaceuticals, is a monopolist which is refusing to allow bio-tech and pharmaceutical companies that use software that competes with IQVIA to have access to this vital warehouse of data.

Without commenting on the merits of Veeva's allegations, how can it be damaging to competition when a monopolist refuses competitors access to data or information needed to compete? Can such an action be an abuse of monopoly power?

Robin Feldman
Arthur J. Goldberg Distinguished Professor of Law
Director, Center for Innovation

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August 2, 2021

Dear Chairman Nadler,

It is with pleasure that I provide the following response to the question submitted for the record following the House Judiciary Subcommittee on Antitrust, Administrative, and Commerical Law's April 29th, 2021, hearing titled, "Treating the Problem: Addressing Anticompetitive Conduct and Consolidation in Health Care Markets."

Question from Representative Eric Swalwell:

> I represent Veeva Systems, a cloud computing company in the healthcare space. It has alleged, in a lawsuit as well as communications with my office and the Federal Trade Commission (FTC), certain antitrust abuses in the healthcare industry. Specifically, it complains that one company, IQVIA, which maintains an enormous database of global sales and reference data on doctors and prescriptions of pharmaceuticals, is a monopolist which is refusing to allow bio-tech and pharmaceutical companies that use software that competes with IQVIA to have access to this vital warehouse of data.
>
> Without commenting on the merits of Veeva's allegations, how can it be damaging to competition when a monopolist refuses competitors access to data or information needed to compete? Can such an action be an abuse of monopoly power?

Reponse:

> I am not familiar with, nor can I comment on, the specific facts of the Veena Systems litigation. In a different context, however, I would note that Congress itself recently expressed concerns about refusals to deal with a competitor in the health care space. The CREATES Act, which was signed into law in December 2019 as part of the Further Consolidated Appropriations Act of 2020, established a private right of action allowing companies that are in the process of applying for approval of generic, biosimilar, or interchangeable drugs to bring suit against brand companies who refuse to provide samples of the brand drug for comparison, thereby hindering FDA approval of the generic, biosimilar, or interchangeable.

Warmest regards,
Robin Feldman

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Distinguished Professor

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Michael A. Carrier
Response to Representative Swalwell's Question for the Record

House Committee on the Judiciary, Subcommittee on Antitrust, Administrative, and Commercial Law
Hearing on "Treating the Problem: Addressing Anticompetitive Conduct and Consolidation in Health Care Markets"

June 11, 2021

I. Monopolist Refusals to License

A. A monopolist's refusal to license can constitute monopolization
B. First, the monopolist can have monopoly power
   1. Monopoly power can be shown indirectly or directly
      a) Indirect evidence: examine market share (90%, possibly 75%) and barriers to entry.[1]
      b) Direct evidence: high prices, output reductions
C. Second, the monopolist could engage in exclusionary conduct
   1. While refusals to license do not often constitute monopolization, some scenarios—like engaging in behavior that makes no economic sense[2] other than harming a competitor—can satisfy this standard
      a) *E.g.:* In *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, the Supreme Court found that an owner of downhill skiing facilities that withdrew from a joint ticketing arrangement was liable for anticompetitive conduct because it was willing to forego ticket sales and sacrifice profits to harm its smaller competitor.[3]
      b) *E.g.*: In *Otter Tail Power Co. v. United States*, the Supreme Court required a company to share electric power transmission with rivals because the "refusal to sell at wholesale or to [transfer] were solely to prevent municipal power systems from eroding its monopolistic position."[4]
      c) Conduct that only makes sense by harming competitors does not have a justification based on improving consumer welfare and can increase price, lower output, and reduce innovation
D. One setting in which courts have found that refusals to license can constitute monopolization involves brand firms' denials of samples generics need to enter the market
   1. Most courts have denied motions to dismiss when plaintiffs have challenged denials pursuant to FDA safety-based requirements known as "REMS" (Risk Evaluation and Mitigation Strategies)
   2. In *Actelion v. Apotex*, the court explained that the Supreme Court's refusal-to-deal decisions were "fact-specific" and "industry-specific" and that the generics "alleged a profit motive which did not exist in [*Verizon Commc'ns v. Law Offices of Curtis V. Trinko*]."[5]
   3. In *Mylan v. Celgene*, the court found that a "prior course of dealing" between the parties was not "dispositive" and that the defendant's motion to dismiss should be denied because of its failure to plead any "legitimate business reason" for its behavior.[6]
   4. In *In re Thalomid and Revlimid Antitrust Litigation*, the court denied the defendant's motion to dismiss, explaining that Supreme Court decisions "indicate that motivation is central" and that "it is too soon to measure motivation on Celgene's part."[7]
      a) The plaintiffs alleged that "Celgene provided samples to researchers who were not seeking to enter the market, but not to competitors, who were" and the court found that Celgene's "continu[ing] to refuse to deal…raises a plausible inference that [its] reliance on its distribution programs is pretextual."[8]

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[1] Michael A. Carrier, *Sharing, Samples, and Generics: An Antitrust Framework*, 103 CORNELL L. REV. 1, 21-22 (2017) (citing sources).
[2] For a collection of cases applying a "no economic sense" analysis, see Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 214 n.240 (2016).
[3] 472 U.S. 585, 605-11 (1985).
[4] 410 U.S. 366, 378 (1973).
[5] Transcript of Motions Hearing, *Actelion Pharm. Ltd. v. Apotex, Inc.*, 1:12-cv-05743, at 115 (D.N.J. Oct. 17, 2013).
[6] Transcript of Oral Opinion, *Mylan Pharms. Inc. v. Celgene Corp.*, No. 2:14-cv-02094-ES-MAH, at 12-13, 17-18 (D.N.J. Dec. 22, 2014); *see also Mylan Pharms. Inc. v. Celgene Corp.*, Case 2:14-cv-02094-ES-MAH, at 35 (D.N.J. Oct. 3, 2018) (denying summary judgment on similar grounds).
[7] 2015 WL 9589217, at *15 (D.N.J. Oct. 29, 2015).
[8] *Id.*

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June 11, 2021

Dear Representative Bishop:

I promised to follow up on the question you posed during the House Judiciary Subcommittee on Antitrust hearings on April 29, 2021, titled, *Treating the Problem: Addressing Anticompetitive Conduct and Consolidation in Health Care Markets,* concerning whether the Affordable Care Act promotes consolidation among hospitals. My expertise is greater in the pharmaceutical industry; in the context of pharmaceutical pricing, I can say that the ACA certainly has had pockets of unanticipated results.

For example, the ACA's mandate that health insurance companies must spend at least 80% of premium dollars on paying medical claims was designed to keep a lid on overall costs. Instead, it has created a perverse incentive in which life can be better for a health insurance company when drug prices rise. To paraphrase one commentator, if I tell my son that he can only have 20% of a bowl of ice cream, a clever child will say, "Make it a bigger bowl."[1] Higher drug prices help make the bowl bigger.

Similarly, under the Act's provisions, the government reinsurance program picks up 80% of the cost of medicine, once a Medicare patient reaches the out-of-pocket threshold. Higher drug prices push patients more quickly into the stage at which government picks up the 80% and the health insurance company pays less. As a result, higher prices can benefit insurance plans under those circumstances.[2]

Whether it is the Affordable Care Act or the antitrust laws, experience on the ground can easily reveal unintended consequences that require additional legislative action. I am grateful for the opportunity to appear before the Committee and to respond to these queries, and I would be happy to provide any additional information that may be useful.

Warmest regards,

Robin Feldman

[1] For a more detailed description of the problem, *see* DRUGS, MONEY, & SECRET HANDSHAKES: THE UNSTOPPABLE GROWTH OF PRESCRIPTION DRUG PRICES 35-36 (Oxford 2019).
[2] For additional discussion of this problem and a related perverse incentive in the Medicare system, *see* Robin Feldman, *Perverse Incentives: Why Everyone Prefers High Drug Prices—Except for Those Who Pay the Bills,* 57 HARV. J. ON LEGIS. 303, 350-351 (2020).