

# COMBATING THE OPIOID EPIDEMIC: EXAMINING CONCERNS ABOUT DISTRIBUTION AND DIVERSION

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## HEARING BEFORE THE SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS OF THE COMMITTEE ON ENERGY AND COMMERCE HOUSE OF REPRESENTATIVES ONE HUNDRED FIFTEENTH CONGRESS SECOND SESSION

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MAY 8, 2018

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## C O N T E N T S

	Page
Hon. Gregg Harper, a Representative in Congress from the State of Mississippi, opening statement .....	2
Prepared statement .....	3
Hon. Diana DeGette, a Representative in Congress from the State of Colorado, opening statement .....	4
Prepared statement .....	6
Hon. Greg Walden, a Representative in Congress from the State of Oregon, opening statement .....	7
Prepared statement .....	9
Hon. Frank Pallone, Jr., a Representative in Congress from the State of New Jersey, opening statement .....	10
Prepared statement .....	11

### WITNESSES

Joseph R. Mastandrea, D.O., Chairman, Miami-Luken, Inc. ....	13
Prepared statement .....	16
Answers to submitted questions .....	124
John Hammergren, Chairman, President, and Chief Executive Officer, McKesson Corp. ....	20
Prepared statement .....	22
Answers to submitted questions .....	131
George S. Barrett, Executive Chairman, Cardinal Health .....	31
Prepared statement .....	33
Answers to submitted questions .....	165
Steven H. Collis, Chairman, President, and Chief Executive Officer, AmerisourceBergen Corp. ....	43
Prepared statement .....	45
Answers to submitted questions .....	173
James Christopher Smith, Former President and Chief Executive Officer, H.D. Smith, LLC .....	57
Prepared statement .....	59
Answers to submitted questions .....	187

### SUBMITTED MATERIAL

Subcommittee document binder <sup>1</sup>	
Slide, “Fatal Prescription Opioid Overdose 2017,” Virginia Department of Health, submitted by Mr. Griffith .....	78
Subcommittee memorandum .....	107
Reports, chief executive officer salaries and compensation, submitted by Ms. Castor .....	116

<sup>1</sup> The information has been retained in committee files and also is available at <https://docs.house.gov/Committee/Calendar/ByEvent.aspx?EventID=108260>.





## **COMBATING THE OPIOID EPIDEMIC: EXAMINING CONCERNS ABOUT DISTRIBUTION AND DIVERSION**

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**TUESDAY, MAY 8, 2018**

HOUSE OF REPRESENTATIVES,  
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,  
COMMITTEE ON ENERGY AND COMMERCE,  
*Washington, DC.*

The subcommittee met, pursuant to call, at 10:00 a.m., in room 2123, Rayburn House Office Building, Hon. Gregg Harper (chairman of the subcommittee) presiding.

Members present: Representatives Harper, Griffith, Burgess, Brooks, Collins, Barton, Walberg, Walters, Costello, Carter, Walden (ex officio), DeGette, Schakowsky, Castor, Tonko, Ruiz, Pallone (ex officio).

Also present: Representatives Blackburn, Bilirakis, McKinley, Johnson, Guthrie, Lance, and Welch.

Staff present: Jennifer Barblan, Chief Counsel, Oversight and Investigations; Mike Bloomquist, Staff Director; Karen Christian, General Counsel; Jordan Davis, Director of Policy and External Affairs; David DeMarco, Deputy IT Director; Adam Fromm, Director of Outreach and Coalitions; Ali Fulling, Legislative Clerk, Oversight and Investigations, Digital Commerce and Consumer Protection; Theresa Gambo, Human Resources and Office Administrator; Brittany Havens, Professional Staff, Oversight and Investigations; Zach Hunter, Communications Director; Perry Lusk, Minority GAO Detailee; Christopher Santini, Counsel, Oversight and Investigations; Jennifer Sherman, Press Secretary; Alan Slobodin, Chief Investigative Counsel, Oversight and Investigations; Hamlin Wade, Special Advisor for External Affairs; Christina Calce, Minority Counsel; Jeff Carroll, Minority Staff Director; Tiffany Guarascio, Minority Deputy Staff Director and Chief Health Advisor; Christopher Knauer, Minority Oversight Staff Director; Miles Lichtman, Minority Policy Analyst; Perry Lusk, Minority GAO Detailee; Kevin McAloon, Minority Professional Staff Member; Andrew Souvall, Minority Director of Communications; and C.J. Young, Minority Press Secretary.

**OPENING STATEMENT OF HON. GREGG HARPER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MISSISSIPPI**

Mr. HARPER. I now call to order this hearing on “Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion.”

One year ago today, on May the 8th, 2017, the committee opened a bipartisan investigation into the distribution of prescription opioids by wholesale drug distributors with a specific focus on unusually large opioid shipments to small pharmacies in West Virginia. The launch of this investigation was spurred by press reports of astonishing levels of opioid distribution to pharmacies in small, rural West Virginia towns.

Between 2007 and 2012, distributors sent more than 700 million hydrocodone and oxycodone pills to the State, or 433 pills for every man, woman, and child in the State. In that timeframe, 1,728 West Virginians fatally overdosed on these two drugs.

The numbers were eye-opening. The Sav-Rite pharmacy in Kermit, West Virginia, population around 400, received nearly 9 million opioids in a 2-year period. Another pharmacy, in nearby Oceana, West Virginia, received 600 times as many oxycodone pills as the Rite Aid drugstore just eight blocks away.

This led the committee, on a bipartisan basis, to request information from the Drug Enforcement Administration and the so-called Big Three drug distributors: McKesson, Cardinal Health, and AmerisourceBergen. These distributors delivered more than 500 million opioids to West Virginia between 2007 and 2012, with Cardinal shipping 241 million opioids, AmerisourceBergen shipping about 119 million opioids, and McKesson shipping more than 150 million opioids.

Later in the investigation the committee also sent letters to two regional distributors with a major presence in West Virginia, Miami-Luken and H.D. Smith. We found that the stunning numbers that led us to start this investigation were much more common than we had hoped.

Among our discoveries are a single pharmacy in Mount Gay-Shamrock, West Virginia, population 1,779, that received more than 16.5 million hydrocodone and oxycodone pills between 2006 and 2016. In nearby Williamson, West Virginia, population 2,900, distributors sent almost 21 million opioids to two pharmacies during the same period. And this is just within the targeted areas that we reviewed.

We have learned much from the investigation but still have many questions. For example, why did the distributors repeatedly fail to report suspicious orders of opioids or exercise effective controls against diversion?

By 2005, internet pharmacies had transformed the DEA regulatory paradigm with unprecedented large volumes of controlled substances being shipped to individual pharmacies. Pill mill doctors and pharmacies began to proliferate. The agency needed help, and given their position in the supply chain and their legal obligations to identify and report suspicious orders, identified the distributors as a main line of defense against diversion.

Through meetings and letters over a period of years, the DEA educated and coached the distributors on their responsibilities. The distributors have contended that the DEA provided insufficient communication and guidance. Distributors have also said that only the DEA can see the full picture with respect to pharmacy volume and that distributors are simply privy to their own data.

But were distributors' capabilities that limited? Distributors conduct due diligence, site visits, and can obtain market data. They can request and analyze a pharmacy's dispensing data, which provides the distributors with the ability to see all the controlled substances being dispensed by a pharmacy and the prescribers over a given period of time.

In some cases, such as what we have seen in West Virginia, the volume of controlled substances a distributor sends on its own should be cause for concern.

Distributors also contend that they do not set demand and simply satisfy orders for prescriptions written by licensed doctors and filled by licensed pharmacists. But what about the distributor's legal responsibility to know their customer and perform due diligence?

And what does our work mean for the rest of the country? West Virginia is far from the only State heavily impacted by the opioid epidemic. It has hit every State, and everyone in this room has been affected in some way.

How many other communities across the country have received millions more opioids than their communities could reasonably sustain? How many other times did a distributor miss the red flags of their own distribution, let alone what could be found with due diligence? How many other Kermits and Williamsons are out there?

It is my hope that we will see some answers today as to how the drug distributors seemingly missed the red flags of diversion.

I want to welcome the witnesses and thank each of you for your participation to help us in this important investigation.

I also thank my colleagues from across the aisle for all of their hard work on this bipartisan investigation.

And I now recognize the ranking member of the subcommittee, Ms. DeGette.

[The prepared statement of Mr. Harper follows:]

#### PREPARED STATEMENT OF HON. GREGG HARPER

One year ago today, May 8, 2017, the committee opened a bipartisan investigation into the distribution of prescription opioids by wholesale drug distributors, with a specific focus on unusually large opioid shipments to small pharmacies in West Virginia.

The launch of this investigation was spurred by press reports of astonishing levels of opioid distribution to pharmacies in small, rural West Virginia towns. Between 2007 and 2012, distributors sent more than 780 million hydrocodone and oxycodone pills to the State—or 433 pills for every man, woman, and child in the State. In that timeframe, 1,728 West Virginians fatally overdosed on those two drugs.

The numbers were eye-opening. The Sav-Rite pharmacy in Kermit, West Virginia—population around 400—received nearly 9 million opioids in a 2-year period. Another pharmacy in nearby Oceana, West Virginia, received 600 times as many oxycodone pills as the Rite Aid drugstore just eight blocks away.

This led the committee on a bipartisan basis to request information from the Drug Enforcement Administration, and the so-called Big Three drug distributors: McKesson, Cardinal Health, and AmerisourceBergen. These distributors delivered more than 500 million opioids to West Virginia between 2007 and 2012, with Car-

dinal shipping 241 million opioids, AmerisourceBergen shipping about 119 million opioids, and McKesson shipping more than 150 million opioids. Later in the investigation, the committee also sent letters to two regional distributors with a major presence in West Virginia: Miami-Luken and H.D. Smith.

We found that the stunning numbers that led us to start this investigation were more common than hoped.

Among our discoveries are a single pharmacy in Mount Gay-Shamrock, West Virginia—population 1,779—that received more than 16.5 million hydrocodone and oxycodone pills between 2006 and 2016. In nearby Williamson, West Virginia—population 2,900—distributors sent almost 21 million opioids to two pharmacies during the same period. And this is just within the targeted areas that we reviewed.

We have learned much from the investigation, but still have many questions. For example, why did the distributors repeatedly fail to report suspicious orders of opioids or exercise effective controls against diversion? By 2005, Internet pharmacies had transformed the DEA regulatory paradigm, with unprecedented large volumes of controlled substances being shipped to individual pharmacies. Pill mill doctors and pharmacies began to proliferate. The agency needed help, and, given their position in the supply chain and their legal obligations to identify and report suspicious orders, identified the distributors as a main line of defense against diversion. Through meetings and letters over a period of years, the DEA educated and coached the distributors on their responsibilities.

The distributors have contended that the DEA provided insufficient communication and guidance. Distributors have also said that only the DEA can see the full picture with respect to pharmacy volume and that distributors are simply privy to their own data.

But were distributors' capabilities that limited? Distributors conduct due diligence, site visits, and can obtain market data. They can request and analyze a pharmacy's dispensing data, which provides the distributors with the ability to see all the controlled substances being dispensed by a pharmacy and the prescribers over a given period of time. In some cases, such as what we have seen in West Virginia, the volume of controlled substances a distributor sends on its own should be cause for concern.

Distributors also contend that they do not set demand, and simply satisfy orders for prescriptions written by licensed doctors and filled by licensed pharmacies. But what about the distributors' legal responsibility to "know their customer" and perform due diligence?

And what does our work mean for the rest of the country? West Virginia is far from the only State heavily impacted by the opioid epidemic. It has hit every State, and every one of us in the room has been affected in some way. How many other communities across the country have received millions more opioids than their communities could reasonably sustain? How many other times did a distributor miss the red flags of their own distribution—let alone what could be found with due diligence? How many other Kermits and Williamsons are out there?

It's my hope that we will get some answers today as to how the drug distributors seemingly missed the "red flags" of diversion.

I welcome the witnesses and thank you for your participation. I also thank my colleagues across the aisle for all of their hard work on this investigation and now recognize the ranking member of the subcommittee, Ms. DeGette.

Mr. HARPER. And I now recognize the ranking member of the subcommittee, Ms. DeGette.

#### **OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO**

Ms. DEGETTE. Thank you so much, Mr. Chairman.

This investigation has been bipartisan. And as you mentioned, it was a year ago today when we sent our first letters to three of the drug wholesale distributors before us today. Those letters described the devastation of the opioid crisis, and they referenced a report that, over 6 years, distributors showered the State with 780 million hydrocodone and oxycodone pills while 1,728 West Virginians fatally overdosed on those two painkillers.

Over the last year, we learned a lot more about the full scope of the epidemic in West Virginia. As the chairman said, we obtained data showing that pharmacies in tiny towns received millions of pills in just a few years.

But our work is not finished. We want to know what these companies knew about the rise of the opioid epidemic, when they knew it, and whether it informed their distribution practices.

In fact, over a decade ago the DEA sent letters to all registered distributors informing them that, quote, “The abuse of controlled prescription drugs is a serious and growing health problem in this country,” end quote.

In 2007, CDC reported that drug overdose deaths nationwide increased by 276 percent between 1999 and 2014, and in West Virginia, drug overdose deaths were up by 550 percent.

A well-publicized 2008 JAMA study specifically implicated prescription opioids in the rise of overdose deaths.

In 2010, the New England Journal of Medicine article, “A Flood of Opioids, a Rising Tide of Deaths,” showed that the prescription opioids death toll continued to rise, particularly in West Virginia.

In 2011, the Charleston Gazette published a major story describing how residents began calling the town of Williamson, quote, “Pilliamson,” because so many opioids had flooded that town.

And this is just a small sampling of the articles that highlighted the rise of this epidemic.

So yet, even as this information was coming out, it appears that, over 3 years, distributors sent more than 11 million pills to one pharmacy in a town of 400 and more than 12 million total pills to two pharmacies in a town of 3,000. I mean, come on.

I know we are going to hear from the distributors that they had systems in place and that they only fill orders by pharmacies that hold valid DEA licenses. At the end the day, however, I think we can all agree, whatever systems were in place did not prevent damage to these communities caused by what appears to be the excessive supply of opioid pills.

Some of the counties that have been the focus of the investigation have the highest death and overdose rates in the Nation. The epidemic has devastated families throughout that State, and it has placed huge burdens on the State’s healthcare system, its child welfare program, and its economy as a whole.

Now, we need to understand the root causes of how we let this happen and why distributors apparently supplied so many opioids to certain small town pharmacies. For example, how did the tiny town of Kermit, with a population of 400, receive 9 million pills in just 2 years? Shouldn’t the distributors’ suspicious order systems have immediately flagged and halted shipment of this magnitude? And shouldn’t the distributors have examined them more closely to determine the appropriateness for shipping them?

I also want to understand why major drug companies failed to have adequate suspicious order reporting programs in place and were forced to have to settle with the DOJ and the DEA not once, but twice during this epidemic. Do the distributors believe that any of their suspicious order reporting system failed? And if so, how?

I hope what we learn today will help us inform investigations all across the country, including in Colorado, which has had similar concerns raised about overdistribution.

Mr. Chairman, let me conclude by saying we agree it is critical that we understand what happened and how the Nation has found itself in the grip of this opioid crisis. But at the same time, I think that the overall committee needs to make sure that we have adequate resources available to help those in need and to get people like those in the hard-hit places we will be talking about today the recovery that they need.

As we look back on what happened, we cannot turn our backs on those who were devastated by this crisis.

Thank you, and I yield back.

[The prepared statement of Ms. DeGette follows:]

#### PREPARED STATEMENT OF HON. DIANA DEGETTE

Exactly 1 year ago today, this committee sent our first letters to three of the drug wholesale distributors before us today. Our letters described the devastation of the opioid crisis, and referenced a report that over 6 years, distributors “showered the State with 780 million hydrocodone and oxycodone pills, while 1,728 West Virginians fatally overdosed on those two painkillers.”

Over the past year, we have learned more about the full scope of this epidemic in West Virginia. We have obtained data showing that pharmacies in tiny towns received millions of pills in just a few years.

But Mr. Chairman, our work is not finished. I want to know what these companies knew about the rise of the opioid epidemic, when they knew it, and whether it informed their distribution practices.

In fact, over a decade ago, DEA sent letters to all registered distributors, informing them that “the abuse of controlled prescription drugs is a serious and growing health problem in this country.”

In 2007, CDC reported that drug overdose deaths nationwide increased by 276 percent between 1999 and 2004, and that in West Virginia, drug overdose deaths were up by 550 percent.

A well-publicized 2008 JAMA study specifically implicated prescription opioids in the rise in overdose deaths.

In 2010, the New England Journal of Medicine article “A Flood of Opioids, a Rising Tide of Deaths,” showed that the prescription opioids death toll continued to rise, particularly in West Virginia.

In 2011, the Charleston Gazette published a major story describing how residents began calling the town of Williamson [quote], “Pill-iamson,” because so many opioids had flooded that town.

And this is just a small sample of the articles highlighting the rise of this epidemic.

And yet, even as all of this information was coming out, it appears that over 3 years, distributors sent more than 11 million pills to one pharmacy in a town of 400, and more than 12 million total pills to two pharmacies in a town of 3,000.

I know that we will hear from the distributors that they had systems in place and that they only fill orders by pharmacies that hold valid DEA licenses. At the end of the day, however, whatever systems were in place did not prevent the damage to these communities caused by what appears to be the excessive supply of opioid pills.

Some of the counties that have been the focus of our investigation have the highest death and overdose rates in the Nation. The epidemic has devastated families throughout that State and it has placed huge burdens on the State’s health care system, its child welfare program, and its economy as a whole.

We need to understand the root causes of how this happened, and why distributors apparently supplied so many opioids to certain small-town pharmacies.

For example, how did the tiny town of Kermit with a population of 400 hundred receive 9 million pills in just 2 years? Should the distributors’ suspicious order systems have immediately flagged and halted shipments of this magnitude, and examined them more closely to determine their appropriateness before shipping them?

I also want to understand why major drug companies failed to have adequate suspicious order reporting programs in place and were forced to settle with DOJ and

DEA not once, but twice during this epidemic. Do these distributors believe that any of their suspicious order reporting systems failed, and if so, how?

I hope that what we learn today will inform investigations in other States, including Colorado, which has had similar concerns raised concerning over distribution, going forward.

Mr. Chairman, let me conclude by saying that it is critical that we understand what happened and how the Nation has found itself in the grip of this ongoing opioid crisis. But at the same time, I also believe we commit to making adequate resources available to help those in need, and get people, such as those in the hard hit places we will be talking about today, the recovery help they need. As we look back at what happened, we cannot turn our backs on those who have been devastated by this crisis.

Thank you.

Mr. HARPER. The gentlewoman yields back.

The Chair now recognizes the chairman of the full commitment, Mr. Walden, for the purposes of an opening statement.

**OPENING STATEMENT OF HON. GREG WALDEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON**

Mr. WALDEN. Thank you, Mr. Chairman.

Over the last few years, the Energy and Commerce Committee has conducted multiple investigations, enacted major bipartisan legislation, and helped authorize historic levels of funding to help those battling this epidemic in our communities all across America. But clearly we have much more work to do, including two important hearings and a full committee markup this week on this issue.

Our efforts continue on two tracks. One is to provide new legislative solutions, new laws, new programs to combat the crisis. And the second track is to continue our yearlong investigation into its causes.

As you have heard before, today's hearing marks a 1-year anniversary since we first asked the Drug Enforcement Administration and the Nation's largest distributors of opioids for information about the overwhelming amount of prescription opiates that flooded into countless communities all across the United States.

After hearing from the DEA in March, it is important that today we hear from the executives who lead the most influential pharmaceutical distribution companies in America. We have tough questions for you today. You know that. But we ask you these questions in order for all of us to find solutions.

Today, a thousand people will go into emergency rooms overdosing on opioids. Today in America, 115 people will die from opioid addiction and overdose. This is why we are moving forward.

A decade ago, the DEA realized that its enforcement strategy had to change to fight the rising tide of internet pharmacies, internet pharmacies and pill mills. With more than a million DEA registrants, the DEA simply could not fight this only at an individual doctor and pharmacy level.

So to more effectively and efficiently combat this emerging law enforcement challenge, the DEA asked the drug distributors to play a more proactive role in identifying, analyzing, and reporting and blocking suspicious orders of controlled substances.

In 2005, the DEA started the Distributor Initiative Program. That program had a goal of educating registrants on maintaining effective controls against diversion and monitoring for and reporting suspicious orders. DEA held individual meetings in 2005 and

2006 with McKesson, with Cardinal Health, and AmerisourceBergen, and instructed companies on how to identify and submit reports of suspicious orders.

In 2006 and 2007, the DEA sent three letters to all DEA-registered distributors to put them on notice about their legal obligations. However, soon after the start of this initiative, each of these three companies faced enforcement actions, in 2007 and 2008, for failures to maintain effective controls against the diversion of controlled substances. Cardinal Health and McKesson each paid civil penalties totaling millions of dollars.

Meanwhile, the opioid crisis worsened over the next decade, especially in ravaged communities like we have heard about this morning and in our investigations in small towns in West Virginia.

Even after the 2008 settlements, while concerns rose over the opioid epidemic, some distributors were still failing to exercise effective controls against diversion. This led to more enforcement actions and more settlements, including a record-setting \$150 million civil penalty by McKesson in 2017. It remains an open question today whether the distributors have finally achieved effective DEA compliance programs.

Since the 1970s, distributors have had a statutory responsibility under the Controlled Substances Act to exercise due diligence to report and avoid filling suspicious orders. This responsibility is due to their unique position in the marketplace. They are the chokepoints in the U.S. prescription drug supply chain.

Three of those that are before us today, McKesson, Cardinal Health, and AmerisourceBergen, account for about 85 percent of the drug supply. So it is not sufficient just to blame the DEA, although we have our own issues with the DEA's role in this. You have a unique set of resources and tools at your disposal and a shared responsibility in flagging suspicious activity and diversion. You are on the front lines of the defense in this crisis.

Instead, the information uncovered by the investigation over the last year is stunning. There is no logical explanation that we can find for why a town of approximately 400 people would receive 9 million opioid pills in 2 years or why a single pharmacy in a town of 1,800 people would receive nearly 17 million opioid pills in a decade. Then there are two pharmacies in a nearby town of 2,900 people which received nearly 21 million opioids in the same timeframe.

No matter how you cut these data, behind each of these numbers was a pill mill, and they proliferated for far too long.

So given what we know about the volume of opioid shipments to small towns in West Virginia and the associated pill mills and diversion schemes in those areas, it is difficult not to be troubled by the compliance efforts by our Nation's distributors.

So we look forward to getting a better understanding of the facts and to finally have this necessary and frank conversation. We owe it to the 115 Americans who will die today and every day from opioid overdoses and to their loved ones to understand what led to this crisis and to identify solutions to stem the tide.

With that, Mr. Chairman, I yield back.

[The prepared statement of Mr. Walden follows:]



## PREPARED STATEMENT OF HON. GREG WALDEN

Mr. Chairman, thank you for holding this hearing. I also want to thank you and Ranking Member DeGette for your work in this bipartisan investigation.

This Energy and Commerce Committee is leading the national fight to combat the opioid crisis. Over the past few years we've conducted multiple investigations, enacted major bipartisan legislation, and helped authorize historic levels of funding—to help those battling this epidemic in communities across the country. But clearly we have more work ahead of us, including two important hearings and a full committee markup this week. Our efforts continue on two-tracks, providing new legislative solutions to combat the crisis and conducting thorough investigations into its causes.

Today's hearing marks 1 year to the day since we first asked the DEA and the Nation's largest opioid distributors for information about the overwhelming amount of prescription opiates that flooded countless communities. After hearing from the DEA in March, it's important that today we hear from the executives who lead the most influential pharmaceutical distributors in the country. We have tough questions for you today, but we ask you these questions in order for us all to find solutions.

More than one decade ago, the DEA realized that its enforcement strategy had to change to fight the rising tide of internet pharmacies and pill mills. With more than one million DEA registrants, the DEA simply could not fight this only at an individual doctor and pharmacy level. To more effectively and efficiently combat this emerging law enforcement challenge, the DEA asked the drug distributors to play a more proactive role in identifying, analyzing, reporting, and blocking suspicious orders of controlled substances.

In 2005, the DEA started the "Distributor Initiative Program," with the goal of educating registrants on maintaining effective controls against diversion, and monitoring for and reporting suspicious orders. DEA held individual meetings in 2005 and 2006 with McKesson, Cardinal Health, and Amerisource Bergen, and instructed the companies on how to identify and submit reports of suspicious orders. In 2006 and 2007, the DEA sent three letters to all DEA-registered distributors to put them on notice about their legal obligations.

However, soon after the start of this initiative, each of these three companies faced enforcement actions in 2007 and 2008 for failures to maintain effective controls against diversion of controlled substances. Cardinal Health and McKesson each paid civil penalties totaling millions of dollars.

Meanwhile, the opioid crisis worsened over the next decade, especially in ravaged communities like the small towns in rural West Virginia.

Even after the 2008 settlements, while concerns rose over the opioid epidemic, some distributors were still failing to exercise effective controls against diversion. This led to more enforcement actions, and more settlements, including a record-setting \$150 million civil penalty by McKesson in January 2017. It remains an open question today whether the distributors have finally achieved effective DEA compliance programs.

Since the 1970s, you have had a statutory responsibility under the Controlled Substances Act to exercise due diligence to report and avoid filling suspicious orders. This responsibility is due to your unique position in the marketplace. You are the chokepoints in the U.S. prescription drug supply chain. Three of you—McKesson, Cardinal Health, and AmerisourceBergen—account for about 85 percent of the drug supply.

It is not sufficient to simply blame the DEA. You have a unique set of resources and tools at your disposal, and a shared responsibility in flagging suspicious activity and diversion. You are supposed to be one of the first lines of defense in this crisis.

Instead, the information uncovered by this investigation over the last year is stunning. There is no logical explanation for why a town of approximately 400 people would receive 9 million opioid pills in 2 years. Or why a single pharmacy in a town of about 1,800 people would receive nearly 17 million opioid pills in a decade. Then there are the two pharmacies in a nearby town of 2,900 people which received nearly 21 million opioids in the same time frame. No matter how you cut this data, behind each of these numbers was a pill mill. And they proliferated for far too long.

Given what we know about the volume of opioid shipments to small towns in West Virginia, and the associated pill mills and diversion schemes in those areas—it is difficult to not be troubled by your compliance efforts and the part you have played in our Nation's opioid crisis.

We look forward to getting a better understanding of the facts, and to finally have this necessary and frank conversation. We owe it to the 115 Americans who die

every day from opioid overdoses, and their loved ones, to understand what led to this crisis and to identify solutions to stem the tide.

Mr. HARPER. The chairman yields back.

The Chair will now recognize the ranking member for the full committee, Mr. Pallone.

**OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY**

Mr. PALLONE. Thank you, Mr. Chairman.

The opioid epidemic continues to devastate this country, and virtually no community in America has been left untouched. West Virginia in particular has been severely affected. For the last several years, West Virginia has had the highest overdose death rate in the country.

This committee's investigation has uncovered some very troubling information about seemingly large shipments of opioids from drug distributors to rural pharmacies in West Virginia over the course of several years.

And I think it is important for us to understand what went wrong and why, but we must also understand what needs to change so that we do not ever find ourselves in this situation again. For example, there is simply no excuse for distributors sending more than 13 million doses of opioids to a single pharmacy in a town of just over 400 people over a 6-year period.

Some of the distributors who supplied high amounts of pills to this pharmacy appear not to have submitted suspicious order reports to DEA even though the law requires them to do so. In addition, some of the distributor's files are either sparse or unavailable, raising additional questions about whether they investigated the risk of diversion before shipping these pills.

In the end, Federal authorities raided and shut down this pharmacy, and its owner went to jail. And we must understand what went wrong here so that we can be sure that no town is ever again flooded with pills.

In another case, two doctors in the town of Williamson prescribed more opiates than entire hospitals did, according to a Justice Department press release, and these doctors were in fact the highest opioid prescribers in the entire State and were widely known to be running pill mills. One of these doctors ultimately went to jail; the other fled overseas.

It appears that certain distributor systems failed to detect the volume of prescriptions these pharmacies were filling for these doctors, which may have led to oversupply and diversion of pills.

It is the distributors' responsibility to know their customers, monitor orders, refuse suspicious orders, and report those orders to DEA. Distributors must perform these functions particularly when pharmacies order high volumes of opioids. But our investigation has shown that this did not always happen.

In fact, some of these distributors paid large fines to DOJ because their systems failed and because they did not report suspicious orders to DEA as required. And these distributors promised to clean up their act, but just a few years later, they were again hit with multimillion-dollar fines for the very same shortcomings.

So I want to know how we can be confident that distributors have sufficiently improved their systems now so that going forward we will not miss key indicators that may help uncover diversion in other situations.

For example, one distributor told us that, with the benefit of hindsight, they wished they had asked different questions of at least two of the pharmacies we have examined. And I would like to know what kind of questions they believe will make the process more effective and reduce the possibility of diversion.

Mr. Chairman, this is a nationwide concern. The problems we found in West Virginia have broader lessons for the rest of the country.

I also want point out that this investigation focused on the role the distributors played in this crisis, but we know that there are many causes of this epidemic. This includes the role of some manufacturers in manufacturing these drugs, the role of some rogue physicians in overprescribing them, and the failure of regulators at the State and Federal level to adequately oversee the opioid supply chain.

But let me also highlight another important aspect of this committee's work which I hope will not be lost as we look at how events unfolded in the past, because this crisis is far from over. Right now countless Americans, including those in the hard-hit areas of West Virginia, still need to access quality healthcare to help them recover from the opioid crisis.

In the past month, we have marked up a substantial number of opioid-related bills, and I am still concerned that we have made this push without taking the time to make sure we get it right without much of an emphasis on treatment. It is not enough to only look backwards at this crisis. We must take the necessary steps to actually help those who are suffering by providing comprehensive treatment to individuals and communities in need.

Unless someone wants my minute, I will yield it back.

Thank you.

[The prepared statement of Mr. Pallone follows:]

#### PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

The opioid epidemic continues to devastate this country, and virtually no community in America has been left untouched. West Virginia in particular has been severely affected. For the last several years, the State has had the highest overdose death rate in the country.

This committee's investigation has uncovered some very troubling information about seemingly large shipments of opioids from drug distributors to rural pharmacies in West Virginia over the course of several years.

I think it is important for us to understand what went wrong and why, but we must also understand what needs to change so that we do not ever find ourselves in this situation again.

For example, there is simply no excuse for distributors sending more than 13 million doses of opioids to a single pharmacy in a town of just 400 people over a 6-year period.

Some of the distributors who supplied high amounts of pills to this pharmacy appear not to have submitted suspicious order reports to DEA, even though the law requires them to do so. In addition, some of the distributors' files are either sparse or unavailable, raising additional questions about whether they investigated the risks of diversion before shipping these pills. In the end, Federal authorities raided and shut down this pharmacy and its owner went to jail. We must understand what went wrong here so that we can be sure no town is ever again flooded with pills.

In another case, two doctors in the town of Williamson prescribed more opioids than entire hospitals did, according to a Justice Department press release. These doctors were in fact the highest opioid prescribers in the entire State, and were widely known to be running "pill mills." One of these doctors ultimately went to jail; the other fled overseas. It appears that certain distributors' systems failed to detect the volume of prescriptions these pharmacies were filling for these doctors, which may have led to oversupply and diversion of pills.

It is the distributors' responsibility to know their customers, monitor orders, refuse suspicious orders, and report those orders to DEA. Distributors must perform these functions, particularly when pharmacies order high volumes of opioids. But our investigation has shown that this did not always happen.

In fact, some of these distributors paid large fines to DOJ because their systems failed and because they did not report suspicious orders to DEA as required. These distributors promised to clean up their act. But just a few years later, they were again hit with multi-million dollar fines for the very same shortcomings.

I want to know how we can be confident that distributors have sufficiently improved their systems now, so that going forward we will not miss key indicators that may help uncover diversion in other situations. For example, one distributor told us that, with the benefit of hindsight, they wish they had asked different questions of at least two of the pharmacies we have examined. I would like to know what kind of questions they believe will make the process more effective and reduce the possibility of diversion.

This is a nationwide concern, and the problems we have found in West Virginia have broader lessons for the rest of the country.

I also want to point out that this investigation focused on the role that distributors played in this crisis, but we know that there are many causes of this epidemic. This includes the role of some manufacturers in marketing these drugs, the role of some rogue physicians in overprescribing them, and the failures of regulators at the State and Federal level to adequately oversee the opioid supply chain.

But let me also highlight another important aspect of this committee's work, which I hope will not be lost as we look at how events unfolded in the past, because this crisis is far from over.

Right now, countless Americans, including those in the hard-hit areas of West Virginia, still need access to quality health care to help them recover from the opioid crisis. In the past month, we have marked up a substantial number of opioid-related bills. I am concerned that we have made this push without taking the time to make sure we get it right or without much of an emphasis on treatment.

It is not enough to only look backwards at this crisis. We must take the necessary steps to actually help those who are suffering by providing comprehensive treatment to individuals and communities in need. I yield back.

Mr. HARPER: The gentleman yields back.

I ask unanimous consent that the Members' written opening statements be made a part of the record. Without objection, it will be entered into the record.

Additionally, I ask unanimous consent that Energy and Commerce members not on the Subcommittee on Oversight and Investigations be permitted to participate in today's hearing. Without objection, so ordered.

I would now like to introduce our witnesses for today's hearing.

First today we have Dr. Joseph Mastandrea, chairman of the board at Miami-Luken; John Hammergren, chairman, president, and CEO of McKesson Corporation; George Barrett, executive chairman of the board at Cardinal Health; Steven Collis, chairman, president, and CEO of AmerisourceBergen Corporation; and finally, J. Christopher Smith, former president and CEO, H.D. Smith Wholesale Drug Company.

You are aware that the committee is holding an investigative hearing. And when doing so, we have the practice of taking testimony under oath.

Do any of you have any objection to testifying under oath?

Seeing none, the Chair then advises you that, under the rules of the House and the rules of the committee, you are entitled to be accompanied by counsel.

Do you wish to be accompanied by counsel during your testimony today?

Seeing none, in that case, if you would please rise. Raise your right hand, and I'll swear you in.

[Witnesses sworn.]

Mr. HARPER. Each of you are now under oath and subject to the penalties set forth in Title 18, Section 1001 of the United States Code.

You may now give a 5-minute summary of your written statement. We will begin first hearing from Dr. Joseph Mastandrea.

You are recognized for 5 minutes.

I ask that everyone pull your microphone close to you, make sure it's on.

And you're recognized for 5 minutes, Dr. Mastandrea.

**STATEMENTS OF JOSEPH R. MASTANDREA, D.O., CHAIRMAN, MIAMI-LUKEN, INC.; JOHN HAMMERGREN, CHAIRMAN, PRESIDENT, AND CHIEF EXECUTIVE OFFICER, MCKESSON CORP.; GEORGE S. BARRETT, EXECUTIVE CHAIRMAN, CARDINAL HEALTH; STEVEN H. COLLIS, CHAIRMAN, PRESIDENT, AND CHIEF EXECUTIVE OFFICER, AMERISOURCEBERGEN CORP.; AND JAMES CHRISTOPHER SMITH, FORMER PRESIDENT AND CHIEF EXECUTIVE OFFICER, H.D. SMITH, LLC**

**STATEMENT OF JOSEPH R. MASTANDREA**

Dr. MASTANDREA. Good morning, Committee Chairman Walden, Subcommittee Chairman Harper, Ranking Members Pallone and DeGette, and distinguished members of the subcommittee. Thank you for the invitation to testify before you today, and thank you for your tireless efforts to address our Nation's ongoing opioid epidemic.

I would like to share some background about Miami-Luken with you. The company was originally cofounded by my father, Robert E. Mastandrea, in 1962 as the Miami Valley Wholesale Drug Company in Dayton, Ohio. Nine years later, in 1971, the acquired the A.G. Luken Drug Company of Richmond, Indiana. It was then that the company Miami-Luken was born.

Since then, the company has made additional acquisitions in Ohio and West Virginia, yet has always remained a relatively small regional distributors.

I first started working for the company at the age of 14 working in the warehouse. After graduating college, I worked a short time with my father learning the day-to-day operations of the business where I was involved in making sales calls, deliveries, and various warehouse duties.

It was a wonderful place to work, and I was proud of my father and what he had achieved. He was born in Italy and came to this country at the age of 13. He subsequently graduated from college and began a business career that would lead to the formation of Miami-Luken. Through my father's leadership, the company's culture was more like a family than just a place to work.

I entered medical school in 1979 and after my residency embarked on a full-time career as a physician in Dayton. Several years later I was asked to serve on the board of directors of Miami-Luken, which I accepted. Some years later, I became the chairman of the board and have held that position since that time.

Management of the company remained pretty much the same until 2007 when a new president was appointed by the board. This individual had extensive managerial experience in both the wholesale drug business and the wholesale grocery business and was more than qualified to lead the company. He was knowledgeable, confident, and well-liked by the company's employees.

It was not until several years later, in 2013, after the board learned that the DEA had issued a number of subpoenas to the company, that we realized the Government had concerns with the company's compliance efforts.

In response, we retained the services of a prominent attorney here in Washington who used to work for the DEA. This attorney worked with management to assist the company in fulfilling its DEA compliance obligations. We also instructed the company's president to purchase a computer program to better identify suspicious orders from customers, which he did.

When we subsequently learned that management was having difficulties with the computer system they purchased, it was apparent to us that we needed someone more capable in that position. The board immediately began looking for a replacement and after considering several individuals hired the company's current president and CEO, Michael Faul.

In addition to hiring Mr. Faul, the company hired a new director of compliance and security who worked with Mr. Faul to implement a number of significant changes in the company's compliance program.

These included more frequent and robust customer visits by compliance staff, greater scrutiny of requests from customers to increase purchase quantities, increased facility and transportation security, implementation of compliance training, purchase of the NTIS database, enhancing the controlled substance profile that customers are required to complete during the on-boarding process, and the complete overhaul of Miami-Luken's standard operating procedures regarding DEA compliance.

The compliance director also worked with the software vendor to recalibrate the company's computerized suspicious orders notification system, improved its effectiveness in identifying suspicious orders on a daily basis, and started the process of uploading all relevant data on shared computer drives providing employees and DEA investigators easier access to information pertaining to individual customers.

He also hired additional staff to assist the company in its compliance efforts and created a new analytical tool on an Excel spreadsheet to assist in conducting due diligence on current and prospective customers. In fact, the compliance director last year was recognized by the National Association of Drug Diversion Investigators for his outstanding work in drug diversion prevention.

As a result of new management's enhanced compliance efforts, Miami-Luken terminated its relationship with multiple customers,

many of whom are still in business purchasing from other sources. Since 2014, we have reduced the sale of oxycodone by approximately two-thirds and the sale of hydrocodone by a similar margin.

It is our understanding that former management took what they believed to be sufficient steps at the time, believing that the State medical boards and State pharmacy boards were in a strong position to monitor the physicians and pharmacists they licensed.

Former management also believed that since Miami-Luken regularly provided the DEA with sales data for all its customers, the Government would have advised us if they had any concerns with sales to specific parties.

Unfortunately, we know that is not enough. And as you know from the materials we have provided this committee last year, Miami-Luken has taken aggressive action going back several years to strengthen its compliance efforts and suspicious order monitoring system and reporting. And as I sit here now, I can assure you that our company employs a compliance program that is second to none.

In closing, I welcome any questions you have and will answer them to the best of my ability. Thank you again for this opportunity and for all your efforts.

[The prepared statement of Dr. Mastandrea follows:]

Joseph R. Mastandrea, D.O.  
Chairman, Miami-Luken, Inc.  
May 8, 2018

Good morning. Committee Chairman Walden, Subcommittee Chairman Harper, Ranking Members Pallone and DeGette, and distinguished members of the subcommittee, thank you for your invitation to testify before you today, and thank you for your tireless efforts to address our nation's ongoing opioid epidemic.

I would like to share some background about Miami-Luken with you. The company was originally co-founded by my father, Robert E. Mastandrea, in 1962 as the Miami Valley Wholesale Drug Company, in Dayton, Ohio. Nine years later in 1971, the company acquired the A.G. Luken Drug Company of Richmond, Indiana. It was then that the company Miami-Luken was born. Since then, the company has made additional acquisitions in Ohio and West Virginia, yet has always remained a relatively small regional distributor.

I first started working for the company at the age of fourteen, working in the warehouse. After graduating college, I worked a short time with my father, learning the day to day operations of the business where I was involved in making sales calls, deliveries and various warehouse duties. It was a wonderful place to work and I was proud of my father and what he had achieved. He was born in Italy and came to this country at the age of thirteen. He subsequently graduated from college and began a business career that would lead to the formation of Miami-Luken. Through



my father's leadership, the company's culture was more like a family than just a place to work.

I entered medical school in 1979 and after my residency, embarked on my fulltime career as a physician in Dayton. Several years later, I was asked to serve on the Board of Directors of Miami-Luken, which I accepted. Some years later I became the Chairman of the Board and have held that position since that time.

Management of the company remained pretty much the same until 2007 when a new president was appointed by the Board. This individual had extensive managerial experience in both the wholesale drug business and the wholesale grocery business and was more than qualified to lead the company. He was knowledgeable, confident and well-liked by the company's employees.

It was not until several years later in 2013, after the Board learned that the DEA had issued a number of subpoenas to the company, that we realized the government had concerns with the company's compliance efforts. In response, we retained the services of a prominent attorney here in Washington D.C. who used to work for the DEA. This attorney worked with management to assist the company in fulfilling its DEA compliance obligations. We also instructed the company's president to purchase a computer program to better identify suspicious orders from customers, which he did.

When we subsequently learned that management was having difficulties with the computer system they purchased, it was apparent to us that we needed someone more capable in that position. The Board immediately began looking for a replacement and after considering several individuals, hired the company's current president and CEO, Michael Faul.

In addition to hiring Mr. Faul, the company hired a new Director of Compliance and Security, Benjamin Mink, who worked with Mr. Faul to implement a number of significant changes to the company's compliance program. These included more frequent and robust customer visits by compliance staff; greater scrutiny of requests from customers to increase purchase quantities; increased facility and transportation security; implementation of compliance training; purchase of the NTIS database; enhancing the controlled substance profile that customers are required to complete during the onboarding process; and a complete overhaul of Miami-Luken's standard operation procedures regarding DEA compliance. Mr. Mink also worked with the software vendor to re-calibrate the company's computerized suspicious orders notification system, improve its effectiveness in identifying suspicious orders on a daily basis; and started the process of uploading all relevant data on shared computer drives, providing employees and DEA investigators easier access to information pertaining to individual customers. He also hired additional staff to assist in the company's compliance efforts and created a new analytical Excel spreadsheet program to assist in conducting due diligence on current and prospective customers. In fact, Mr. Mink last year was recognized by the National

Association of Drug Diversion Investigators for his outstanding work in drug diversion prevention.

As a result of new management's enhanced compliance efforts, Miami-Luken terminated its relationship with multiple customers, many of whom are still in business purchasing from other sources. Since 2014, we have reduced the sale of Oxycodone by 61 percent, and the sale of Hydrocodone by 50 percent.

It is our understanding that former management took what they believed to be sufficient steps at the time, believing that State Medical Boards and Pharmacy Boards were in a stronger position to monitor the physicians and pharmacists they licensed. Former management also believed that since Miami-Luken regularly provided the DEA with sales data for all its customers, the government would have advised them if they had concerns with sales to specific parties. Unfortunately, we now know that that is not enough, and as you know from the materials we provided this Committee last year, Miami-Luken has taken aggressive actions going back several years to strengthen its compliance efforts and suspicious order monitoring system. And as I sit here now, I can assure you that our company employs a compliance program that is second to none.

In closing, I welcome any questions you have and will answer them to the best of my ability. Thank you again for this opportunity and for all your efforts.

Mr. HARPER. Thank you, Dr. Mastandrea.

The Chair will now recognize John Hammergren, chairman, president, and CEO of McKesson Corporation, for 5 minutes.

#### STATEMENT OF JOHN HAMMERGREN

Mr. HAMMERGREN. Mr. Chairman, Ranking Member DeGette, and members of the subcommittee, my name is John Hammergren, and for almost two decades I've had the privilege to serve as the chief executive officer of McKesson Corporation.

The impact the opioid epidemic has had on our Nation is devastating. Millions of Americans have been affected, including employees of McKesson and their families. We recognize the importance of this committee's investigation, and I appreciate the opportunity to appear before you today to help the committee address this crisis. I will also explain the steps that we ourselves are taking.

Our company has over 70,000 employees worldwide. Our distribution business receives 275,000 orders every day, serving 40,000 pharmacies and hospitals. Like all distributors, we have two critical priorities: to deliver medicines to pharmacies and hospitals when and where they need them and to help protect the integrity of the supply chain.

As a distributor, we don't manufacture prescription drugs, we don't market them to doctors or patients, nor do we market any particular category of drugs, such as opioids, to pharmacists. Distributors respond to pharmacy orders, which are based on doctor's prescriptions.

For years we have reported every controlled substance transaction that we have made in West Virginia and across the country to the DEA. Other distributors provide similar information so that only the DEA has an overall view of opioids distributed in this country.

Distributing controlled substances represents a small share of McKesson's total business. The two schedules of controlled substances that include the most commonly abused prescription opioids constitute approximately 3 to 4 percent of our total revenue.

The committee has highlighted a large volume of opioids distributed to pharmacies in West Virginia by McKesson and other distributors. Over a 6-year period addressed by the committee, McKesson distributed approximately 151 million doses of oxycodone and hydrocodone there.

To put that into some perspective, if you look at all prescription drugs of any kind that McKesson distributed, the total number was nearly 2 billion doses in West Virginia during the same period.

There is no question that a key driver of the crisis, as the CDC has said, is the overprescribing of opioids by doctors across the country. At the same time, there clearly were certain pharmacies in West Virginia that were bad actors that McKesson itself terminated. In hindsight, I would have liked to have seen us move much more quickly to identify the issues with these pharmacies.

We learned important lessons, so let me tell you how we're applying those lessons today.

Over the last 5 years, we have successfully used the latest technology and the best available expertise to strengthen controls. We have invested millions of dollars in enhancing our controlled substance monitoring program, or CSMP. A key part of that is sophisticated data analytics designed by outside experts which harness the power of advanced statistical models to set caps on sales to individual pharmacies. And then we block sales that exceed those caps, which are constantly monitored and fine-tuned.

Our CSMP team is independent of the business and has unilateral authority to deny a customer access to controlled substances. Our team includes former DEA agents with more than 240 years of collective DEA enforcement experience.

And the CSMP is working. In fact, over the last decade, we blocked and reported to the DEA over 1 million suspicious orders nationwide.

With a strong program in place today to monitor sales of opioids, we are extremely focused on advancing solutions to the country's opioid crisis more broadly.

First, we are moving forward with the development of a prescription safety alert system. This would be an electronic system to provide doctors and pharmacies with real-time red flags based on a patient's nationwide prescription history. Congress and the FDA can help make this a reality.

Second, we are requiring our customers to accept electronic prescriptions in 2019. Handwritten prescriptions are more prone to fraud.

Third, we're pushing for opioid manufacturers to use limited dose packaging, such as blister packs, to facilitate smaller prescription sizes.

And fourth, we've announced the formation of a foundation to fight the opioid epidemic and committed \$100 million dollars to launch its mission.

McKesson and I personally fully understand the gravity of this crisis and our essential role in helping to address it.

Thank you again for the opportunity to testify today. I would be happy to address your questions.

[The prepared statement of Mr. Hammergren follows:]

## **McKesson**

Testimony of

John Hammergren  
Chairman, President, and Chief Executive Officer  
McKesson Corporation

Subcommittee on Oversight and Investigations  
Committee on Energy and Commerce  
United States House of Representatives

May 8, 2018

Mr. Chairman, Ranking Member DeGette, and members of the Subcommittee, my name is John Hammergren. For almost two decades, I have had the privilege to serve as Chief Executive Officer for McKesson Corporation. I appreciate the opportunity to appear before you today to describe our efforts to respond to the nationwide opioid crisis. In particular, I will address the ways in which we have significantly enhanced our monitoring systems and procedures, so that we can quickly identify and block suspicious orders, and cut off bad actors' access to controlled substances. I will also address other steps the company is taking to help proactively combat the crisis. We recognize the importance of, and understand the reasons for, the Committee's investigation, and we appreciate the opportunity to respond.

The impact the opioid epidemic has had on our nation is devastating. Millions of Americans have been affected, including employees of McKesson and their family members. This epidemic's human costs are felt by us directly, and all of us at McKesson are committed to doing what we can to respond to this complex public health challenge. We are actively engaged in a range of initiatives that address our responsibility to help protect the integrity of the pharmaceutical supply chain and that also contribute to finding solutions to the cycle of addiction that so many American families are struggling with. I have personally learned about those struggles in conversations with McKesson employees and others whose lives have been impacted by the opioid addiction epidemic.

Over the last five years in particular, McKesson has successfully used the latest technology and the best available internal and external expertise to strengthen controls and to help reduce the risk that opioids and other controlled substances could be diverted to abuse or other illegitimate uses. And since 2008, McKesson has blocked the shipment of over a million orders for controlled substances nationwide.

Before explaining the steps we have taken, let me first provide you with some background about McKesson. We are a company with a long history. In 1833, to help meet the growing demand for medicine, John McKesson and Charles Olcott opened a small drug and chemical shop in New York City's wholesale district. Throughout the company's 185 years in business, McKesson has contributed to building a safe, secure pharmaceutical supply chain, including with technological innovation recognized by the Smithsonian. Over more than a

century, McKesson expanded and improved the nation's infrastructure for distributing drugs and other medical products to a far-flung network of pharmacies and health care providers. Today, we have over 70,000 employees around the world, including nearly 23,000 employees in the United States, with distribution centers located in 26 states.

One of McKesson's primary missions is to help ensure that medicines prescribed by licensed doctors are delivered to licensed pharmacies so they are available for patients who need them, when they need them, where they need them. Our U.S. Pharmaceutical business does that by responding rapidly to 275,000 orders that we receive daily from pharmacies and hospitals across the country at our 28 distribution centers. In the case of controlled substances particularly, we have to balance our mission to deliver medicines to pharmacies and hospitals when and where they need them against our important efforts to prevent and detect illegal diversion of those drugs. This is a constant balancing act for all pharmaceutical distributors.

McKesson supplies branded, generic, and over-the-counter pharmaceuticals to more than 40,000 customers, including retail pharmacy chains, independent pharmacies, hospitals, health systems, integrated delivery networks, and long-term care providers. We enable the American health care system to deploy medicines very rapidly to patients who need them and to protect against dangerous shortages of critical drugs. In many cases, McKesson is able to accomplish delivery of prescription drugs to pharmacies across the country within a matter of hours, in both urban and rural areas.

Distributing controlled substances represents a small share of our overall business. The two schedules of controlled substances that include the most commonly abused prescription opioids constitute approximately three to four percent of McKesson's total revenue. The bulk of our business involves the distribution of *non*-controlled prescription drugs, along with over-the-counter products and other health care related lines of business. For example, we provide a range of medical-surgical supplies and equipment to physicians' offices, home care agencies, and surgery centers. In addition to distribution, McKesson has a robust technology and connectivity business, and we use Six Sigma to help health care organizations strengthen their businesses, control costs, work more efficiently, and improve quality.

#### *Distribution of Controlled Substances to West Virginia Pharmacies*

As a distributor, McKesson does not manufacture prescription drugs, and we do not market them to doctors or patients. Nor do we market any particular category of drugs, such as opioids, to pharmacies. Distributors respond to pharmacies' orders, which in turn are placed based on doctors' prescriptions. McKesson does not supply prescription drugs in amounts greater than pharmacies order, and we do not ship to a particular state or pharmacy without an order from a Drug Enforcement Administration ("DEA")-registered and state-licensed pharmacy.

No single distributor knows the total volume of any drug distributed in a particular state or region, let alone to a particular pharmacy. That information is known to DEA, however. McKesson for years has reported every controlled substance transaction in West Virginia and across the country to DEA, and DEA gathers similar information from other distributors, in a proprietary DEA database called Automation of Reports and Consolidated Orders System

(“ARCOS”). Neither McKesson nor the other distributors have access to ARCOS. Only DEA has visibility over the entire landscape and can track and analyze aggregate data on the distribution of controlled substances in particular jurisdictions.

The Committee has highlighted the large volume of opioids distributed to certain pharmacies in West Virginia by McKesson and other distributors. For example, over a six year period addressed by the Committee, from 2007 through 2012, McKesson distributed approximately 151 million doses of oxycodone and hydrocodone in West Virginia. While that is a very large number, it’s important to put that data in context. During the same six-year period of time, McKesson distributed nearly 2 *billion* doses of all prescription drugs in West Virginia. Put another way, West Virginia pharmacies overall were, and continue to be, very high volume customers for prescription drugs generally.

There is no question that beginning more than a dozen years ago, and continuing to this day, physicians have prescribed large numbers of opioids to millions of Americans for a wide range of conditions. In 2014 alone, according to the *New England Journal of Medicine*, doctors wrote 245 million prescriptions for opioids in the United States.<sup>1</sup> As the Director of the Centers for Disease Control and Prevention (“CDC”) noted in 2016, “[o]verprescribing opioids—largely for chronic pain—is a key driver of America’s drug-overdose epidemic.”<sup>2</sup>

The total volume of opioid shipments is sometimes compared to the population of a particular county in West Virginia, resulting in disturbingly large figures for the number of prescription opioid pills in a given county on a per-resident basis. These comparisons can be misleading, for several reasons.

First, these figures generally have been aggregated over a long period of time, often five or six years, or even longer. Over a sufficiently long time period, any per capita calculation of the number of opioid pills sold will appear high. This is all the more misleading if the figure for opioid orders is not considered in the context of total sales of prescription non-controlled substances during the same period of time.

Second, calculations based on population do not include any comparative baseline for the number of persons in the geographic area who have a legitimate need for opioids. Without such a baseline to compare against, it is not always clear whether shipments are “too high” relative to the legitimate need.

Third, these figures imply that town and county lines define the customer base for a particular pharmacy. That is often not the case. Pharmacies located in areas that are not densely populated, and especially in areas that border one or more other counties or states, may serve a much larger customer population than the population of the specific town or county in which the

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<sup>1</sup> Nora D. Volkow and A. Thomas McLellan, *Opioid Abuse in Chronic Pain — Misconceptions and Mitigation Strategies*, 374 NEW ENG. J. MED. 1253, 1253 (2016).

<sup>2</sup> CDC Director Tom Frieden, Mar. 5, 2016 (quoted in “CDC Releases Guideline for Prescribing Opioids for Chronic Pain”) available at <https://www.cdc.gov/media/releases/2016/p0315-prescribing-opioids-guidelines.html> (visited on Apr. 29, 2018).



pharmacy is located. A small West Virginia town near the Kentucky border does not serve only the few hundred town residents any more than a pharmacy in Manhattan serves the millions of people who live and work in New York City. Comparing the number of units sold for a particular drug to the number of people in the town or county in which a pharmacy sits is not a meaningful way to assess whether drugs are being diverted to illegitimate uses.

A more refined calculation can account for some of these limitations. We can do this by calculating pills per capita on a monthly basis—instead of over a long period of time—for all counties in a particular area or on a statewide basis. And we can estimate the typical monthly number of pills for patients who receive opioid prescriptions from their physician by using public information and CDC surveys.

For example, if we look at data from January 2006 to November 2017, McKesson shipped a total of 342.8 million oxycodone and hydrocodone pills into West Virginia over that nearly 12-year period. The state had a population of 1.85 million (1.47 million adults) as of the 2010 census, so in per capita terms, McKesson could be said to have shipped approximately 185 pills of oxycodone or hydrocodone for each resident of West Virginia. Though this figure is significant, for meaningful analysis it should be compared to other data that reflect the prevalence of lawful opioid prescriptions and the volume of pills that physicians typically prescribe for a patient being treated with opioids.

If we take that same data and calculate per capita pills *per month*, the result is 1.6 pills per adult, per month. As an average, this figure is still subject to misinterpretation. It is certainly not the case that every adult in West Virginia received 1.6 pills each month. Studies suggest an average patient whose doctor prescribes oxycodone or hydrocodone is prescribed between two and three pills per day, or between 60 and 90 pills per month. Based on this range, a volume of 1.6 pills per adult per month works out to enough to fill legitimate prescriptions for roughly 1.8% to 2.7% of the adult population of West Virginia. While that is certainly not an insignificant share of the population by any means, to put it in context, CDC data from 2011-2012 reported that 6.9% of adults nationwide were prescribed opioids in any given month, and research suggests this means about 5% of adults were prescribed oxycodone or hydrocodone in any given month.

So while the large figures that are often highlighted in the media for the number of opioid pills prescribed and sold by pharmacies in West Virginia are significant, on a statewide basis, they reflect a volume of pharmacy opioid orders supplied by McKesson that is not inconsistent with the rate at which opioids were being prescribed by doctors and sold by pharmacies nationwide. Again, McKesson does not know at any given time how much is being shipped by other distributors, as we do not have access to DEA's ARCOS database that would shed light on the bigger picture. Finding a way to give all distributors access to that data, so that we can track how orders we receive relate to the total volume of controlled substances ordered by particular pharmacies or in particular geographic regions, is an important step that Congress and the states can take to help distributors conduct effective monitoring.

The data I summarized above is another way of saying that in recent years, doctors have been prescribing a tremendous volume of opioids to patients with a wide range of conditions,

both in West Virginia and across the country. As the Committee is well aware, and has investigated extensively, this is part of a major public health crisis in this country, a root cause of which is the over-prescribing of opioids. That trend recently has begun to recede, though opioid prescription volumes remain high nationwide, including in West Virginia.

We recognize that even if statewide volumes of orders for opioids seem consistent with national trends, particular counties or regions could have been outliers, with higher levels of orders relative to regional populations, though there are a variety of possible reasons for those variances across jurisdictional lines.

In its letters to McKesson, the Committee focused particularly on a pharmacy called “Sav-Rite No. 1.” Kermit, the small town in which Sav-Rite No. 1 was located, is in Mingo County, but it sits near the intersection of Mingo County, Wayne County, and Martin County, KY, which have a combined population of over 80,000 people. The Committee also referred to Family Discount Pharmacies, with locations in Mount Gay-Shamrock and Stollings, West Virginia. Logan County, where both Family Discount Pharmacies are located, has a population of about 35,000, putting it near the top quarter of West Virginia counties by population.

To be clear, while a simple comparison of the volume of opioid sales to the local town or county’s population is not by itself a reliable way of identifying suspicious orders, the volume of sales certainly is relevant to identifying suspicious orders. And in fact, in the specific case of Sav-Rite No. 1, McKesson did in November of 2007, more than a decade ago, *terminate* Sav-Rite No. 1’s access to controlled substances because of what we deemed to be a pattern of suspicious orders from that pharmacy.

Likewise, in 2014, McKesson terminated the Mount-Gay-Shamrock pharmacy’s controlled substance access after observing a suspicious volume of hydrocodone and alprazolam ordered by the pharmacy and because of concerns about some of the physicians whose prescriptions the pharmacy was continuing to fill. It also appears that several years before that, we had for a period of time cut off sales of controlled substances to that same pharmacy.

In hindsight, I would have liked to have seen us move more quickly to identify issues with those pharmacies and terminate their access to controlled substances, and we have learned lessons from that experience, which inform our approach today. As described below, with the benefit of sophisticated data analytics tools that are available today, over the last five years we have implemented a more robust and more heavily resourced system to survey and analyze large volumes of data, in order to quickly identify bad actors.

#### ***McKesson’s Controlled Substance Monitoring Program***

Over the last five years, McKesson has invested millions of dollars in enhancing our Controlled Substance Monitoring Program (“CSMP”), which provides ongoing review and monitoring of the pharmacies and hospitals that purchase from us to help mitigate the risk that controlled substances, including opioids, are diverted to abuse and other inappropriate uses. In 2014, we began working with an outside consulting firm to design sophisticated data analytics for the CSMP. Among other enhancements, these analytics enable us to identify patterns in

pharmacy orders for controlled substances and to set thresholds for each pharmacy based on better statistical methods and computer-assisted analytics than we ever had available in the past. Our CSMP is a nationwide program and it applies to all independent pharmacies, including those that operate in West Virginia. We provided an overview of these enhancements to DEA in 2016.

**Advanced analytics capabilities.** McKesson has implemented a cutting-edge controlled substances threshold management program, using complex data analytics to set and manage individual customer thresholds for controlled substances. Our model analyzes each pharmacy's and hospital's order against established monthly thresholds to determine whether that order should be filled. If an order exceeds the monthly threshold, that order is blocked and not filled. McKesson reports each blocked order to DEA, and to state agencies when required. The thresholds are determined based on computer analysis of controlled substance orders by pharmacies of similar size in a broader geographic region (though not just the same town or county, for reasons explained above) and the pharmacy's own past pattern of controlled substance orders compared to non-controlled prescription orders.

**Expanded Compliance Team.** In order to further enhance its compliance program, McKesson has added a number of subject matter experts to its CSMP team. In addition to hiring former DEA Special Agents and Diversion Investigators, McKesson has hired industry experts with experience in the retail pharmacy industry, experience as state and board of pharmacy investigators, experience with pharmaceutical manufacturers, and experience with data analytics. McKesson's team now includes individuals with more than 240 years of collective DEA enforcement experience. Moreover, the team leading our CSMP is independent of our sales function and has unilateral authority to terminate a pharmacy or hospital's access to controlled substances and to reject the onboarding of new pharmacies and hospitals.

**Due diligence.** McKesson performs comprehensive due diligence on prospective pharmacy customers before agreeing to supply controlled substances. We require all prospective customers to complete a detailed questionnaire, provide three months of dispensing data for analysis, undergo a site visit, and provide copies of all licenses. We also proactively monitor pharmacies' and hospitals' purchasing patterns and external events that might indicate a need to review that location more closely. For example, on many occasions, McKesson has performed a complete diligence review when a pharmacy or hospital requests an increase in its monthly threshold for a controlled substance. In addition, McKesson often performs a complete review when we receive a subpoena for information about a particular pharmacy or when we otherwise become aware of adverse information about a pharmacy. For example, in 2017, we terminated a West Virginia pharmacy's ability to purchase controlled substances after becoming aware that the West Virginia Attorney General had filed a lawsuit against the pharmacy related to its controlled substances dispensing practices.

**Education.** McKesson has been proactive with respect to educating the pharmacies and hospitals that purchase from us about the importance of compliance with DEA and state agency regulations. McKesson educates them and provides them with literature on how to identify the warning signs of prescription abuse and diversion. Similarly, McKesson has trained hundreds of our own employees on the company's regulatory obligations, including CSMP-specific training sessions at annual meetings.

As a result of these ongoing efforts, from 2008 through 2017, we blocked and reported to DEA over one million suspicious orders nationwide.

*Additional Steps McKesson Is Taking To Address The Opioid Crisis*

We are also looking ahead to find innovative ways to fight the opioid crisis more broadly, both through our company activities and through a foundation we recently formed to address opioid abuse.

We are working to develop an innovative solution contemplated by the leading not-for-profit standards setting organization in the healthcare solutions space, the National Council for Prescription Drug Programs (“NCPDP”), and now being advocated by the Health IT Now Opioid Safety Alliance. Such a prescription safety alert system, which other technology vendors could also develop, would help provide doctors and pharmacies with real-time red flags based on a patient’s nationwide prescription history, so that they can more easily identify prescriptions that may indicate potential abuse or misuse, such as doctor or pharmacy shopping. Today, when a patient fills an opioid prescription, the pharmacist may be unaware that the patient has recently filled other opioid prescriptions at other pharmacies, or that he or she has received multiple opioid prescriptions from multiple doctors. Our shared vision is that a pharmacy would receive a real-time clinical alert based on a patient’s prescription history. This information would allow the pharmacist to gather more information prior to dispensing the prescription, such as conducting a check with the prescribing clinician or reviewing the information from the state’s prescription drug monitoring program. Such a prescription safety alert system would work across state lines to encompass all prescriptions and all pharmacies, including failed attempts to fill prescriptions and transactions conducted in cash.

We are moving forward with the development of this innovative solution, which is in line with President Trump’s proposal for a nationwide prescription drug monitoring program. We understand from the pharmacy community that the system would meet a critical need. To maximize success, a truly effective solution must have access to data from all entities dispensing covered controlled substances. Thus, effective implementation would require support from the Food and Drug Administration (“FDA”) or Congress and require all pharmacies and providers to participate.

We believe that e-prescribing (electronically-delivered prescriptions) can also help prevent diversion. That is why, in 2019, McKesson will stop filling opioid prescriptions at pharmacies that are unable to accept e-prescriptions. Handwritten prescriptions can be forged, altered, or otherwise diverted to enable illegal access to opioids. All 50 states currently allow for e-prescribing, but only a handful of states require it. We aim to bring those pharmacists who are unable to accept e-prescriptions up to date with that ability, and move the industry toward an e-prescription-only opioids system. Congress and state legislatures could help by mandating e-prescribing by providers, in order to supplement industry efforts.

Because over-prescribing of opioids has played such a large role in the crisis, we also support providing opioids in limited-dose packaging. FDA could help by requiring that opioids be distributed in limited-dose packaging, usually “blister packs” and specially designed bottles. We plan to proactively engage with opioid manufacturers to develop plans to use limited-dose

packaging, with the goal of providing only what is needed and making it easier to do so for everyone involved. FDA Commissioner Dr. Scott Gottlieb has indicated his support for a move toward limited-dose packaging.

Additionally, as a distributor, McKesson plays a key role in getting those drugs manufactured by others into pharmacies and to patients quickly. We will work with manufacturing partners to put new *non-opioid* pain relievers into the hands of pharmacists and hospitals as soon as possible. We are often able to get new drugs to pharmacists within less than twelve hours of their availability—a tool we used, for example, to help the CDC distribute the H1N1 flu vaccine during that crisis. We understand that some new non-opioid pain relievers are under FDA review.

Pharmacist training is another key tool in preventing opioid abuse and overdose deaths. McKesson is committed to providing pharmacists with free training on how to identify patients who may be at risk of overdose and may potentially benefit from the use of naloxone or other overdose reversal medications. These trainings have been independently developed by the Accreditation Council for Pharmacy Education, an accredited continuing education program from the *Pharmacist's Letter*. Members of our HealthMart network, which services 5,000 independently owned pharmacies, all now have access to the HealthMart Operations Toolkit, which offers: (1) opioid education and training courses; (2) drug abuse prevention solutions; (3) best practices to prevent drug abuse when filling prescriptions; and (4) community outreach resources with strategies to promote drug abuse prevention at the local level.

McKesson also provides funding and support to the Healthcare Distribution Alliance's Allied Against Opioid Abuse initiative, which is a national education and awareness initiative to help prevent the abuse and misuse of opioids. And we are working with the Community Anti-Drug Coalitions of America (CADCA) to launch a substance abuse prevention pilot program tailored specifically to veterans.

Among our other efforts, we have partnered with the Pennsylvania Attorney General to help combat opioid abuse by delivering 300,000 drug deactivation pouches to local communities in 12 counties, in order to reduce diversion.

Finally, McKesson has set up a new foundation dedicated to fighting the opioid epidemic and committed \$100 million to support the foundation's mission. The standalone foundation will have independent subject matter experts on its Board of Directors. We expect foundation funds to support, among other things, educating providers on evidence-based clinical best practices in the treatment of pain, prevention and intervention initiatives and education on the dangers of opioid use, and increasing access to opioid treatments, including medication-assisted therapy and life-saving overdose reversal drugs.

### *Policy Solutions*

In addition to the steps McKesson itself is taking, we support public policy changes to discourage opioid abuse and to help those battling opioid use disorder. We appreciate the Committee's efforts to date and pledge our continued collaboration in the development of

effective legislation. We are particularly supportive of legislative efforts the Health Subcommittee recently passed that would promote greater use of electronic prescribing; standardize electronic prior authorization; encourage prescriber, dispenser, and patient education around the risks of opioid use; and establish programs for the return and destruction of unneeded opioids. We also support the President's declaration of the opioid crisis as a national emergency, and we provided the President's Commission on Combating Drug Addiction and the Opioid Crisis with our recommendations to consider for its final report, some of which were included.

Since 2015, our McKesson Opioid Task Force—composed of clinical, operations, regulatory, and policy experts—has been working on identifying and developing real world policy solutions to the crisis, issuing two white papers on the topic. The most recent, "[Call to Action: Execute Solutions Today to Combat the Opioid Crisis](#)," recommends incentivizing implementation of opioid stewardship or similar clinical excellence programs; ensuring proper patient education on opioids and their alternatives; requiring e-prescribing of controlled substances; requiring electronic prior authorization by payers to ensure that prescriptions are medically necessary; piloting pharmacist-led opioid care management programs; and implementing a prescription safety alert system, a concept initially conceived by NCPDP.

We encourage Congress to prioritize a prescription safety alert system to ensure that all stakeholders who have been impacted by opioid abuse, especially patients and their loved ones, can benefit from this promising solution. Further, we urge Congress to require use of electronic prior authorization to better align prescribing with best clinical practices, prevent misuse, and ensure access to patients with legitimate need.

\* \* \*

McKesson, like DEA and the other key players in the pharmaceutical supply chain, has learned important lessons as we have responded to the opioid crisis. We are acting on those lessons, and I believe we have significantly enhanced our capability to identify problematic pharmacies and quickly cut off their access to opioids and other controlled substances. We fully understand the gravity of this crisis, and our essential role in helping to address it.

Thank you again for the opportunity to testify today. I would be happy to answer your questions.

Mr. HARPER. Thank you, Mr. Hammergren.

The Chair will now recognize George Barrett, executive chairman of the board at Cardinal Health.

Thank you.

#### **STATEMENT OF GEORGE S. BARRETT**

Mr. BARRETT. Chairman Harper, Ranking Member DeGette, and members of the subcommittee, Chairman Walden, Ranking Member Pallone, and other members of the full committee, thank you for the opportunity to be here today. I also want to extend my thanks to your staff for their professionalism and courtesy.

My name is George Barrett, and I have committed my professional career to healthcare in a wide range of roles for over three decades. Between 2009 and 2017, I was privileged to serve as CEO and chairman of Cardinal Health, which today is composed of more than 50,000 dedicated men and women.

We simply cannot look at the impact of opioid abuse on so many lives and not feel sorrow. I speak for the entire Cardinal Health team when I say that we care deeply about the devastation that opioid abuse is causing families and communities around our country. We are resolved to be a constructive part of the effort to alleviate this complex national public health crisis.

Some of the issues we will discuss today involve the healthcare system in our neighboring State of West Virginia where hundreds of our employees live and work. The people of West Virginia are not just the recipients of the medicine and the medical products we distribute to hospitals and pharmacies, they are our coworkers, friends, neighbors, and family members.

I have visited the State to hear firsthand about the challenges of opioid abuse and how Cardinal Health can play a constructive role in addressing these challenges.

To the people of West Virginia, I want to express my personal regret for judgments that we'd make differently today with regard to two pharmacies that have been a particular focus of this subcommittee. With the benefit of hindsight, I wish we had moved faster and asked a different set of questions. I'm deeply sorry that we did not.

Today I'm confident that we would reach different conclusions about opioid orders from those two pharmacies. We've taken responsibility with our regulators. Cardinal Health has not distributed oxycodone or hydrocodone to either of these two pharmacies for years.

We understand that no antidiversion program is perfect, which is why we are so focused on continuous improvement. We are at the table focused on alleviating this critical national health problem. We are committed to working with Congress, regulators, and others in the healthcare system to combat this crisis and address its effects.

There is no single root cause of the crisis, and addressing it requires that all healthcare participants work together, and we have to do it now.

We recognize the challenge posed by lawful yet high-volume prescribing of opioids. On the one hand, we know there are many individuals who rely on these medications to address suffering associ-

ated with terminal illnesses, painful neurological conditions, severe injuries, and other medical conditions.

On the other hand, we share the recent judgments of policy-makers, including senior leadership at HHS, the FDA, the surgeon general, the CDC, and others, that there have been too many prescriptions for too many pills.

As a pharmaceutical wholesale distributor, we have a dual responsibility: to ensure that prescription medications are available for healthcare providers and their patients when needed while working to limit the potential for those prescription medicines to fall into the wrong hands.

Pharmaceutical wholesale distributors do not and should not have visibility into the medical judgment or the patients for whom prescriptions are written. However, we can play a role by raising awareness of the dangers of overprescribing, which we are doing.

Our antidiversion tools are built around a core commitment to spot, stop, and report potential diversion. Our program is supported by a dedicated antidiversion team of investigators, auditors, analysts, former law enforcement officers, compliance officers, and pharmacists deployed nationwide and augmented by substantial external resources and technology.

From 2008 to the present, we have stopped suspicious orders for the shipment of hundreds of millions of opioids. We will not ship an order for hydrocodone or oxycodone to pharmacies that do not meet our standards. We have refused to onboard pharmacies that cannot pass our rigorous screening, and we have cut off existing customers that do not have effective controls.

But with a problem as large and complex as opioid addiction, we know there is always room to do better, and we will never stop working to continuously improve and refine our systems.

For over a decade, we have funded education and prevention programs that have been used in every State and more than 100 colleges and pharmacies. We have also launched an opioid action program including the free distribution of opioid reversal medication to law enforcement and first responders beginning in four of the Nation's hardest-hit States across Appalachia.

As I indicated earlier, Cardinal Health is at the table and intends to be here for as long as the problem persists. Today I'll do my best to answer your specific questions and hope that our dialogue will continue.

Thank you.

[The prepared statement of Mr. Barrett follows:]



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**HEARING BEFORE THE UNITED STATES HOUSE OF REPRESENTATIVES  
COMMITTEE ON ENERGY AND COMMERCE, SUBCOMMITTEE ON OVERSIGHT  
AND INVESTIGATIONS**

May 8, 2018

Testimony of George S. Barrett  
Executive Chairman, Cardinal Health

**I. INTRODUCTION**

Chairman Harper, Ranking Member DeGette, and Members of the Subcommittee, Chairman Walden, Ranking Member Pallone, and other Members of the full Committee: thank you for the opportunity to be here for today's hearing on "Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion."

My name is George Barrett, and from 2009 to 2017, I was privileged to serve as CEO and Chairman of Cardinal Health, which today is composed of more than 50,000 dedicated men and women. I have devoted a career to healthcare in a wide range of roles for over three decades, and I appreciate the opportunity to share my perspective with you today.

The people of Cardinal Health are deeply committed to serving the American healthcare system. Although this hearing is focused on one aspect of our pharmaceutical wholesale distribution business, Cardinal Health is a global, integrated healthcare company, providing customized solutions for hospitals, healthcare systems, pharmacies, ambulatory surgery centers, clinical laboratories, and physician offices worldwide. Our pharmaceutical wholesale distribution business delivers thousands of products from hundreds of manufacturers and suppliers. Each year, we process in excess of 400 million orders. The overwhelming majority of

medications we distribute are non-opiate medicines such as antibiotics, or treatments for cancer, heart disease, diabetes, and other chronic conditions. With respect to all our distribution, our objective is simple: to enable the healthcare providers we serve to use these products to bring health and healing to their patients. We also recognize that in our role as a pharmaceutical wholesale distributor we have a dual responsibility—to ensure that prescription medications are available for prescribers and their patients when needed, while working to limit the potential for those prescription medications to fall into the wrong hands.

To meet our responsibilities, Cardinal Health has developed and implemented a constantly adaptive and rigorous system to combat controlled substance diversion. Despite the development of a quality system, we have not always gotten every decision right, and in the past we have entered into settlements with regulators to address aspects of our anti-diversion program. We have learned from our settlements and experience, and our anti-diversion program today is stronger and more effective as a result. While no program can ever be perfect given the evolving threats we face and the realities of human error and judgments, our goal is always to get it right, and we have stopped suspicious orders for the shipment of hundreds of millions of dosage units of controlled substances over the last decade.

At the end of last year, I passed on my duties as CEO to my successor, and I currently serve as the Executive Chairman of Cardinal Health's Board of Directors. All of us at Cardinal Health are acutely aware of the devastation that opioid abuse is causing families and communities around our country, including some within our own company. We simply cannot look at the impact of opioid abuse on so many lives and not feel sorrow. And on behalf of the entire Cardinal Health community, we are resolved to be a constructive part of the effort to alleviate this complex national public health crisis. We are engaged and at the table. There is no single root cause of the crisis and addressing it requires that everyone work together.

One of the key public policy issues we must address is the challenge posed by lawful yet high-volume prescribing of opioids. On the one hand, we know there are many individuals who

rely on these medications to address suffering associated with terminal illnesses, painful neurological conditions, severe injuries, and other medical conditions. On the other hand, we share the recent judgment of policymakers, including senior leadership at the Department of Health and Human Services, the Food and Drug Administration, the Surgeon General, the Centers for Disease Control and Prevention, and others, that there have been too many prescriptions for too many pills.

Pharmaceutical wholesale distributors do not and should not have visibility into clinical prescribing decisions or the patients for whom prescriptions are written. However, there are other steps we can take, and are taking, to raise awareness of the dangers of over-prescribing. We also have made available Narcan, an opioid overdose reversal medication, free-of-charge to first responders and law enforcement. Through these efforts and other elements of our Opioid Action Program, Cardinal Health is seeking to make a meaningful difference, focusing initially on some of the nation's hardest-hit states. We are also continuously focused on enhancing our own anti-diversion programs in collaboration with our regulators and others in our industry.

## **II. CARDINAL HEALTH – WHAT WE DO**

As discussed above, Cardinal Health is a global, integrated healthcare services and products company. In our role as a pharmaceutical wholesale distributor, we serve more than 24,000 pharmacies and are in nearly 85% of U.S. hospitals. We make available nearly 400,000 unique products that ultimately support patients across the full continuum of care. We have been privileged to be able to assist in some of the most acute crises this country has faced. For example, in the aftermath of Hurricanes Harvey, Irma, and Maria, the men and women of Cardinal Health worked tirelessly to fulfill the needs of hospitals, pharmacies, critical care centers, and shelters so they could aid those in need. We did far more than simply move products from manufacturers to pharmacies. Our team went to extraordinary lengths to secure diesel fuel, high-water vehicles, planes, and helicopter support for the transport of products to critical locations, and on the ground worked under difficult conditions, putting the welfare of

patients ahead of their families' personal needs to ensure critical life-saving drugs and medical supplies were delivered to local hospitals. The level of commitment reflected in our team's actions during those crises is matched day in and day out as they perform their regular jobs, ranging from logistics management to anti-diversion monitoring and analysis. This is who we are.

Cardinal Health, in its role as a pharmaceutical wholesale distributor, does not manufacture medications or market them to patients, nor does it diagnose medical conditions, write prescriptions, or otherwise practice medicine. Opioid prescriptions, like any other prescription medications, are written by healthcare providers for their patients, who take those prescriptions to licensed pharmacies to be filled. These licensed pharmacies in turn place inventory fulfillment requests with pharmaceutical wholesale distributors. As an intermediary in the pharmaceutical supply chain, Cardinal Health does not ultimately control either the supply of or the demand for opioids. Our role is to provide a secure channel to deliver medications of all kinds, from the hundreds of manufacturers who make them, to the thousands of hospitals and pharmacies that dispense them. We help ensure that pharmacies, hospitals, and the patients they treat receive medication—when and where they need them. At the same time, we also work diligently and with a sense of purpose to prevent the diversion of pain medications. We have developed and implemented robust suspicious-order monitoring and reporting systems, and we continuously strive to improve and adapt to address the ever-changing methods of drug diversion and abuse.

### **III. CARDINAL HEALTH'S ANTI-DIVERSION EFFORTS**

Our anti-diversion program is rigorous, and over the last decade, we have invested tens of millions in continually upgrading our program to make sure it continues to be robust and effective in the face of evolving risks. Our goal is to spot, stop, and report the suspected diversion of medications out of the clinical setting for improper use. Our program has three key components, each of which is outlined in greater detail below. The program is supported by a

dedicated anti-diversion team that consists of nearly a hundred trained individuals, including investigators, statistical auditors and data analysts, former law enforcement officers, pharmacists, and compliance officers deployed on-site at our pharmaceutical distribution centers, in the field, and at our corporate headquarters, augmented by substantial external resources.

Over time, we have continued to enhance our anti-diversion program and have entered into settlements with the DEA and the state of West Virginia. We have learned and improved from each of them. From 2008 to the present, we have stopped suspicious orders for the shipment of hundreds of millions of dosage units of controlled substances. We also have terminated or refused to distribute controlled substances to over a thousand pharmacies. On our own initiative and in response to regulators, we have increased the size of our anti-diversion team, including bringing in personnel with additional regulatory, pharmaceutical, and law enforcement experience to further enhance the anti-diversion program. We have developed an analytical model to evaluate customers, assigned threshold ordering volumes, created a centralized database to store and track data on customers and orders, and designed new policies and procedures for anti-diversion personnel. Over the years, we have also trained thousands of our people on anti-diversion practices.

Know Your Customer. Know Your Customer is the ongoing process by which we learn about pharmacies to, among other things, better understand the range of legitimate requirements for controlled substances and establish distribution thresholds on a customer-specific basis using objective, statistical data and other criteria. Cardinal Health uses a multi-factor process to evaluate customers, even before they can be accepted as a Cardinal Health customer. These factors include verifying the customer is licensed by the Drug Enforcement Administration (DEA), and evaluating the product mix dispensed by the customer within certain drug families, as well as the location and business model of the pharmacy, the historic volume of controlled substances dispensed, and the ratio of controlled to non-controlled substances. Cardinal Health uses an escalation process through management to evaluate higher volume customers which

includes two-person approval for certain threshold levels and regular review of higher volume customers by a committee of anti-diversion management and specialists.

Electronic Monitoring. All Cardinal Health customers are subject to electronic monitoring, which occurs prior to order fulfillment. Threshold limits are established by the anti-diversion team for over 120 families of controlled substances, including oxycodone and hydrocodone, for each pharmacy or other healthcare provider. The thresholds are based on various factors specific to the customer and analysis of third-party data detailing dispensing volumes of customers nationwide. Through electronic monitoring, Cardinal Health monitors dosage units for each controlled substance drug family, as well as certain strengths of specific drugs known to be more frequently misused (e.g., oxycodone 15mg and 30mg products). When a customer's accrued orders hit the established threshold, the order is held and, outside of a rare occurrence, the order is cancelled. Cancelled orders are reported to the DEA and any required state regulators.

Site Visits. Cardinal Health conducts regular site visits to its customers across the country as part of its anti-diversion program. Site visits may be announced or unannounced. In 2017, Cardinal Health representatives conducted over 48,000 on-site inspections nationwide. These representatives look for any visible signs of diversion, such as long lines, a high volume of customers from out-of-state, lack of product diversity in non-prescription products offered for sale, or groups of people traveling together to fill prescriptions. As warranted by the circumstances, the teams also speak with the pharmacist-in-charge and/or other staff and review aggregate pharmacy dispensing data to identify any risk of diversion. The data reviewed includes aggregate prescription volume, percentage of cash business, ratio of controlled to non-controlled substance dispensing, and information about the pharmacy's customer base (e.g., hospice, orthopedics, oncology, pain clinics, etc.). However, it is important to note that privacy laws, such as HIPAA and other laws, prohibit Cardinal Health representatives from reviewing patient-specific prescriptions.

#### IV. LEARNING FROM OUR WEST VIRGINIA EXPERIENCE

Given the questions that have been raised by the Subcommittee and others, I would like to directly address our work in the state of West Virginia over the past decade and, in particular, the volume of opioid medications that Cardinal Health distributed in response to orders from DEA-licensed pharmacies.

As I noted previously, we share the judgment of policymakers that there have been too many prescriptions for too many pills across the country over the past decade. With regard to two of the pharmacies that have been a particular focus for the Subcommittee, Family Discount of Mt. Gay and Hurley Drug Company, we reached decisions at the time based in part on the demographics of the surrounding area, the characteristics of the individual pharmacy, and the views of our internal staff. Those decisions allowed the two pharmacies to continue to receive certain volumes of hydrocodone and oxycodone from Cardinal Health for longer than I think they should have based on what I have since learned about the circumstances surrounding those pharmacies. With the benefit of hindsight, I wish we had moved faster and asked a different set of questions. I am deeply sorry we did not. Today, I am confident we would reach different conclusions about those two pharmacies. Although both pharmacies continue to maintain active and valid DEA registrations and West Virginia Board of Pharmacy licenses, Cardinal Health has not distributed oxycodone or hydrocodone to Family Discount of Mt. Gay since 2012, or to Hurley Drug Company since 2014. We have also taken responsible actions by instituting improvements in our anti-diversion program and reaching settlements with our regulators, including the state of West Virginia. We understand no program is perfect, which is why we are so focused on continuous improvement. And we are at the table now, focused on alleviating this critical national health problem.

There are a variety of other factors that informed our historical decisions about our overall distribution volumes in West Virginia, including the fact that Cardinal Health's distributions of oxycodone and hydrocodone to West Virginia reflected only a small portion of

the company's total distributions of prescription medications in the state. For example, in 2008 oxycodone and hydrocodone constituted only around 7% of the prescription medications that Cardinal Health distributed to independent retail pharmacies in West Virginia. In addition, our distributions were made against the backdrop of what the Centers for Disease Control and Prevention has now chronicled as then widely accepted and publicized medical norms guiding physicians' prescribing practices. During that time period, those norms favored broader opioid treatments for longer periods of time with higher potency.

## V. THE PATH FORWARD

Improving our anti-diversion program has been our primary focus. Yet, our commitment to alleviating the national problem of opioid abuse and misuse does not end there. For over a decade, we have funded education and prevention programs in communities across the country through Generation Rx, which the Cardinal Health Foundation developed in partnership with the Ohio State University School of Pharmacy. Generation Rx is a national prescription drug misuse prevention program that has been used in every state, at more than 100 colleges of pharmacy, and has provided more than a million people with tools and educational resources to prevent and address the issues that drive opioid abuse.

More recently, we launched our Opioid Action Program (OAP). We piloted OAP in four of the nation's hardest-hit states across Appalachia—Ohio, Kentucky, Tennessee, and West Virginia—to alleviate the opioid epidemic. It has four elements, each of which has been cited by leading experts as essential to the fight to reduce opioid abuse and casualties:

1. Narcan. We have distributed Narcan, an overdose reversal medication, free-of-charge to first responders and law enforcement. To date, we have distributed nearly 80,000 dosages.



2. Drug take-back events. We have sponsored drug take-back events in various communities, including sponsoring 39 drug take-back events across these four states during the DEA's National Prescription Drug Take Back Day in the past two weeks.
3. Student and prescriber education. We have successfully funded millions in expanded grants focused on youth prevention education, prescriber opioid awareness and reduction efforts, and community responses to the epidemic.
4. Medical school training. We have partnered with a leading school of medicine to refine and share medical school curricula that address opioid abuse and treatment through a collaboration with over 20 medical schools nationwide.

In addition, our employees have volunteered thousands of hours to community service to support drug take-back days and community awareness and education efforts at schools, senior centers, and elsewhere.

We also support practical reforms to alleviate the opioid crisis, including the creation of a national prescription drug monitoring program through collaboration with industry participants and state and federal regulators. And we support appropriate prescribing limits on opioids and legislation that would require prescriptions to be issued electronically. While none of these is a complete fix or a substitute for collaborative efforts by participants across the system, each would be an important step in the right direction.

## VI. CONCLUSION

I believe the steps I have outlined above can make a genuine difference in our ability to combat the diversion of opioid medications. The men and women at Cardinal Health know there is much more to be done, and that we, as a country, have a long way to go. We at Cardinal

Health are committed to doing our part to alleviate this national challenge and welcome the opportunity to continue the search for solutions with the Subcommittee.

Thank you for the opportunity to be here. I look forward to your questions.

Mr. HARPER. Thank you, Mr. Barrett.

The Chair will now recognize Steven Collis, chairman, president, and CEO of AmerisourceBergen Corporation.

Mr. Collis.

#### STATEMENT OF STEVEN H. COLLIS

Mr. COLLIS. Thank you. Thank you, Chairman Walden, Subcommittee Chairman Harper, Ranking Member Pallone, Ranking Member DeGette, and distinguished members of the committee. On behalf of AmerisourceBergen's over 21,000 associates, thank you for the opportunity to be here today. We are committed to working with you and all stakeholders to help combat the tragic opioid abuse epidemic.

I will begin today by sharing three distinct perspectives that have shaped my thinking on this urgent issue.

First, like so many others, I have been touched and saddened by the excruciating stories that demonstrate the destruction wrought by the disease of addiction, many shared by your colleagues as they relayed the devastation that opioids have left in their States. Some time ago, a Member shared a story of a mother who overdosed, leaving her two children starving and unattended for several days. Stories like this, and sadly so many that tell similar tragic tales, are always on my mind.

Second, I have seen friends, family, and those in my community fight through uncontrolled pain and have experienced firsthand the sad necessity of pain medications. This topic is frequently brought up in my conversations with doctors and healthcare professionals and was the focus of a recent discussion I had with the CEO of a world-class cancer treatment center in which he articulated his concern that the reaction to the opioid crisis would prevent his team from providing necessary and appropriate end-of-life care.

Lastly, I have spent the majority of my 30-plus-year career in healthcare providing services surrounding the pharmaceutical industry with a focus on working to enable patient access to the medications they need.

As you all know, AmerisourceBergen's role in regard to prescription opioid medications is one of a logistics provider and distributor. We are responsible for getting FDA-approved drugs from pharmaceutical manufacturers to DEA-registered pharmacies that dispense them based on prescriptions by licensed healthcare providers.

We have no ability and no desire to encourage the prescribing or dispensing of pain medication. We do not manufacture or promote the prescribing of these medications. And we are not qualified to interfere with the very personal clinical decisions made between patients and their physicians.

Here are some things that AmerisourceBergen does do. For more than a decade, we've reported every opioid order we distribute on a daily basis to the DEA. So every order, every shipment, every day. We use statistical-based algorithms and data analytics tools to monitor and assess every order we receive in an effort to identify, stop, and report suspicious orders.

Just as importantly, we continuously focus on enhancing our diversion control efforts. And our best-in-class diversion-control team

endeavors to track patterns and behaviors beyond just individual suspicious orders that have led us to refuse service or terminate service to pharmacies we've identified as problematic, including several of the pharmacies we have all heard about today in West Virginia.

And we collaborate with and support others who are also working hard to address the crisis, partnering with others across the country to provide drug deactivation and disposal resources, and with our customers, not-for-profits, and innovators to support take-back programs and advance ideas that could help combat the opioid abuse epidemic.

We believe we've taken meaningful action, but this epidemic cannot be solved unless we improve the ways we work together. Communication and technology between the DEA and pharmaceutical distributors should be enhanced. Specifically, the sharing of the DEA's comprehensive data of all opioid sales to all pharmacies on a de-identified basis would alert distributors if pharmacies are receiving controlled substances from other DEA registrants.

Beyond improved data sharing, additional DEA guidelines for distributors with uniform standards for suspicious ordering monitoring programs would create a more consistent approach across the more than 900 registered distributors in the industry and, in turn, more actionable input for law enforcement professionals.

We also support a number of solutions that are not specific to distributors, including revising prescriber guidelines, mandatory e-prescribing for controlled substances, enhanced prescription drug monitoring programs to enable physicians and regulators to determine if patients are obtaining prescriptions in more than one State, and a number of the proposals the subcommittee considered just last week.

Our work to play a role in combating abuse while supporting clinically appropriate access will never be complete. We always strive to be better. I join you today with an open mind and a sincere desire for additional guidance and ideas from this committee.

Thank you.

[The prepared statement of Mr. Collis follows:]

**AmerisourceBergen Corporation**  
WRITTEN STATEMENT  
OF STEVEN H. COLLIS  
CHAIRMAN, PRESIDENT, AND CHIEF EXECUTIVE OFFICER  
AMERISOURCEBERGEN CORPORATION

BEFORE THE  
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS  
COMMITTEE ON ENERGY AND COMMERCE  
U.S. HOUSE OF REPRESENTATIVES

PRESENTED  
MAY 8, 2018

**Written Statement of Steven H. Collis  
Chairman, President, and Chief Executive Officer  
AmerisourceBergen Corporation  
Before the Subcommittee on Oversight and Investigations  
Committee on Energy and Commerce  
U.S. House of Representatives  
May 8, 2018**

I am Steven H. Collis, Chairman, President, and Chief Executive Officer of AmerisourceBergen Corporation (“AmerisourceBergen” or “the Company”). I thank the Committee for the opportunity to express my concern, and the Company’s concern, about the tragic epidemic of opioid abuse, as well as our desire to be part of much-needed, and unquestionably multi-faceted, solutions to address this public health crisis.

The epidemic raises many complex problems. AmerisourceBergen associates and I see firsthand the struggles of individuals impacted by the opioid epidemic. Like so many others, the AmerisourceBergen family is impacted by opioid addiction in many ways. We have seen our families and friends struggle with addiction and we have been touched personally by harrowing stories of the devastation it has caused in communities throughout this country. But we also know that FDA-approved opioid medications play an important role for many Americans who struggle with debilitating pain and severe sickness, such as cancer. We cannot forget that opioids are approved as safe and effective treatments to ease the pain and suffering of many patients who need them, and they can be vital in end-of-life care. Opioids also allow others to function in spite of medical conditions and pain that would otherwise make life unbearable.

The critical challenge we face lies in finding the appropriate balance: preventing the abuse of these treatments, while providing clinically appropriate access to the medications that many patients need. AmerisourceBergen Drug Corporation is a distributor – a logistics provider that purchases pharmaceutical products from manufacturers and supplies Drug Enforcement Administration- (“DEA”) and state-licensed pharmacies, hospitals, and clinics that dispense to

patients based on prescriptions written by board-certified physicians. Our place in the supply chain provides AmerisourceBergen Drug Corporation with neither the information nor the expertise to override clinical decisions by trained doctors and pharmacists or to determine the appropriate supply of medications. While we believe it is important to recognize our limited but vital role in the supply chain, we are committed to working with the Committee and all stakeholders on ways that all distributors, and AmerisourceBergen in particular, can leverage our expertise and position in the supply chain to help address this crisis. We welcome an ongoing dialogue on how to move forward expeditiously and effectively.

**AmerisourceBergen Drug Corporation Is a Logistics Provider That Distributes Legal, FDA-Approved Products to DEA-Licensed Customers**

The wholesale pharmaceutical distribution business is not well known to the American public. The lack of awareness and understanding of a distributor's limited but vital role in the healthcare supply chain has led to significant misunderstandings about what AmerisourceBergen Drug Corporation does and does not do.

AmerisourceBergen Drug Corporation facilities do not manufacture pharmaceuticals. We are a wholesaler that plays a critical role in ensuring the safety and security of America's pharmaceutical supply chain. We purchase some 15 million innovative brand and generic medicines, the vast majority of which are non-controlled substances, directly from manufacturers. We are responsible for getting those medicines to tens of thousands of sites of care every day, including pharmacies, hospitals, and clinics, which administer or dispense the medicines on prescriptions written by licensed health care providers. By acting in this logistics role, AmerisourceBergen Drug Corporation contributes to a secure supply chain and an efficient

distribution system that has been estimated to save the United States health care system \$42 billion a year.<sup>1</sup>

AmerisourceBergen Drug Corporation's distribution role in the system is vital, yet limited in many ways. Prescription opioids represent less than 2% of AmerisourceBergen's annual revenue. AmerisourceBergen Drug Corporation delivers the products that our customers order from us, but does not promote the prescribing or use of medications, including opioids. We do not offer our sales representatives special compensation or incentives of any kind that target opioid orders in particular. We have no ability, and no desire, to encourage the prescribing or dispensing of pain medicines.

Further, as a wholesale distributor, AmerisourceBergen Drug Corporation does not control how any medications we deliver are prescribed, dispensed, or ultimately used. Strict statutory privacy requirements (including HIPAA) prevent us from obtaining information about the particular patients for whom medicines are prescribed, the specific medical purpose for which medicines are prescribed, or how they are used by the patients. This is true for all medicines AmerisourceBergen Drug Corporation distributes, including opioids. AmerisourceBergen Drug Corporation has absolutely no role in the clinical decisions made between a doctor and a patient.

The number of opioids shipped by AmerisourceBergen Drug Corporation was and is driven by the number of pills ordered by our customers. Until very recently, AmerisourceBergen Drug Corporation has never known (unless a customer discloses that information voluntarily) whether a pharmacy customer buys opioids from other distributors. Even with the DEA's new rules for sharing information on a pharmacy's other distributors, AmerisourceBergen Drug

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<sup>1</sup> See Center for Healthcare Supply Chain Research, *The Role of Distributors in the U.S. Healthcare Industry: A 2011 study prepared by Booz & Company*. Arlington, VA: The Center, 2011.



Corporation does not know what types of opioids or how many opioids its customers order from other distributors. AmerisourceBergen Drug Corporation only has access to its own distribution data. This is in fact why we have been a vocal advocate for increased data transparency across the supply chain, including the sharing of scrubbed ARCOS (Automation of Reports and Consolidated Order System) data. Such data, which is only visible to the DEA, would allow us to make more informed decisions when evaluating orders of controlled substances as well as the customers who are placing those orders.

**All Participants in the Supply Chain of Prescription Opioids Are Closely Regulated by the DEA and Must Safeguard Against Diversion, Within the Areas They Control**

Federal law regulates prescription opioids at every link in the closed system of distribution. All prescription medicines, including opioids, are evaluated and approved as safe and effective by the FDA based on their ability to effectively and safely treat a medical condition, such as cancer, diabetes, high cholesterol or chronic pain. The DEA sets annual quotas for the manufacture of opioids, based on the anticipated legitimate medical need, which is informed in part by the number of prescriptions written the previous year. AmerisourceBergen has never had any involvement in the evaluation and determination of these quotas. All participants in the closed system of distribution of prescription opioids and other controlled substances (other than the end user/patient) must be registered with the DEA. All participants – manufacturers, distributors, pharmacies, hospitals, and physicians – have different roles and responsibilities within the closed system and must safeguard against diversion and abuse in the areas within their control.

Physicians and other authorized practitioners must be licensed by their state board of pharmacy and the DEA in order to prescribe opioids. Any prescriptions they write for opioids must be issued for a legitimate medical purpose and in the usual course of their professional

practice. Most states (including West Virginia) operate Prescription Drug Monitoring Programs (“PDMPs”) that require physicians to provide information to a state-run database about the prescriptions they write for opioids. Unlike distributors, physicians have the right (and state law may require them) to search the PUMP database to determine if a patient has “doctor-shopped” and sought opioids from multiple sources.

Pharmacists also play a critical gatekeeping role in ensuring that opioids are prescribed for a legitimate medical purpose. A pharmacy may dispense opioids only if it is registered with the DEA and has a valid state license to dispense controlled substances. The pharmacy may dispense opioids only pursuant to a prescription from a licensed medical practitioner who is registered with the DEA. Pharmacists are prohibited from dispensing opioids based on illegal or falsified prescriptions, and must act diligently in determining whether a prescription is issued for a legitimate medical purpose based on their education and training. Unlike distributors, pharmacists are required to know the practitioner who issued the prescription, the number of other prescriptions the practitioner wrote that the pharmacy filled, and whether the patient has presented prescriptions obtained from more than one doctor. Pharmacists can also observe the demeanor of the patient who presents the prescription.

Like physicians and pharmacists, distributors have duties to help prevent diversion, within the areas in which we have some visibility and control. We must maintain the physical security of controlled substances in our possession, distribute controlled substances only to DEA-registered customers, and report all opioid sales to the DEA. Distributors must also design and implement systems to detect the “suspicious orders” we receive and report those suspicious orders to the DEA.

**AmerisourceBergen Drug Corporation's Rigorous Anti-Diversion Controls**

AmerisourceBergen Drug Corporation's obligation to safeguard controlled substances and prevent their diversion is one we take very seriously. AmerisourceBergen Drug Corporation has refused to service and has terminated service to hundreds of pharmacies that it identified as problematic, including some of the pharmacies in West Virginia that news reports have claimed were diverting opioids. We are licensed with the DEA to buy, possess, and distribute controlled substances. We have invested heavily in physical security to ensure that our facilities have the best possible protocols and technology to minimize the risk of theft or diversion of any controlled substances from the time they enter AmerisourceBergen Drug Corporation facilities to the time they are delivered to our customers. We also devote significant resources to our anti-diversion program. AmerisourceBergen Drug Corporation employs a team of diversion-control experts who perform the many aspects of its diversion control program.

AmerisourceBergen Drug Corporation's diversion control team performs due diligence to determine whether prospective new customers are suitable purchasers of controlled substances. The procedure to review prospective customers has varied over time but since 2007 has generally included the following elements: the completion of a Retail Customer Questionnaire; site visits; verification of the pharmacy's DEA registration and state licensure; review of the pharmacy-provided information; and online investigation (including internet licensing and disciplinary searches) for the identified pharmacy, owner, and pharmacist-in-charge. The questions on the questionnaire are based on guidance from the DEA.

Since at least the 1980s, AmerisourceBergen Drug Corporation has had in place a system to monitor the orders it receives (the "Order Monitoring Program," or "OMP"). We worked with the DEA to enhance the system in 1998, and again in 2007, and have continually reviewed and improved it, including a comprehensive 2015 revision to build on current data, respond to trends

in prescription drug abuse, and adopt improved technological capabilities, including data-driven analytical tools. The OMP's innovative program uses sophisticated technology to test every order of controlled substances that AmerisourceBergen Drug Corporation receives. Orders that the system identifies as "of interest" are held electronically and investigated, and shipment is automatically blocked until the investigation is complete and the order is determined to be appropriate. If the order is deemed suspicious after that review, the order is reported to the DEA and is not shipped. Using the OMP, AmerisourceBergen Drug Corporation reported and refused to ship more than 800 such orders for oxycodone and hydrocodone from West Virginia from 2008 to 2016. AmerisourceBergen Drug Corporation ends relationships with customers that it determines have an increased potential for diversion. In addition, the AmerisourceBergen Drug Corporation maintains a "Do Not Ship" list, which includes customers that the diversion control program has identified through its order monitoring program and other ongoing diversion control efforts.

On a daily basis, for every order of opioid-based medication we ship, AmerisourceBergen Drug Corporation provides the DEA with detailed information about the order, including the type of opioid, quantity, and the recipient. On a monthly basis, AmerisourceBergen Drug Corporation also reports to the DEA's Automation of Reports and Consolidated Orders System ("ARCOS") all sales of Schedule II and reportable Schedule III controlled substances. AmerisourceBergen Drug Corporation uses analytical tools to review aggregate purchase data for trends that are not captured in the review of flagged individual orders. AmerisourceBergen Drug Corporation conducts on-site investigations of customers when issues or concerns are identified by its monitoring activities, the OMP, personnel at its distribution centers throughout the country, or external bodies such as the DEA or state agencies. AmerisourceBergen Drug

Corporation also provides substantial training in diversion control: It trains its dedicated diversion-control teams, all associates in compliance-sensitive positions at its distribution centers throughout the country, and its sales associates, and also offers anti-diversion training to its pharmacy customers.

**AmerisourceBergen Is Committed to Fighting the Opioid Crisis**

AmerisourceBergen is and has been committed to ensuring a pharmaceutical supply system that is safe, secure, and marked by integrity. As such, we want to be part of the solution to the opioid crisis, which we believe can be conquered while keeping opioids available for patients who legitimately need them. But in order to conquer this problem, it is imperative that the DEA come to the table and work with all stakeholders in the supply chain in a more cooperative and collaborative manner. The Controlled Substances Act (“CSA”) under which the DEA operates was enacted and the regulations promulgated in 1970. We would recommend updating the regulations and guidance implementing this important law to standardize suspicious order monitoring programs across the 900+ distributors that are regulated under this system to ensure the highest standards across the board for all distributors’ suspicious order programs.

In addition, AmerisourceBergen Drug Corporation reports all opioid orders daily, submits ARCOS data monthly, and reports suspicious orders to the DEA. If the DEA could utilize this data to alert those of us in the supply chain who have no “real time” visibility to customers that may be receiving shipments from multiple sources, this could help prevent what has occurred in West Virginia from happening in the future. AmerisourceBergen supports a number of other proposed solutions including revision of prescribing guidelines, which will likely reduce the number of opioids prescribed. Indeed, AmerisourceBergen funded a grant to the Health Care Improvement Fund to support prescriber education for post-surgical procedures. AmerisourceBergen also supports mandatory e-prescribing, which would generate real-time

information on opioid use and reduce the number of opioids obtained through fraudulent prescriptions or doctor shopping. We support policies to make state PDMPs interoperable, which would allow physicians and regulators to determine if patients are obtaining prescriptions from physicians in more than one state. We are also the only distributor member of the Collaborative for Effective Prescription Opioid Policies (“CEPOP”), which supports policies to reduce prescription opioid abuse and promote treatment options.

AmerisourceBergen is also eager to collaborate with policymakers and stakeholders throughout the pharmaceutical supply chain to improve distributors’ ability to assess and act on possibly suspicious orders of prescription opioids. As part of the National Association of Drug Diversion Investigators, AmerisourceBergen has presented on effectively combatting drug diversion at the distribution level and collaborating with law enforcement. AmerisourceBergen also supports increased fees for DEA registration to help support such enhanced data capabilities.

AmerisourceBergen believes that education about opioids and the safe storage and disposal of opioids are equally critical to resolving the opioid crisis. To this end, AmerisourceBergen participates in, and funds, numerous industry, non-profit and policy group initiatives that support the fight against opioid abuse. For example:

- AmerisourceBergen Foundation has partnered with The Prevention Action Alliance and Everfi to launch the Prescription Drug Safety Network, an interactive online educational platform designed to teach high school students to make informed decisions about prescription medications.
- AmerisourceBergen is a member of the Anti-Diversion Industry Working Group which, working with the National Association of Boards of Pharmacy, funded production of the “Red Flags of Diversion” educational video that many state

pharmacy boards, including West Virginia's, use to educate pharmacies about diversion control.

- AmerisourceBergen has partnered with Walgreens, Pfizer, Prime Therapeutics and Blue Cross Blue Shield to install safe disposal kiosks for medication in hundreds of Walgreens stores across the country and near military bases and other areas where the opioid epidemic has challenged communities. This partnership has already collected 155 tons of unused medications and is expected to collect an additional 300 tons.
- AmerisourceBergen Foundation launched a Municipal Support program that has provided drug deactivation pouches to 17 municipalities and non-profit organizations in six states, and also sent resources to Americares, a health-focused relief and development organization that responds to people affected by poverty or disaster. Americares distributes the deactivation pouches to free clinics and community health centers nationwide that serve low-income and uninsured patients in need. To date more than 60,000 pouches that allow consumers to dispose of unused medications at home, safely and in an environmentally friendly manner, have been distributed.
- AmerisourceBergen Foundation provided a grant to The Moyer Foundation to support community programs that serve youth who have been affected by a family member's substance abuse.
- AmerisourceBergen recently launched the AmerisourceBergen Foundation Opioid Resource Grant Program, which will provide funding to efforts to address opioid abuse with direction from an external advisory council.

- AmerisourceBergen Foundation announced a grant to Thomas Jefferson University to hold a substance abuse symposium.

**Conclusion**

I and AmerisourceBergen share Congress's concern, and indeed the entire nation's concern, about the tragic abuse of opioids. AmerisourceBergen is committed to the continuous analysis and ongoing improvement of our programs and policies. We look forward to additional ideas and guidance from this Committee, industry regulators, and other experts about how we can continue to improve our efforts and help alleviate the crisis while supporting clinically appropriate access to opioid medications for legitimate medical needs. On behalf of AmerisourceBergen, I thank the Committee for this opportunity to share more information, our views and our eagerness to help address this crisis.



Mr. HARPER. Thank you, Mr. Collis.

The Chair will now recognize J. Christopher Smith, former president and CEO of H.D. Smith Wholesale Drug Company.

Mr. Smith.

#### **STATEMENT OF JAMES CHRISTOPHER SMITH**

Mr. SMITH. Good morning, Chairman Walden, Chairman Harper, Ranking Member DeGette, and members of the subcommittee. Thank you for inviting me here today.

I would like to start by telling you a little bit about H.D. Smith, how it began, and the vision that guided it from the very beginning.

My grandfather, who was a pharmacist, had the idea for it. And with that idea from his own father, my father founded H.D. Smith in Springfield, Illinois, in 1954, because he saw that there was a true need for a wholesale drug distributor that would commit to serving small town and rural independently owned mom-and-pop pharmacies and downstate hospitals as there was no other wholesale drug distributor like that in Springfield.

My father's vision in starting the company was to make certain that a wholesale drug distributor would not only commit to serving these underserved communities, but he did so with the mission that patient care should never be disrupted because a rural small town pharmacy, hospital, or later, inner-city pharmacy, could not quickly and reliably supply the medicines that the patients in these communities needed right when they needed them.

This is the mission and vision he taught to me and my brother as we later joined the company and rose through its ranks over time. As a child, I sometimes accompanied my father when he, himself, would make emergency deliveries at night or over weekends. And as an employee of H.D. Smith, I did the same as well, along with many others. That is and always was our legacy.

I first began working for H.D. Smith full-time in 1980 as a buyer and gradually moved my way up through the ranks over the years. In September 2007, I was appointed president and COO. In March 2015, I became president and CEO.

In January 2018, H.D. Smith was acquired by AmerisourceBergen, and I no longer hold any office, position, or employment with H.D. Smith.

But it is important to remember that since its founding in 1954 until its acquisition in 2018, H.D. Smith always remained a family-owned business, which I am very proud to have served. I am certain, absolutely certain, that H.D. Smith's new management will observe my family's guiding principles just as loyally as I tried so hard to do myself.

I share the committee's grave concern about the opioid crisis and am committed to doing all we can to address it. We always took seriously our responsibilities to distribute controlled substances appropriately. We had a DEA license. We sold only to DEA- and State-licensed pharmacies and hospitals. We followed DEA regulations in handling controlled substances. We reported all our purchases and sales of controlled substances to the DEA.

My company distributed all kinds of pharmaceutical products. Only a small percentage were controlled substances, including pain

medication. We didn't advertise or promote the medication or do anything else to encourage doctors to prescribe them or pharmacies to dispense them. Our job as a distributor was to fill orders that pharmacies sent us.

In fact, as a distributor, we could only see part of the distribution chain—the pharmacy that we supply. We didn't see the prescriptions the pharmacy filled or know the doctors who wrote them or have any contact with knowledge of the patients.

As a distributor, we had to manage to the twin imperatives of ensuring that we distributed pharmaceuticals appropriately, for legitimate purposes, and ensuring the pharmacies that they had the products they needed when the patient arrived with a prescription so as to ensure uninterrupted patient care.

To meet this challenge, we created strong diversion control systems and continually improved them overtime. We always did our very best to make sure that all orders we shipped went to pharmacies that dispensed medications only on legitimate prescriptions for legitimate medical reasons.

I am certain AmerisourceBergen will continue my company's proud tradition and do everything that can be done to help with the solutions to the opioid crisis in this country.

Thank you.

[The prepared statement of Mr. Smith follows:]

**WRITTEN STATEMENT OF JAMES CHRISTOPHER SMITH  
FORMER PRESIDENT AND CHIEF EXECUTIVE OFFICER, H.D. SMITH LLC**

**BEFORE THE**

**SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS  
COMMITTEE ON ENERGY AND COMMERCE  
U.S. HOUSE OF REPRESENTATIVES**

**PRESENTED  
MAY 8, 2018**

**Written Statement of James Christopher Smith  
Before The Subcommittee on Oversight and Investigations  
Committee on Energy and Commerce  
U.S. House of Representatives  
May 8, 2018**

H.D. Smith was a family-owned wholesaler for more than 60 years. We began by and grew serving an under-served segment of the market – local, independently owned, mostly mom-and-pop pharmacies and rural hospitals in small towns, rural communities, and later in inner cities, taking pride in providing excellent customer service. We recently were acquired by AmerisourceBergen Corporation (“AmerisourceBergen”). I thank the Committee for the opportunity to share my concern about the opioid epidemic plaguing our country, and to explain what H.D. Smith did to prevent diversion during my tenure.

At all times, H.D. Smith has been committed to doing its very best to balance the needs of patients for prescription medications with our efforts to prevent diversion. Fighting the opioid epidemic is unlike fighting other drug abuse. While preventing the abuse of these powerful drugs, we cannot lose sight of ensuring that suffering patients have access to the prescription medications they need when they need them. But H.D. Smith was only one part of a complex supply chain, and we could not see all the information up and down the chain that could flag a potential problem. As a wholesale distributor, H.D. Smith could not second-guess physicians’ prescribing decisions, and could not itself assess the medical needs of the patients of those prescribing physicians. There are difficult policy and medical decisions that are needed to balance access against diversion and we did the very best we could with the limited information to which we had access.

**H.D. Smith's Role as a Middleman That Purchased Medicines from Manufacturers and Filled Orders from Licensed Pharmacies**

H.D. Smith was a wholesaler. We purchased prescription and generic medicines directly from manufacturers, and distributed them to the licensed pharmacies that ordered them for patients with prescriptions. As a wholesale distributor, H.D. Smith did not interact directly with patients, nor were we in a position to make or second-guess clinical decisions. We also had no way of knowing whether or to what extent our customers were purchasing medicines, including opioids, from other distributors, unless this information was voluntarily disclosed.

H.D. Smith did not manufacture, market or otherwise promote medications, including opioids, to customers, patients or their physicians. We had no control over or involvement with controlled substance manufacturing quotas, which are set by the DEA in consultation with other federal regulators and manufacturers, and which were routinely and significantly increased over the years until recently. The distribution of prescription opioids comprised only a small fraction of our annual revenue.

**H.D. Smith's Robust Diversion Control Efforts**

H.D. Smith has always strived to do what we could to prevent the diversion of controlled substances, and I am confident it will continue to do so under its new ownership. I can tell you what H.D. Smith did to prevent diversion during my tenure. In addition to taking physical security measures to safeguard against theft and diversion of opioids and other medicines, H.D. Smith developed and maintained a robust anti-diversion program, which was designed to identify potentially suspicious orders. That program came to include, among other components, a controlled substance order monitoring program, focused investigations conducted by an experienced group of former law enforcement and drug diversion investigators, and comprehensive customer and sales force anti-diversion training. We also performed extensive

due diligence on prospective new customers before allowing them to purchase controlled substances, and those due diligence measures continued to evolve over time and continued throughout our relationships with customers.

Before 2006, as was consistent with the DEA's expectations communicated to wholesale drug distributors, H.D. Smith reviewed customer orders manually to detect suspicious orders and to then report them to the DEA. As the DEA's expectations changed, in May of 2008, we implemented an electronic controlled substance order monitoring program (the "CSOMP"), and provided extensive training to our personnel in how best to reliably utilize that system, just as we trained our sales representatives to be alert to any signs of diversion or irregularities at the individual pharmacies we served. H.D. Smith's CSOMP used sales volume data-based algorithms to test orders of controlled substances and blocked the shipment of orders flagged by the system, along with any additional orders for any drug within the same family by that customer. The flagged orders would be placed on the daily CSOMP report, and reviewed by members of the Corporate Compliance and Security Department team. H.D. Smith maintained an ongoing dialogue with the DEA throughout its development of its CSOMP to ensure that the system complied with the DEA's expectations.

For some time after the rollout of CSOMP, H.D. Smith reported to the DEA all orders automatically flagged and blocked – even if only temporarily blocked – by the system as "suspicious." Then, in 2009, H.D. Smith changed our reporting practices upon learning from the DEA that we were over-reporting and that orders were not "suspicious" simply because they were flagged for initial review by the company's electronic anti-diversion CSOMP. After this time, H.D. Smith reported orders to the DEA only if we determined after further review and due

diligence that the order was indeed “suspicious” and should be rejected. H.D. Smith also reported a number of physicians and pharmacies to the DEA when concerns arose.

H.D. Smith worked to adjust its CSOMP to meet what we understood to be changing instructions from the DEA, including the DEA’s complaints that H.D. Smith was reporting too many orders as suspicious because they exceeded the ordering limitations imposed on a particular customer. H.D. Smith invested substantial resources in improving the program, including by hiring additional personnel for its Corporate Compliance and Security Department. The elements and robustness of our anti-diversion program continued to evolve and improve over time. We experienced some frustration in working with the DEA, however; during some periods of time, the DEA rebuffed the industry and refused to give guidance to help distributors in their efforts to detect suspicious orders. Regardless, I can say with confidence that H.D. Smith used its best efforts to safeguard against diversion.

**Combating the Opioid Abuse Crisis Will Require the Cooperation of All Participants in the Supply Chain**

Wholesale distributors have statutory and regulatory obligations including to design a system to identify and report suspicious orders to the DEA, but these obligations are, of course, limited by their role in the supply chain. In order to obtain a DEA registration number to sell controlled substances, distributors must report sales of opioids to the DEA, keep the opioids in their possession physically secure, implement a system to detect “suspicious orders,” and report such orders to the DEA. However, distributors are but one link in the heavily federally regulated supply chain. All participants, including manufacturers, pharmacies, and physicians, must fulfill their respective duties to prevent the diversion of controlled substances in the areas within their control.

Physicians are the first line of defense against diversion and abuse, as it is a crime to obtain or dispense prescription opioids without a prescription. Physicians must be state-licensed and DEA-registered and may only prescribe opioids for a legitimate medical purpose and in the usual course of their professional practice. Pharmacists similarly must be duly registered and may only dispense opioids pursuant to legitimate prescriptions. And unlike distributors, pharmacists have access to, and indeed may have the duty to consider, prescription-level information, including the identity and location of the patient and physician, the frequency at which that physician writes prescriptions for controlled substances, and the number of prescriptions presented by the patient.

Additionally, the Prescription Drug Monitoring Programs (PDMPs) in many states require physicians and pharmacists to provide patient and prescription information to state-run databases about the prescriptions they write or fill for opioids. In West Virginia in particular, the DEA and other federal and State law enforcement agencies have immediate and unlimited access to this database, as do various professional licensing boards, but notably distributors do not. Thus, in addition to the ARCOS data that is automatically reported by manufacturers and distributors to the DEA, the DEA has access all the way down to prescriber-specific, pharmacy-specific, and patient-specific data on each and every opioid prescription written and filled and the patient to whom each opioid was dispensed. Wholesale drug distributors, however, cannot access this data.

### **Conclusion**

We fully trust that H.D. Smith's new owner, AmerisourceBergen, will handle its business responsibly. We also strongly believe that the DEA can help distributors be part of the solution to the opioid crisis by collaborating more and sharing information with the industry. Without help from the DEA, and particularly guidance about the reporting of suspicious orders,



distributors cannot make complete assessments about pharmacies' purchasing habits, and are, therefore, limited in their ability to detect suspicious orders. I again thank the Committee for the opportunity to contribute to this important conversation.

Mr. HARPER. Thank you, Mr. Smith.

I ask unanimous consent that the contents of the document binder be introduced into the record and to authorize staff to make any appropriate redactions. Without objections, the documents will be entered into the record with any redactions that staff determines are appropriate.<sup>1</sup>

At this point, each Member will have the opportunity to ask questions, and I will recognize myself first for 5 minutes.

I want to thank you all for participating in today's very important hearing. As the subcommittee closely examines this very serious opioid crisis, I think it would be helpful at the outset to help establish a baseline of understanding. And I would like for each of you to answer each question that I am going to ask now.

First, do you believe that the actions that you or your company took contributed to the opioid epidemic?

Mr. Barrett.

Mr. BARRETT. Thank you, Mr. Chairman.

Mr. HARPER. We're really looking here, because I've got a lot of questions, "yes" or "no." And if it is not either one——

Mr. BARRETT. No. No, sir, I do not believe that we contributed to the opioid crisis.

Mr. HARPER. We'll come back to you then.

Dr. Mastandrea.

Dr. MASTANDREA. Yes.

Mr. HARPER. Mr. Hammergren.

Mr. HAMMERGREN. No.

Mr. HARPER. Mr. Smith.

Mr. SMITH. I believe H.D. Smith conducted itself responsibly and discharged its obligations.

Mr. HARPER. Is that a no?

Mr. SMITH. That is a no.

Mr. HARPER. OK.

Mr. Collis.

Mr. COLLIS. No. I believe we—it's a no for AmerisourceBergen.

Mr. HARPER. Do you acknowledge—another question for each of you—do you acknowledge that your company had past failings in maintaining effective controls to prevent the diversion of opioids?

Mr. Barrett.

Mr. BARRETT. I believe that our organization understood the responsibilities and conducted them as best they could with the understanding at that time. I have no reason to challenge the good faith of the decisions made by people many years ago. But I can say that the decisions, as I mentioned in my commentary today, that we might have made on some of those pharmacies would look differently today.

Mr. HARPER. Is that a no?

My question was, do you acknowledge that your company had past failings in maintaining effective controls to prevent the diversion of opioids?

Mr. BARRETT. I think our organization understood its obligations. We did resolve with regulators where we had areas where we

<sup>1</sup>The information has been retained in committee files and also is available at <https://docs.house.gov/Committee/Calendar/ByEvent.aspx?EventID=108260>.

thought we could have done better, and I think those resolutions satisfied the right balance of serving patients and satisfying those controls, sir.

Mr. HARPER. So is that a yes, it's now a no? I'm trying—I mean, I'm a little—

Mr. BARRETT. I am looking back on history. And what I'm describing is an organization that I believe did its job at the time understanding its responsibilities to address the responsibilities of controlled drugs.

Mr. HARPER. Dr. Mastandrea, the question is, do you acknowledge that your company had past failings in maintaining effective controls to prevent the diversion of opioids?

Dr. MASTANDREA. Yes.

Mr. HARPER. Mr. Hammergren.

Mr. HAMMERGREN. Our organization has worked for decades to try to meet our obligations under the DEA regulations. And we continue to work today to evolve our processes to understand what they're asking us to do and make sure that we have state-of-the-art capabilities in place.

Mr. HARPER. It seems like a pretty simple question. Do you acknowledge that your company had past failings in maintaining effective controls to prevent the diversion of opioids?

Mr. HAMMERGREN. In the past we've had challenges understanding the expectations that our regulator would like us to follow.

Mr. HARPER. Mr. Smith.

Mr. SMITH. Again, I believe H.D. Smith has acted responsibly. So the answer would be no.

Mr. HARPER. Mr. Collis.

Mr. COLLIS. I believe we've always discharged our duties effectively and responsibly and have maintained an adequate diversion program.

Mr. HARPER. The number of opioids shipped to pharmacies in small towns of West Virginia has been astonishing: nearly 800 million opioids in total distributed to West Virginia in just a 5-year period, 20.8 million opioids to Williamson, and nearly 17 million opioids to a single pharmacy in Mount Gay-Shamrock over a decade, 9 million opioids in just 2 years to Kermit.

Do the extraordinary volume of opioid shipments to pharmacies in small towns of West Virginia indicate a breakdown in the suspicious order monitoring system?

Mr. Barrett.

Mr. BARRETT. Mr. Chairman, it is a very important question. I don't believe that the volume in relation to the size of the population is a determining factor. We often know that there's a small population, a town, which serves a large service area that may have a medical center or a cancer institute in the nearby area.

I have said, and I said in my statements, and I repeat here, that I think some of the decisions on particular pharmacies in West Virginia, knowing what we know today, we would have made different decisions, sir.

Mr. HARPER. Dr. Mastandrea.

Dr. MASTANDREA. Yes.

Mr. HARPER. Mr. Hammergren.

Mr. HAMMERGREN. We had a pharmacy in Kermit, West Virginia, called Sav-Rite that we actually terminated in that period of time.

What I can say is that, knowing what we know today, in hindsight, we wish we would have terminated that relationship sooner.

Mr. HARPER. Mr. Smith.

Mr. SMITH. Can you repeat the question?

Mr. HARPER. The question is, do the extraordinary volume of opioid shipments to pharmacies in small towns of West Virginia indicate a breakdown in the suspicious order monitoring system?

Mr. SMITH. I don't believe we had a breakdown in our system.

Mr. HARPER. Mr. Collis.

Mr. COLLIS. If you're talking specifically about AmerisourceBergen, we didn't ship to any of those pharmacies. If you're talking about the industry, I believe it probably did.

Mr. HARPER. My time has expired.

The Chair will now recognize the ranking member of the subcommittee, Ms. DeGette, for 5 minutes.

Ms. DEGETTE. Thank you, Mr. Chairman.

Gentlemen, each of you in your own way spent time very carefully telling this committee what your companies do not do in terms of prescribing or things like that. But in fact each of your companies, under the Controlled Substances Act, has a duty to make sure that that controlled substances are distributed correctly.

Would you agree with that statement, Mr. Barrett, yes or no?

Mr. BARRETT. Yes, we do.

Ms. DEGETTE. And, Dr. Mastandrea.

Dr. MASTANDREA. Yes.

Ms. DEGETTE. Mr. Hammergren.

Mr. HAMMERGREN. We have a duty to support—

Ms. DEGETTE. "Yes" or "no" will work.

Mr. HAMMERGREN. We have a duty to support the—

Ms. DEGETTE. You have a duty to make sure that controlled substances are distributed appropriately, correct?

Mr. HAMMERGREN. We have a responsibility to—

Ms. DEGETTE. OK.

Mr. Smith.

Mr. SMITH. Yes, we have a responsibility.

Ms. DEGETTE. Mr. Collis.

Mr. COLLIS. Yes, we have a responsibility.

Ms. DEGETTE. And in fact I would direct your gentlemen's attention to exhibit 59 in the binder, which was a letter dated September 27, 2006, which was sent to every commercial entity in the United States registered with the DEA to distribute controlled substances.

And on page 3 of that letter, it lists an entire panoply of things that your companies are supposed to do. The letter was then followed up on two times in 2007.

I want to start with you, Dr. Mastandrea, and I want to ask you, Federal regulations require you to design and operate a system to disclose Federal operators from pharmacies. Is that correct?

Dr. MASTANDREA. I'm sorry. I really don't understand—

Ms. DEGETTE. Federal regulations require you to design and operate a system to disclose suspicious orders from pharmacies.

Dr. MASTANDREA. Yes, I believe that to be correct.

Ms. DEGETTE. Yes, they do. OK.

And according to—and I want to focus a little bit on Kermit, which is a town of 600—I'm sorry, 400.

According to data that Miami-Luken provided to the committee, in 2007 your company supplied Sav-Rite pharmacy in Kermit with nearly 1.5 doses of opioids. Is that correct?

Dr. MASTANDREA. I believe so.

Ms. DEGETTE. In 2008 your company supplied Sav-Rite with nearly 2 million doses of opioids. Is that correct?

Dr. MASTANDREA. It's my understanding that is correct.

Ms. DEGETTE. And then in 2009 you supplied Sav-Rite with another 800,000 pills. Is that correct?

Dr. MASTANDREA. I believe so.

Ms. DEGETTE. Now, in fact you continued supplying Sav-Rite until 2011 even though the pharmacy was actually raided by Federal authorities in early 2009. Is that correct?

Dr. MASTANDREA. I believe so.

Ms. DEGETTE. Now, Dr. Mastandrea, we asked Miami-Luken to provide us with its entire due diligence file on the Sav-Rite pharmacy, and this is what we got from you.

Do you recognize these documents?

Dr. MASTANDREA. No.

Ms. DEGETTE. OK. We can have somebody hand them to you, but I will assure you it's about 15 pages of purchase orders and sales orders.

Do you think this is a sufficient due diligence file for all of the number of opioids that you were sending to this one Sav-Rite pharmacy in Kermit, West Virginia?

Dr. MASTANDREA. No.

Ms. DEGETTE. OK. Thank you. And you know what, thank you for your honesty today. I appreciate it.

I want to ask you now, Mr. Hammergren, a question. Now, in 2006, McKesson supplied Sav-Rite pharmacy with nearly 2.3 opioid pills, which is more than 190,000 a month. Is that correct?

Mr. HAMMERGREN. I believe so.

Ms. DEGETTE. And in 2007, McKesson again supplied Sav-Rite with over 2.6 million opioid pills, or more than 222,000 pills per month. Is that correct?

Mr. HAMMERGREN. I believe so.

Ms. DEGETTE. Now, in your written testimony, Mr. Hammergren, you put a lot of thought into using population statistics and other arguments to justify your shipments to Sav-Rite and other pharmacies. We just heard Mr. Barrett talking about that, too. But when the committee asked you to provide McKesson's due diligence file for Sav-Rite, you gave us a single document from 2007.

Do you recognize this document, sir?

Mr. HAMMERGREN. No, I don't.

Ms. DEGETTE. OK. It's exhibit 3 in the binder.

Do you recognize that document now? You don't.

Mr. HAMMERGREN. This is first time I've seen this document.

Ms. DEGETTE. OK. Well, I will tell you for the record that this document, which says, "Declaration of Controlled Substances Purchases," which is a two-page document, is the only documentation

that McKesson gave to this committee when we asked for the due diligence file for Sav-Rite.

Do you think that this fulfills the requirements of the DEA that your company do due diligence for distribution of opioids to this city?

Mr. HAMMERGREN. I believe our relationship with Sav-Rite should have been terminated immediately.

Ms. DEGETTE. Yes or no, do you think this is sufficient documentation to show compliance with the rules of the DEA?

Mr. HAMMERGREN. We continue to evolve our diligence—

Ms. DEGETTE. “Yes” or “no” will work, sir.

Mr. HAMMERGREN. I’ve not reviewed the document. I can’t provide an answer to that.

Ms. DEGETTE. OK. Thank you very much.

Thank you, Mr. Chairman.

Mr. HARPER. At this time, the Chair will recognize Chairman Walden, chair of the full Committee for Energy and Commerce, for 5 minutes.

Mr. WALDEN. Thank you, Mr. Chairman.

And I appreciated the opportunity I had yesterday to meet with several of you and talk about how we work together going forward as a country to prevent this kind of disaster from continuing or ever happening again.

Mr. Hammergren, between 2006 and 2007 McKesson supplied Sav-Rite pharmacy in Kermit, as you’ve heard, a town of 400, 5.6 million opioids. Our research has indicated this pharmacy was fueled by prescriptions from a pill mill. This was widely known in the community.

In fact, our investigators have uncovered that the pill mill was widely known, and there were reports even in the media over years that indicated customers were selling pills in the parking lot, and that the cash drawer was so full it could not be shut.

Now, McKesson started a program in 2007, I think you called it the Lifestyle Drug Monitoring Program, under which McKesson reviewed every single customer for high-volume orders for certain drugs. Is that correct?

Mr. HAMMERGREN. That’s correct.

Mr. WALDEN. Including hydrocodone and oxycodone. I think we referenced that in tab 1 in the binder.

So the initial threshold, as I understand it, set by McKesson was 8,000 pills a month. The document indicates that you picked that number as a reasonable monthly threshold, correct?

Mr. HAMMERGREN. That’s correct.

Mr. WALDEN. And so do you know the average number of hydrocodone dosage units or pills McKesson distributed to that Sav-Rite pharmacy that you terminated a relationship with back in 2007?

Mr. HAMMERGREN. I do not.

Mr. WALDEN. So we did some research. It appears it’s 9,650 pills a day, which averages to 289,500 hydrocodone pills in a 30-day month, which is more than 36 times the initial monthly threshold set by the program.

The program required distribution centers to review any order in excess of the threshold and document why orders above the threshold were shipped.

Now, according to a document produced by McKesson, all customers had been reviewed by June 12, 2007. This clearly should have identified Sav-Rite, considering your own distribution was 36 times higher than the threshold you set. I think that document's in tab 2.

So did this program identify the Sav-Rite pharmacy?

Mr. HAMMERGREN. It did not, sir. It should have been terminated sooner.

Mr. WALDEN. And if so, on what basis did McKesson decide to continue supplying hydrocodone far above your own threshold? This is what we're trying to figure out.

Mr. HAMMERGREN. Our systems at the time were not automated enough, certainly, and we didn't flag it fast enough and get it fast enough.

Mr. WALDEN. So are there any documents justifying the continued distribution to Sav-Rite?

Mr. HAMMERGREN. I don't know, sir. But, as I've testified, we terminated that relationship as soon as we became aware that the purchases were as you described.

Mr. WALDEN. In your testimony you note that the large distribution figures highlighted by the press in this investigation reflect a volume of opioid orders "not inconsistent" with the rate at which opioids were prescribed.

If this is the case and 9,600 pills a day distributed by McKesson to Sav-Rite in 2007 is reasonable, then why set the initial monthly limit at 8,000 per month? Or is this something you just—the system did not catch?

Mr. HAMMERGREN. We did not properly manage that Sav-Rite relationship and certainly didn't do it soon enough.

Mr. WALDEN. I see. So what we're trying to figure out is, are there other Sav-Rites out there today? And this would apply to everybody on the panel. What is it in the systems you have or the DEA have that allowed this to happen then, and are they in place today to prevent this from happening? How do we shut down these pill mills?

Mr. HAMMERGREN. We certainly learned, Mr. Chairman, from that experience at Sav-Rite, and we realized that we needed automated systems that don't allow any order to ship out of our facilities that are past those thresholds.

So today Sav-Rite pharmacy wouldn't get a single order from McKesson. Our systems block those orders as they're inbound. And if they want to have that order shipped, we have to go out and do an investigation at that pharmacy to justify any increase.

So if they open—if a pharmacy somewhere was going to open a new relationship with a hospice, our people would go out and view that and understand whether that is a legitimate business reason, exactly for your purpose.

Mr. WALDEN. And are your systems in place today that would identify an overprescribing physician or facility that is driving too many pills? How does that work?

Mr. HAMMERGREN. That's one of the challenges, frankly, with the systems that McKesson has. We don't see the prescribing systems that are reported out of the pharmacy. So the way we have to manage it is to determine a suspicious order based primarily on quantities compared to average pharmacies that are similar.

And clearly, the challenge in that is that suspicious is really an isolated individual customer-by-customer evaluation that isn't informed by the physician population, the prescribing habits, et cetera.

Mr. WALDEN. Unfortunately, my time has expired. I'm sure we'll have questions for the record. I'd appreciate the feedback from all of you on that topic, because we're trying to find solutions here.

Thank you, Mr. Chairman.

Mr. HARPER. Thank you, Chairman Walden.

The Chair will now recognize the ranking member of the full committee, Mr. Pallone, for 5 minutes.

Mr. PALLONE. Thank you, Mr. Chairman.

I'm trying to run through this quickly, so I may have to try to have you summarize.

This committee's investigation has uncovered a number of shortcomings in the way that some distributors handled the distribution of opioids as this horrible epidemic unfolded. But what I really want to know is, moving forward, how do we ensure that adequate systems are in place to detect the kinds of problems that have clearly led to the oversupply and diversion problems we've seen in West Virginia?

For example, in Kermit, population 400, several distributors each sent millions of pills to a single pharmacy, and it's hard to understand why certain distributors didn't have systems to flag and prevent some of these shipments.

Another example, Miami-Luken alone sent almost 1.5 million pills to Sav-Rite in 2007 and almost 2 million pills in 2008, and on its face these levels seem ridiculous. At the end of the day, this pharmacy was raided and its owner was sentenced to prison.

So let me start with Dr. Mastandrea.

Have you made changes to your system to compare the number of pills you send a pharmacy against the population of that region to catch something like this before it gets out of control? Quickly, because I have more questions.

Dr. MASTANDREA. Thank you, Congressman.

Yes, we have made changes. We've made significant changes. We have a full-time compliance officer that monitors all—we're not that big, so it's not that hard to monitor our opioid distribution.

We have purchased a commercial algorithm-based system that stops the suspicious order in real time, is reported to the DEA in real time. We have site visits. We have an investigator that makes site visits. We review the accuracy and timeliness—

Mr. PALLONE. I'm going to have to cut you off, only because I want to ask Mr. Barrett a question.

Cardinal provided two pharmacies, Hurley Drug and Family Discount, which filled prescriptions for Dr. Katherine Hoover, and her clinic was widely known as the pill mill and Federal authorities closed it in 2010. Dr. Hoover was the number one prescriber in the



entire State, yet she seemed to be able to write scripts for local pharmacies for years before her clinic was shut down.

One of your fellow distributors reported that Dr. Hoover alone was responsible at one time for 69 percent of the hydrocodone prescriptions at Hurley Drugstore in Williamson and more than half of the hydrocodone prescriptions at Family Discount.

So, Mr. Barrett, are there lessons that you believe can be taken from what happened with Dr. Hoover that will change how you conduct due diligence going forward?

Mr. BARRETT. Ranking Member Pallone, thank you. And the answer is yes, I think we would do things very differently today. That kind of order volume would have been picked up and stopped just statistically by our algorithms.

I think the subjectivity of judgment of whether a pharmacy is legitimate or not legitimate today is really not the question. We look at data, and if the data tells us there is an aberrant pattern, we simply stop.

In this case, as it turned out, there was a bad actor in the area, a doctor, which we later found out, which is why we shipped shipment. But today's systems would simply stop that.

Mr. PALLONE. All right. Let me go to McKesson.

McKesson has reached two settlements with DOJ about alleged failures to monitor for suspicious orders.

So, Mr. Hammergren, how will it be different this time? What serious changes have you made to your systems to flag suspicious orders?

Mr. HAMMERGREN. We certainly have learned lessons from our experience in the past. And our systems today are automated and not subjective. As Mr. Barrett just said, we shut those orders off inbound in the door.

We also have hired very experienced, DEA experienced people to come out and help us investigate facilities before we bring them online and to make sure that we've not brought a bad actor on at any point in the process.

I think the thing that would continue to help us is if we can put physicians in a place where they have more information when they're prescribing, and certainly at the pharmacy level help the pharmacies understand red flags of patients that may be getting multiple doses in different directions.

So I think there's more that we can do as an industry. Blocking the orders is certainly important, but you can imagine every time we block an order, there are legitimate patients in some of those pharmacies looking for their medications. So it's a little bit of a blunt force.

Mr. PALLONE. Last question, going back to Mr. Barrett.

Cardinal also reached two settlements with DOJ over these same issues, and it's only fair I ask you the same question. How will this time be different? How can you assure us that you've addressed the issues raised in the settlement agreements? What specific enhancements have you made to your system?

Mr. BARRETT. Thank you for the question.

The settlement in 2008 reflected the rising of what was internet pharmacy. Our organization I think was doing what it thought was right to adapt to that.

At the same time, we saw emergence over the next few years of pain clinics, many of which were legitimate, by the way, but as it turns out some were not.

And I think we had to learn during that process of the shift of this crisis. I think we've learned that and our systems today reflect that learning.

Mr. PALLONE. Thank you.

Thank you, Mr. Chairman.

Mr. HARPER. The Chair will now recognize Mr. Barton for 5 minutes.

Mr. BARTON. Thank you, Mr. Chairman.

And thank each of you for attending voluntarily. We didn't have to subpoena you. We appreciate that.

And, Mr. Collis, I understand that you forego back surgery to appear today, so we really appreciate you. I noticed you stood up a little bit ago and walked. Dr. Burgess will prescribe an opioid if you don't make it through the hearing.

This is an unusual hearing because each of you provides a much-needed list of products that are legal, and all of you represent corporations that have generally had a very positive record in your industry. And yet, we have a huge problem, 115 people a day are dying of opioid overdoses, and most of those are from legally prescribed opioids.

I'm an industrial engineer. I'm kind of a simplistic person. Our system that we're looking at starts with the patient and the doctor relationship. The doctor prescribes an opioid. It's sent to a pharmacy. The pharmacy accumulates orders and sends to a wholesale distributor, which is one of your companies in most cases. You get your drugs from a manufacturer.

The whole system is overseen by the DEA and is a part of a culture which has evolved that pain is something that should be addressed in any way possible. And at the time the epidemic really took off, there wasn't a huge public outcry over opioid prescriptions. It's different today. The culture today is looking at the problem differently than it did 10 years ago or 15 years ago.

My first question, since you folks are part of the legal distribution system, is the overuse of legal opioids a solvable problem, yes or no? Legal opioids.

Let's start with the gentleman down at the end and work our way down.

Mr. BARRETT. Yes, Congressman. Thank you for the question.

I think the practice of medicine is evolving, and I think that we know more than we did today. And I think, in fact, the prescribing of legal opioids, high-potency opioids, is declining.

Mr. BARTON. I really just need—

Mr. BARRETT. I think the answer is yes, it can be solved.

Mr. BARTON. Yes or no?

Dr. MASTANDREA. Yes, sir.

Mr. HAMMERGREN. Yes, better informed physicians will solve the problem, I think.

Mr. BARTON. Mr. Smith.

Mr. SMITH. The use of drugs always come with a risk-return tradeoff. So I think there will always be some risk-return tradeoff

to this category of drugs and any other. So I'm not exactly sure what you mean by solve.

Mr. BARTON. Well, I think "solve" is a pretty common term.

Mr. SMITH. But I think we can greatly improve the situation.

Mr. BARTON. You know, fixed.

Mr. SMITH. I think that we can bring it back into much more acceptable levels.

Mr. BARTON. I've got a minute and a half left.

Mr. COLLIS. There are already significant changes in prescription trends for legal opioids, but I think it can be vastly improved. I don't know if completely solved.

Mr. BARTON. Generically, everybody said yes, with some modification. I think it can be, too.

Now, this is a little bit trickier question. What percent responsibility do you believe your part of the chain of the industry have in solving the problem, from zero percent, we have no responsibility, to 100 percent, it's all our responsibility?

You just all said that it is solvable. Now, what percent of responsibility do you think the distribution, wholesale distribution system has in solving the problem?

Again, we'll just start at one end and go to the other.

Mr. BARRETT. Congressman, I don't feel qualified to give a percentage of responsibility. I think all of us in the healthcare system have to work together to address this, and I think we should.

Mr. BARTON. Do you agree that you have some responsibility?

Mr. BARRETT. I believe that we've got a role in an integrated healthcare system.

Mr. BARTON. So you have some responsibility.

Dr. MASTANDREA. Congressman, I believe that it's a shared responsibility among many different players, physicians, pharmacists, State medical boards, State pharmacy boards, DEA.

Mr. BARTON. But you agree you have some responsibility?

Dr. MASTANDREA. I have said that, yes.

Mr. BARTON. Your company, your industry, not you personally.

Dr. MASTANDREA. The percentage is shared.

Mr. HAMMERGREN. We have a role to play, Congressman, certainly. And in your example, one of the most important roles we play is to make sure we find suspicious customers and suspicious orders and cut off the supply to those customers.

Mr. BARTON. My time has expired, but I'll let each of you two.

Mr. SMITH. Well, I would just say that H.D. Smith had its role as a distributor to play and did so.

Mr. COLLIS. I get the benefit of going last, so I just would say it's very difficult to ascribe a percentage, given the shared responsibility.

Mr. BARTON. Well, I think you do have a responsibility, I think it's a significant responsibility, but I don't think you have a majority of the responsibility. And hopefully, by the time we end these hearings, we'll get all the players in here.

Thank you, Mr. Chairman.

Mr. HARPER. The Chair now recognizes the gentlewoman from Florida, Ms. Castor, for 5 minutes.

Ms. CASTOR. Well, thank you, Mr. Chairman.

This committee's investigation has made plain that drug wholesale distributors flooded areas of West Virginia and other parts of the country with massive amounts of opioids. This has fed into the public health epidemic that is costing us at least \$8 billion per year nationwide and costing lives, 116 deaths every day. We focused on West Virginia because it has the highest opioid death rate in the country.

Mr. Barrett, your company Cardinal shipped 1.5 million opioid pills each year from 2009 to 2011 to a single pharmacy, Family Discount, in the small town of Mount Gay. That is an average of about 4,000 pills per day.

At the subcommittee's March 20 hearing, DEA testified that that amount shipped to that single pharmacy was, indeed, excessive. And this was after Cardinal had been sanctioned by the DOJ through a settlement agreement for not following the law.

Mr. Barrett, you've said that the wholesalers don't control demand, but clearly you have a responsibility under the law to highlight and flag these suspicious orders. How did Cardinal estimate what was appropriate for a given pharmacy?

Mr. BARRETT. Congresswoman, thank you for your question.

I think our organization recognizes it as a dual responsibility. One is to provide medicine to a system requiring it as prescribed, and the other is to do what we can to prevent those from falling in the wrong hands.

We've evolved over the years. We've become more attuned to the changes. I think today—

Ms. CASTOR. But this kept happening even after DOJ had warned you and you had accepted responsibility and said you would do a better job.

In more recent years, this pharmacy's total purchases of these drugs declined dramatically. In 2015 and 2016, it was down to about 500,000 pills. And that wasn't just from Cardinal, that was from everyone, from all distributors. That was but a fraction of what Cardinal alone had shipped them in earlier years.

So isn't this a clear reflection that that was not the medical need in the community? The amount being shipped didn't reflect what could have been appropriately used in rural West Virginia, especially after DOJ had already warned you.

Mr. BARRETT. Congresswoman, let me make two points about that, if I may.

One is, I've acknowledged earlier that I had wished that we had moved earlier to stop shipping to that pharmacy, which we have many years ago.

Second, I think the evolution was of our looking at a system that was focused on the legitimacy of a pharmacy—which, by the way, is still in business—and the awareness of something happening in the system, which was a bad doctor. And we should have moved more quickly on that.

Ms. CASTOR. I'd now like to turn to McKesson.

Mr. Hammergren, your company McKesson distributed over 1.8 million opioid pills each year in 2006 and 2007 to Family Discount Pharmacy. That's an average of about 5,000 pills per day in this rural small town. Based upon a figure cited by DEA, McKesson shipped Family Discount roughly six times the amount of

hydrocodone that an average pharmacy in rural West Virginia would have received during those years.

So a similar question to you. McKesson delivered millions of pills to the single pharmacy. Clearly, that's not reasonable and you should have flagged that and stopped that right away. Why didn't you?

Mr. HAMMERGREN. We did terminate the relationship with that pharmacy. And like Mr. Barrett, I would have liked us to have made a decision faster. That's the answer. We caught a bad pharmacy and shut it down.

Ms. CASTOR. And as I mentioned, this pharmacy's total purchases of oxycodone and hydrocodone dropped dramatically, but that wasn't until 2015, 2016. And that means the amount of opioids your company alone shipped back in 2006 was over three times as much as the pharmacy got from all distributors in 2016.

Now, you in your testimony, you pointed to, well, overprescribing by doctors, maybe the DEA should have done more, pharmacy bad actors. But you can't reasonably claim that this pharmacy's dispensing filled the medical need. I mean, it took you years to respond. Why was that?

Mr. HAMMERGREN. I can't comment on the medical need, Congresswoman. What I can say is that today in our systems, any shipment that was outside those boundaries would never have happened. It would have been shut down and reported immediately.

Ms. CASTOR. Why didn't you address—given that this community was ravaged by opioid deaths and addiction, and the town of Williamson was even nicknamed Pilliamson, don't you take responsibility for what was happening back then? Was it the profit motive simply overcame the—you saw that paying the penalties under settlement agreements was a cost worth paying because you were making so much money?

Mr. HAMMERGREN. Congresswoman, we take all of these matters very seriously. Any settlement with a regulator we take very seriously. Our systems have evolved, and we continue to invest heavily to make sure that situations like that don't happen again.

Ms. CASTOR. I think this was the opposite of due diligence that was required under the law, and we're going to be looking for greater accountability.

Thank you, and I yield back.

Mr. HARPER. The Chair now recognizes the vice chairman of the subcommittee, Mr. Griffith, for 5 minutes.

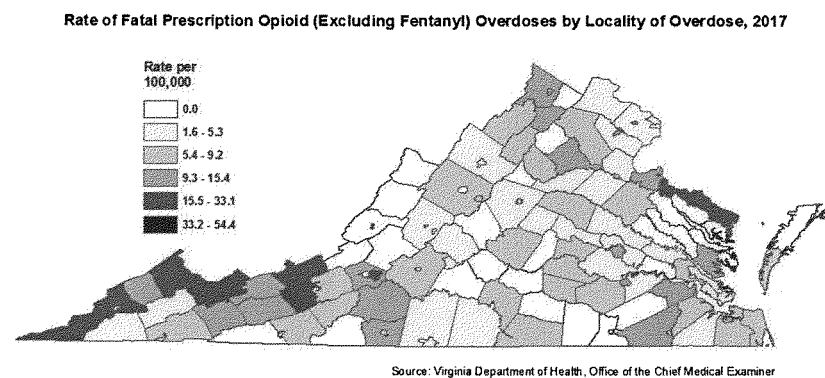
Mr. GRIFFITH. Thank you, Mr. Chairman.

Mr. Hammergren, in the limited time I have, I'm going to ask you a series of yes/no questions. But first, as background, my district borders southern West Virginia. McKesson was a major supplier of pharmacies there, as were some of the others, distributing millions of pills, most into West Virginia in towns that were between 30 and 60 miles from my district.

And last week, I was at an opioid conference, and look at this map that they gave us.

[Slide follows.]

# Fatal Prescription Opioid Overdose 2017



Mr. GRIFFITH. That dark brown area are the deaths per capita in the Commonwealth of Virginia, and you will note there's a correlation with the dark brown areas most common to the border with West Virginia.

And so, gentlemen, when you say that, you know, you're not sure that you have a role—not all of you have said that—it flies in the face of that map and the people of my district.

So, Mr. Hammergren, in May of 2008 McKesson Corporation and the Justice Department and DEA entered into a memorandum agreement, tab 4 in the binder there. You signed on behalf of McKesson Corporation on page 10 of the settlement and release agreement and page 7 of the settlement agreement.

Do you recall signing the document, yes or no?

Mr. HAMMERGREN. Yes.

Mr. GRIFFITH. The conduct at issue in this first settlement with the DEA was that the DEA believed certain McKesson distribution centers did not report suspicious orders and did not have effective controls against diversion. Because of the serious commitments that McKesson made to the U.S. Government and the \$13.25 million civil penalty—you recall that, don't you?

Mr. HAMMERGREN. I do.

Mr. GRIFFITH. Two months later, you presided over a July 23, 2008, board of directors meeting. And according to the board minutes at tab 12 in the binder, public policy issues were discussed affecting the corporation. In an accompanying slide at tab 13, DEA suspicious orders, defined as orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency were categorized as high, in terms of the degree of political urgency, and impact to, and the level of engagement of the corporation.

The urgency of the DEA suspicious orders issue was tied to the May 2008 settlement, wasn't it, yes or no?

Mr. HAMMERGREN. We certainly took the settlement, Congressman, very seriously.

Mr. GRIFFITH. The corporation's high level of engagement meant McKesson management would put in a high level of effort to carry out the promises made in your 2008 memorandum of agreement. Isn't that correct?

Mr. HAMMERGREN. It is correct that it was a top priority for us.

Mr. GRIFFITH. In your experience as an executive at McKesson Corporation, when the company makes a legal commitment, especially one with a high level of engagement, the corporate leadership gives a directive and the appropriate personnel carry it out. Isn't that correct?

Mr. HAMMERGREN. Congressman——

Mr. GRIFFITH. Yes, correct?

Mr. HAMMERGREN. Congressman, we took it very seriously.

Mr. GRIFFITH. Yes. However, according to media reports, from 2008 to 2013, the McKesson Aurora, Colorado, warehouse filled 1.6 million orders, but only reported 16 suspicious orders. The Landover, Maryland, warehouse, which supplied West Virginia, routinely failed to report and fulfilled suspicious orders placed by numerous pharmacies in West Virginia.

While the Landover facility was closed in 2012, the serious lack of suspicious order reporting does not show a high level of engagement by McKesson, does it, yes or no?

Mr. HAMMERGREN. We took our responsibilities very seriously.

Mr. GRIFFITH. Yes or no? Failing to live up to the 2008 agreement does not show a high level of commitment, does it?

Mr. HAMMERGREN. That's not true. We had a high level of commitment, Congressman.

Mr. GRIFFITH. And you failed. The DEA alleged that McKesson distribution centers ignored thresholds and supplied pharmacies volumes of controlled substances that exceeded their assigned amount without a proper review. That also does not show a high level of engagement, does it, yes or no?

Mr. HAMMERGREN. Congressman, we had a high level of engagement.

Mr. GRIFFITH. Were any McKesson personnel fired in connection with any of the failures noted in the 2017 memorandum of agreement? That's at tab 5.

Mr. HAMMERGREN. Congressman, the people involved today in the CSMP are vastly different than the people in 2008.

Mr. GRIFFITH. Was anybody fired?

Mr. HAMMERGREN. Congressman, the people are different today. Many of them have left the corporation.

Mr. GRIFFITH. But they weren't fired.

Mr. HAMMERGREN. We don't talk about specific—

Mr. GRIFFITH. I'm not asking you to talk about specifics. I'm asking you to tell me if anybody got fired. Did you hold anybody personally responsible for what was happening in West Virginia and in Colorado and other parts of the country?

Mr. HAMMERGREN. Congressman, everybody at the company is accountable to do what's right.

Mr. GRIFFITH. But no one was fired. All right.

In January 2017, McKesson Corporation and the Justice Department and the DEA entered into another memorandum of agreement, because you didn't live up to 2008. As a result of this agreement, McKesson paid a record-setting \$150 million fine.

In this memorandum of agreement, in section 2, acceptance of responsibility, McKesson acknowledged it failed to identify or report to DEA certain orders by certain pharmacies which should have been detected by McKesson as suspicious. This involved 12 out of 30 McKesson distribution centers. More than a third of your distribution centers were involved in these failures.

That is a widespread systemic failure. Wouldn't you agree?

Mr. HAMMERGREN. Congressman, our organization in 2008 was working closely with the DEA.

Mr. GRIFFITH. This is 2017.

Mr. HAMMERGREN. I understand. And we have created a program that really we believe is meeting their needs, focused on suspicious customers and knowing our customers.

Mr. GRIFFITH. And a third of them were out of compliance.

Mr. Chairman, I yield back.

Mr. HARPER. The gentleman yields back.

Before I recognize the next person, Mr. Hammergren, it seems like a pretty easy question to answer if anyone was fired in re-



sponse to Mr. Griffith's question. And the answer is yes, no, I don't know, or I refuse to answer. What is your answer?

Mr. HAMMERGREN. Yes, people were fired as a result of this.

Mr. HARPER. Thank you very much, Mr. Hammergren.

I'll now recognize the gentlewoman from Illinois, Ms. Schakowsky, for 5 minutes.

Ms. SCHAKOWSKY. I have to say that I'm pleased that you're all with us today to discuss the role your companies played in supplying the opioid epidemic, but I have to also say that this reluctance even to answer that simple question, or reluctance, always qualifying your responsibility—clearly, you had a responsibility.

And, Mr. Hammergren, you acknowledge that you wish you had terminated your relationship with Sav-Rite earlier and that you did end that relationship. But why did you then—why did you ship 5 million pills before you shut it down?

Mr. HAMMERGREN. Congresswoman, thank you for the question. Certainly, we've learned from our experience during the 2006, 2007, over a decade ago, and today's systems are much more robust than they were then. Our orders actually aren't even processed today if they're above thresholds. In those early phases of 12 years ago, our systems weren't as automated as they are today.

Ms. SCHAKOWSKY. You know, all of you, I hope, will acknowledge that since 1971, your companies are required by Federal law to halt and report suspicious orders of prescription opioids.

Did you, before all of this broke, have a process to do that, if I could just go down, to obey the 1971 law?

Mr. BARRETT. Yes. Our organization, Congresswoman, has had a clear sense of the Controlled Substance Act and reported all orders to the DEA of narcotics.

Ms. SCHAKOWSKY. OK.

Mr. Mastandrea?

Dr. MASTANDREA. Yes, we did have a system in place, Congresswoman.

Mr. HAMMERGREN. Congresswoman, we also reported all orders required.

Ms. SCHAKOWSKY. Mr. Smith.

Mr. SMITH. At different points in time, the expectations of the DEA were different.

Ms. SCHAKOWSKY. Microphone, please.

Mr. SMITH. At different points in time, the expectations of the DEA were different. Up till about 2007, the DEA expectation was for us to report suspicious orders after the fact with monthly reporting, and we did so.

It was in 2007 that the DEA expressed a very different expectation concerning controlled substance orders and that if it was suspicious they asked that we develop a system to hold those orders at the time they were received.

Ms. SCHAKOWSKY. OK, I'm going to move on.

Mr. SMITH. We implemented that system in 2008.

Ms. SCHAKOWSKY. Sir.

Mr. COLLIS. Congresswoman, AmerisourceBergen didn't exist. There were many predecessor companies. I'm not aware of any of them that weren't committed to compliance with all Federal statutes.

Ms. SCHAKOWSKY. I just think it's really important to put on the record that this is not a new requirement, that yes, maybe there wasn't the kind of enforcement, but nonetheless, your companies had a responsibility.

I also want not only to look back and see what went wrong, but also to look forward to see how to do better. And it is apparent now that pharmaceutical corporations are taking advantage of the opioid epidemic by spiking the price of life-saving drugs like naloxone, and that that, in my view, is unacceptable. Pharmaceutical corporations can't start this epidemic with irresponsible and reckless on day—recklessness one day—and then turn around and profit the next.

So I wanted to again ask Mr. Hammergren, McKesson distributes Evzio, which has raised its price from \$690 to \$4,500. So what does McKesson earn net per unit for Evzio?

Mr. HAMMERGREN. I can't answer that question, Ms. Congresswoman. I would say that we don't set the prices for branded drugs. Those are set by the manufacturers.

Ms. SCHAKOWSKY. And how much does McKesson net annually for the distribution of Evzio?

Mr. HAMMERGREN. Congresswoman, I don't have that information. I'd be happy to get it for you.

Ms. SCHAKOWSKY. McKesson also distributes Narcan. What does McKesson earn net per unit for Narcan?

Mr. HAMMERGREN. Congresswoman, I don't know the answer to that question.

Ms. SCHAKOWSKY. And how much does McKesson earn net annually for its distribution of Narcan?

Mr. HAMMERGREN. I don't know that question.

Ms. SCHAKOWSKY. So I would expect that we'll put that in writing and that we'd get this information. Because, you know, you can't have it both ways, fellas. You know, the opioid epidemic is there, and now for life-saving drugs those prices are going through the roof.

And I yield back.

Mr. GRIFFITH [presiding]. I thank the gentlelady and now recognize the gentleman from Texas, Dr. Burgess.

Mr. BURGESS. Thank you, and thanks for having the hearing.

Mr. Hammergren, let me just continue on that line for a moment, because I think this is an important point. You as a distributor do not set the list price of the compounds that you were being questioned about. Is that correct?

Mr. HAMMERGREN. I don't believe so. If they're branded patented drugs, we don't set the price.

Mr. BURGESS. So you receive an order and you fill an order. You're agnostic as far as the price. That is set by the person selling the product. Is that correct?

Mr. HAMMERGREN. Congressman, the manufacturer sets those prices, to the best of my understanding.

Mr. BURGESS. Mr. Collis, you mentioned—it was almost an off-handed mention, but it is important—one of the first hearings that I sat through in this subcommittee in 2005 was a hearing on why don't doctors prescribe enough pain medicine. And you referenced that there are some people who are watching this debate who are

concerned are they going to be able to get the medicines for the treatments for which they are being treated.

And I think that is a legitimate concern and we do need to be mindful. We cannot overlook the fact that there are serious, serious problems that need to be fixed. But I thank you for bringing that up, because that is an important reference point that we sometimes overlook.

Mr. Smith, let me just ask you, we've actually heard some back-and-forth, and I think there was a question on the other side dealing with a document or a letter from Mr. Rannazzisi at the DEA, Drug Enforcement Administration, that said, don't just report to us the total sales.

Mr. Collis, I think you said, we just report, we're not making a judgment whether it's suspicious, this is what we deliver to place A, B, or C. Is that correct?

Mr. COLLIS. We do report every day, and we also report on a monthly basis all cost data, but we do make determinations of what is a suspicious order and we hold them.

Mr. BURGESS. Sure, and I appreciate that. This is what is so frustrating to me for an all-hands-on-deck situation. The DEA says, don't just report your raw data. But you have algorithms. The DEA should have algorithms. I think the Center for Medicare and Medicaid Services probably should have algorithms in their database so that they can identify who are the outliers.

Not saying that someone is doing something wrong, it may be a pain clinic, it may be a cancer clinic, but let's afford some extra scrutiny if this is the amount of product that's going out so we don't end up with a situation such as in Kermit.

Now, Mr. Smith, let me ask you, your company, and I think you testified to this, your company reports suspicious orders. What does the DEA do with that information when you report it?

Mr. SMITH. I don't really know.

Mr. BURGESS. You've sold your company, I understand that.

Mr. SMITH. But I don't really know. And the DEA, as we talk about the DEA, the DEA has not been the same in their outlook, attitude, and interaction with the industry over my career. For most of my career, the interactions with the DEA were very collaborative and very purposeful, in terms of working with them to try to control controlled substance distribution.

Back about 10 years ago, with the advent of this expectation of holding orders, it became very, very difficult to interact with the DEA and to get feedback. They were, in fact, as evasive as possible in the midst of this crisis to us, in terms of giving us guidance. More recently, that attitude has been changing and improved.

Now, as you point out, as of 2018, I was pretty much out of the picture. I can only hope that the DEA will continue to work collaboratively with the industry going forward.

Mr. BURGESS. And what you have just related is information that independently I and my staff have acquired, that the number of administrative actions against registrants by the DEA—now I'm merely talking about doctors, because that was my focus when I began this—but when you look at the numbers in the committee's memo, how things have just been going up through the roof, the number of administrative actions, I'm not talking about for West

Virginia, I'm talking about for the whole country, 21 in 2014, at the same point that point in the graph was probably at its apex.

I've got to believe that the DEA—I'm not saying that everything that you've reported—I want you to do your job, but I want the DEA to do their job, and it doesn't look like they have been. And I'll just share with you, they've been very, very difficult to get information out of the agency.

I hope you're right, Mr. Smith, I hope it is changing. But we cannot fix this problem if the agency required to be in charge simply is insensitive to our requests for information.

I thank all of you for being here today.

Mr. Chairman, I yield back.

Mr. GRIFFITH. I thank the gentleman, and now recognize the gentleman from New York, Mr. Tonko, for 5 minutes.

I understand you have a UC request.

Mr. TONKO. I'll yield to Ms. Castor.

Ms. CASTOR. Thank you, Mr. Chairman.

I'd like to ask unanimous consent to submit for the record information relating to the salaries of the CEOs of the Big Three drug wholesalers, including the McKesson CEO, who made over \$692 million in the 10 years leading up to 2017.

Mr. HARPER [presiding]. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Ms. CASTOR. I yield back.

Mr. TONKO. Thank you, Mr. Chair.

Mr. Barrett, I asked about Cardinal's sales to pharmacies that filled prescriptions written by two doctors, Katherine Hoover and Diane Shafer. Federal law enforcement put both of these doctors out of business around 2010.

Dr. Shafer was sentenced to 6 months in prison after she admitted to writing illegal opioid prescriptions. According to the United States Attorney's Office for the Southern District of West Virginia, she wrote more prescriptions than entire hospitals did between 2003 and 2010.

Dr. Hoover was the single largest prescriber of controlled substances in West Virginia between 2002 and 2010. When her clinic was raided, she fled to the Bahamas.

Cardinal served two pharmacies, Hurley Drug and Family Discount, which filled prescriptions from Dr. Hoover. In September 2008, a Cardinal employee raised an alarm about Hurley Drug in a memo, which noted that Hurley filled prescriptions from Dr. Katherine Hoover even though other pharmacies refused to fill her prescriptions.

According to this document, another pharmacist stated that he would not fill Hoover's prescriptions because, quote, "He had ridden by the office of Dr. Hoover and there are lines of people standing outside waiting to get into the office," close quote.

In fact, according to a 2011 news report in the late 2000s, quote, "Crowds of people filled the lot outside Dr. Hoover's clinic," and it was, in quote, "an open secret that it was essentially a pill mill."

Is that accurate? And did your employee observe the lines of people outside that office as early as 2008, which could indicate a possible pill mill?

Mr. BARRETT. Congressman, I've been briefed on those memos.

Mr. TONKO. Pardon me?

Mr. BARRETT. Yes, I've been briefed on that report.

Mr. TONKO. OK. So your employee's memo appears in Cardinal's due diligence file for Hurley, but it is unclear what actions Cardinal took based on it. For example, Cardinal continued to supply Hurley for another 6 years.

So why? Do you know whether Cardinal ever followed up on this memo?

Mr. BARRETT. So we've not shipped that company high-potency opioids for many years. I mentioned earlier that based on what I've seen, I wish we had taken action earlier. I think we had a system that allowed for too much subjectivity about the legitimacy of a pharmacy.

Today's system simply would have taken the data, seen outlier data, and shut it off. And, as I said earlier, I've seen enough to know that I wish we would have acted earlier.

Mr. TONKO. Cardinal also supplied Family Discount Pharmacy, sending it more than 5.5 million pills from 2009 to 2012, after which you ended your relationship with them.

According to a document in another distributor's files, in 2009, 51 percent of Family Discount's hydrocodone prescriptions came from Dr. Hoover. That distributor also reported to the committee that Dr. Hoover was responsible for 69 percent of Hurley Drug's hydrocodone orders, which the distributor considered a, quote, "cause of concern."

Mr. Barrett, in your written testimony, you say you wish you had asked a different set of questions before distributing to this pharmacy. It appears that Cardinal may have missed the red flags connecting Dr. Hoover to both Hurley Drug and Family Discount. So I'd like to know how this will be fixed going forward.

Mr. BARRETT. Congressman, it is a great question. It is fixed going forward. As I mentioned earlier, I think both of the pharmacies to which you referred were influenced by this same doctor who, as it turns out, was a bad doc.

Today's systems would not allow subjectivity. Today's systems would simply say, we set thresholds or limits, based on certain criteria, primarily relationship between controlled drugs and on other drugs and the nature of the community. And if it crossed those thresholds, we simply would shut the order down, and that's what we do today.

Mr. TONKO. So is it your belief that these two situations would have been caught much earlier?

Mr. BARRETT. In today's system, absolutely.

Mr. TONKO. It's unbelievable that these numbers of pills were being sold and that this pill mill was getting away with activity.

I just hope that all of the distributors before us have much more rigorous due diligence standards in place today that can help them spot these red flags.

And with that, Mr. Chair, I yield back.

Mr. HARPER. The gentleman yields back.

The Chair will now recognize Mrs. Brooks for 5 minutes.

Mrs. BROOKS. Thank you, Mr. Chairman.

Mr. Smith, I'd like to talk about Family Discount Pharmacy that has been mentioned here already. Your company terminated Fam-

ily Discount Pharmacy's ability to purchase controlled substances in 2011. Is that correct?

Mr. SMITH. I believe that we discontinued selling them anything at that—around that time.

Mrs. BROOKS. Correct, in 2011. But prior to that, was H.D. Smith aware of the prescriber we've heard about, Dr. Katherine Hoover, who was responsible for providing over 262,000 hydrocodone prescriptions to Family Discount Pharmacy as well as other nearby pharmacies in February of 2008? Was H.D. Smith aware of the Dr. Hoover problem?

Mr. SMITH. I am not aware of the specific timing of when our due diligence team became aware of that issue. I do know that with Family Discount that when we implemented our controlled substance ordering monitoring program, we began to limit the controlled substances that we sent and—

Mrs. BROOKS. Excuse me. Did Dominic Grant work for you.

Mr. SMITH. I beg your pardon?

Mrs. BROOKS. Did Dominic Grant for you? Did George Euson work for you?

Mr. SMITH. George Euson worked for me.

Mrs. BROOKS. In 2008?

Mr. SMITH. Uh-huh.

Mrs. BROOKS. Where I have an email indicating that Dr. Hoover had prescribed, had filled over 262,000.

Mr. SMITH. OK.

Mrs. BROOKS. So I do believe that your director of corporate security was aware of that.

Mr. SMITH. Thank you.

Mrs. BROOKS. If you turn to tab 16 you'll see that over a year later H.D. Smith noted in a November 12, 2009, report—2009—that Dr. Katherine Hoover was responsible for 51 percent of the hydrocodone scripts being filled by Family Discount.

Now, knowing that, was Family Discount Pharmacy—had that become a concern for your company in November of 2009?

Mr. SMITH. It appears that it was at that time.

Mrs. BROOKS. And did H.D. Smith report this to the DEA?

Mr. SMITH. I'm not sure what the timing of what we would have reported to the DEA was.

Mrs. BROOKS. Well, in fact, we know that Family Discount did make some reports to the DEA between May of 2008 and May of 2009, but not at this time, in November of 2009.

In April of 2015 then, interestingly, did H.D. Smith—so you then terminated with Family Discount in 2011, but then, going to April of 2015, did H.D. Smith make the decision to resume its business relationship with Family Discount Pharmacy?

Mr. SMITH. That's possible. We have a robust program, and that includes reviewing new data that comes along. It is possible that we could reopen an account if we saw that there were indications that the situation was different.

On the other hand, that doesn't end our robust due diligence. We can continue to do that and can decide to close it again.

Mrs. BROOKS. Let's talk about the due diligence. Were you aware that Family Discount had been dropped by some of the other dis-

tributors here at the table when you renewed your relationship? Were you aware of that?

Mr. SMITH. No, I was not aware.

Mrs. BROOKS. So please turn to tab 19, speaking of due diligence. An email was sent by an H.D. Smith employee in January of 2016 expressing concern that the company was providing controlled substances to Family Discount's other location, located just 3 miles away, despite the fact the company, your company, had never performed any new customer due diligence on that pharmacy. Were you aware of that?

Mr. SMITH. No.

Mrs. BROOKS. The employee's email also noted that this pharmacy had reached its hydrocodone threshold only 12 days into a month. Were you aware of that?

Mr. SMITH. No.

Mrs. BROOKS. And did you report the suspicious activity to DEA?

Mr. SMITH. I do not know.

Mrs. BROOKS. I would assume you did not.

Following the January 2016 correspondence, did either Family Discount location continue to place controlled substance orders that exceeded the monthly thresholds established by H.D. Smith, this new amazing system you put in place?

Mr. SMITH. I do not know.

Mrs. BROOKS. Well, you might want to take a look at emails in June and October of 2016 showing that Family Discount had placed orders in excess of established thresholds, that, in fact, one of your employees indicated that the justification was to meet our guideline to obtain our monthly discount. What monthly discount?

Mr. SMITH. I'm not sure what that refers to.

Mrs. BROOKS. A monthly discount with the manufacturer?

Mr. SMITH. No.

Mrs. BROOKS. Monthly discount—no idea what monthly—what deals were being cut?

Mr. SMITH. I'm not sure what that refers to.

Mrs. BROOKS. H.D. Smith then blocked Family—H.D. Smith block Family Discount's ability to purchase controlled substances on February 16 of 2018. Were you in charge at that time of the company?

Mr. SMITH. No. My managerial responsibilities ended at the acquisition of H.D. Smith in January of 2018.

Mrs. BROOKS. In January of 2018. Well, I will say that according to a document we received, the committee, the company cited its reason for taking this action and finally terminating the relationship with Family Discount was due to reference negative news articles.

With that, I yield back.

Mr. HARPER. The Chair will now recognize Mr. Ruiz for 5 minutes.

Mr. RUIZ. Thank you, Mr. Chairman.

This crisis continues to overwhelm our healthcare system, and as an emergency physician I have been involved in the front lines taking care of opioid-addicted and overdosed patients way before it made national headlines. Doctors struggle with treating pain adequately and identifying drug seekers.

Hospitals in my district are seeing an increase in uncompensated care, because they are seeing more and more patients with chronic opioid-related kidney, heart, and lung complications, not to mention overdoses.

It is good that more funds are going to fight the opioid epidemic. I agree with that. I encourage that. But if you eliminate mental health coverage, emergency care coverage as an essential health benefit, or if you repeal Medicaid expansion, then you actually are taking 1 step forward and 10 steps back and are actually hurting patients and making the problem worse.

Moving forward, I think it is critical that the various players—DEA, hospitals, physicians, pharmacists, manufacturers, and distributors—work together to identify and implement systems and processes that move us forward to identify and implement solutions.

I understand that as this crisis has continued to escalate, many of you have put internal systems in place to increase accountability, but we have been told that before and it turned out to be untrue. And there's a difference between what you have on paper and what you are actually implementing.

At our March 20 hearing, members of this committee described the quantity of opioid pills sent to particular pharmacies in this region and asked DEA Administrator Patterson whether those amounts were excessive and whether the distributors failed to adequately exercise due diligence. The DEA agreed on both counts.

So I'd like to quickly go down the line and find out whether the problems that led to this overdistribution have been fixed.

Dr. MASTANDREA, Miami-Luken distributed substantial quantities of pills to certain places in West Virginia. For example, your company sent Sav-Rite pharmacy in Kermit, a population of only 400, nearly 2 million pills in just 1 year.

Would Miami-Luken's current system discover these large shipments and more closely examine them to determine if such a large volume was appropriate and not going to a rogue operation, such as a pill mill?

Dr. MASTANDREA. Yes, sir.

Mr. RUIZ. And how can you guarantee us that that system will be implemented?

Dr. MASTANDREA. It's already implemented.

Mr. RUIZ. So you're saying that there's no mistakes currently being done that you know of? There's no way of—what is your system to find and review in case you do make a mistake?

Dr. MASTANDREA. Each order is reviewed by our—we purchased a Buzzeo system. It's a computer algorithm that tells us whether or not the order deviates from frequency, pattern, size. And we stop it in real time if it does. We pend the order. If the order is adjudicated to be an appropriate order, then we release it. If it's not, then we report it.

Mr. RUIZ. The DEA data indicate that McKesson also supplied the Sav-Rite in Kermit, population of 400, with almost 5 million opioids over a 2-year period.

So, Mr. Hammergren, if a pharmacy serving a comparable population placed those large orders today, particularly in an area hard hit by opioid diversion, would McKesson's monitoring systems be



capable of flagging these orders for further review to make sure that they are not affiliated with a pill mill?

Mr. HAMMERGREN. Congressman, that's a good question. We would not ship to Sav-Rite today.

Mr. RUIZ. OK. So, in terms of your system, if this happened to another comparable city, do you have a system in place to flag? The first question.

Mr. HAMMERGREN. We have a system in place that would block the order if it was a pharmacy that was outside of a boundary, a threshold being set.

Mr. RUIZ. So why hasn't that happened? Why did you have another settlement in 2017, when you told us this exact same thing in 2008?

Mr. HAMMERGREN. We had a system in place from 2008 to block suspicious orders. Our settlement in 2017 was really related to our reporting of suspicious orders.

Mr. RUIZ. And so the implementation of those reporting and also the shipping of orders.

So I think it's very important that we also identify, which we see on multiple scenarios where corporations and agencies will hold up their policy on paper, but then the actual implementation of those are either not enforced or they're not transparent to determine what's working and what's not working.

Mr. Collis, since you are now responsible for H.D. Smith's customers as well as your own, this question is for you. Without debating the merits of the West Virginia litigation that's currently undergoing, do you now have a way to assess orders for high volumes of pills against the populations receiving them?

Mr. COLLIS. I believe we do. I believe we have a robust system and we've always had one.

Mr. RUIZ. OK. I yield back my time.

Mr. HARPER. The Chair will now recognize the gentleman from Michigan, Mr. Walberg, for 5 minutes.

Mr. WALBERG. Thank you, Mr. Chairman. And thank you for having these hearings.

As we look at the various players—and today, of course, we have distributors—we had the opportunity to have DEA in front of us, and that was an amazing time of testimony as well with amazing failings that went on in DEA also.

But this epidemic knows no boundaries. When we talk of losing 115 Americans every day to the opioid epidemic, these are people that are our neighbors, our friends, our fathers, our family members, our sons, our daughters, our mothers. It knows no bounds. But the sheer number of opioids dumped into small town America is simply baffling and incomprehensible to me.

Many of us have tragic stories of pill mills in our district. And my district in Michigan is, unfortunately, no different. In Monroe County, one doctor alone was able to get his hands and prescribe over 2 million pain killers in just two short years.

I, for one, am interested to have the distributors here today to tell us exactly how and why this type of thing happens and to hear the steps that they have or will take.

Mr. Collis, you wrote in an editorial last year that AmerisourceBergen has, and I quote, "reported and stopped tens of

thousands of suspicious orders since 2007,” end quote. If a specific pharmacy is reported for suspicious orders multiple times during a short period, would that trigger a heightened investigation of that customer?

Mr. COLLIS. I believe it absolutely would. I wouldn't say we don't make mistakes, but I will tell you one of pharmacies that's been mentioned several times, we had them on service for 38 days, and we reported them 36 of the 38 days. And on the 38th day we stopped servicing them.

Mr. WALBERG. In the editorial, you also noted that AmerisourceBergen uses, and I quote, “complex algorithms to identify and stop orders that are deemed to be suspicious.” From 2012 to 2015, AmerisourceBergen reported 394 suspicious orders for a single West Virginia pharmacy, Beckley Pharmacy.

If the company opens an investigation of a pharmacy like Beckley, the investigators would want to know the percent of controlled substance prescriptions the pharmacy filled, correct?

Mr. COLLIS. That's correct.

Mr. WALBERG. Whether there are signs of drug activity around the pharmacy. Is that correct?

Mr. COLLIS. We would review the type of business that they are servicing. Some of my colleagues on the panel here have talked about the type of business. If they service a hospice account or pain management clinic, we would investigate that.

Mr. WALBERG. If there are any known pill mill doctors writing prescriptions, you would want to note that, correct?

Mr. COLLIS. If we knew that they were servicing a pill mill doctor, by your description, we would not service that pharmacy. If their business was designed around that, we would not service that.

Mr. WALBERG. AmerisourceBergen reported 199 of its suspicious orders for Beckley Pharmacy between 2013 and March of 2014. But documents your company provided to the committee indicate that Amerisource didn't investigate the pharmacy until February 2015.

Please, if you would, turn to tab 46 to see the investigator's February 2015 report, which found, and I'll read that:

The pharmacist said that 50 percent of prescriptions he filled were for controlled substances and that customers told him other pharmacies wouldn't fill their prescriptions. Some of the pharmacies top 10 prescribers were among the top hydrocodone prescribers in the State, and the pharmacy security guard referred to customers as drug addicts and drug dealers and said he witnessed numerous drug deals in the parking lot after customers filled oxycodone prescriptions.

Amerisource didn't stop doing business with that pharmacy until November 2015, 10 months after the investigator's report, which itself came only after your company filled hundreds of suspicious orders. The company is supposed to use, and I quote, “complex algorithms” to identify problems pharmacies have.

So why did it take so long?

Mr. COLLIS. I have a team, some of them are behind me. We trust them. I think that we—I have never heard of this pharmacy before. But we're committed to continuous learning. And if we made mis-

takes, hopefully we'll rectify them and they won't happen in the future.

Mr. WALBERG. Well, if we could get the response to that question, since you're not aware of it. It comes from your reports and the reports that we have in front of us.

Mr. COLLIS. We ship 100,000 orders a day. It's not feasible that I would know about all the orders.

Mr. WALBERG. Well, we'll appreciate the response to that.

Mr. Chairman, I have other questions I'll have included in the record.

Mr. HARPER. Certainly. Each of the witnesses will be aware, you may be getting written questions following this. We'd ask for your response to those as quickly as possible, including an answer to that question, Mr. Collis, at your earliest convenience.

At this time, the Chair will recognize the gentlewoman from California, Mrs. Walters, for 5 minutes.

Mrs. WALTERS. Thank you, Mr. Chairman.

And, Mr. Barrett, these questions will be asked of you.

When Cardinal began setting threshold limits for pharmacies in 2008, the company set Family Discount's hydrocodone threshold at 27,000 doses a month. In a little over a year, Cardinal adjusted the pharmacy's threshold 14 times. And by August 2009, it was cleared to receive 110,000 hydrocodone pills a month.

The pharmacy's threshold for hydrocodone reached a peak of 150,000 dosages a month in January 2010, a level it remained at for a year and a half before Cardinal officials reviewed and reduced it.

Mr. Barrett, when a pharmacy goes over its monthly drug threshold, does Cardinal inquire about the reason for the higher drug order?

Mr. BARRETT. Thank you, Congresswoman.

Today, if an order reaches its threshold, it simply stops. So the process is the threshold is set, and the threshold is set based on a number of factors, the size of the community it serves, not just the population but the community it serves. Other factors. Does it serve a hospice center, a surgical center, et cetera. If an order reaches that threshold, that limit, it simply stops.

Mrs. WALTERS. But in the past, did it question it, before today?

Mr. BARRETT. So as I look back at some of the historical documents, I think the thresholds probably should have been set with a different set of eyes. I've mentioned this notion of asking different questions. And I think today we'd probably set those quite differently.

But I think at the time of those pharmacies you referred to, thresholds probably should have been adjusted down more quickly.

Mrs. WALTERS. Did they—did Cardinal make an assessment as to whether the explanation for increasing its threshold made sense and verified it in any way?

Mr. BARRETT. It's hard for me to answer that fully. Again, this is part of the history. I have no reason to question the good intent of those doing that kind of assessment. They were professionals. I think they were looking at the incoming order of prescribing.

I think now we know some of that prescribing was driven by some behavior that we would have liked to have caught in the physician world. And today that simply could not happen.

Mrs. WALTERS. OK. In Family Discount's case, the pharmacy gave several explanations as to why it needed higher drug threshold. But in April 2009, the pharmacy said its hydrocodone volumes increased because of the closure of a nearby pharmacy called Sav-Rite pharmacy.

Mr. Barrett, do you know why Sav-Rite closed in 2009?

Mr. BARRETT. I'm sorry, Congresswoman, I don't.

Mrs. WALTERS. OK. Well, it closed because it was raided by the DEA as part of a crackdown on prescription drug diversion.

Sav-Rite, which is located about 30 miles away from Family Discount, closed after it was raided by the DEA, as I just mentioned. And the raid was covered in the local media at the time, but due diligence files Cardinal provided the committee do not indicate that the company knew about this event. Is that something Cardinal should have investigated or known?

Mr. BARRETT. I think today under our procedures in our, essentially, know your customer model, we try to take into account what factors that we can that are fact. Those weigh into the judgment along with various analytical tools that relate to the nature of the community of practices that a pharmacy serves. So very likely today that would have been a factor that would have been—it would have been caught in the system.

Mrs. WALTERS. OK. Cardinal's policies indicate that, as of 2016, two people must now sign off on the decision to raise certain drug threshold levels above 20,000 and above 40,000 a month. Before that policy was adopted, was Cardinal failing to properly vet threshold level adjustments?

Mr. BARRETT. I'm not sure, Congresswoman, that I could say that we were failing to reflect that. I think we were using the tools of the moment. And it was probably much more subjective judgment than what would happen today. Today it is a much more rigorous, evidence-based, data-based decision, and it doesn't have the same kind of subjectively I think that was present at that moment.

Mrs. WALTERS. OK. Cardinal Health has advised the committee staff that, starting in 2012, your corporation implemented stronger compliance systems. However, I would note that, in March 2017, the California State Board of Pharmacy filed a complaint against Cardinal's Valencia, California, facility for shipping suspicious orders, including hydrocodone, during 2012 to 2015, to Pacific Plaza Pharmacy.

I would further note that the conduct of the Cardinal Valencia facility figured in the 2008 \$34 million settlement with the Justice Department and DEA. The shipments to Pacific Plaza involved sharp increases in the volume of controlled substances over a period of time. There were also orders of significant amounts of the highest available strength of drug compared to lower strengths, a red flag for illegitimate pharmacy dispensing.

I understand Cardinal is contesting the complaint. But, Mr. Barrett, shouldn't Cardinal Health's stronger compliance system have been able to detect and to prevent these transactions?

Mr. BARRETT. Congresswoman, if I'm responding, I think, to the case that you referred to, and, again, this is important, we ship to a pharmacy that had an employee that stole a product. We were then criticized for shipping to the pharmacy and not being able to detect that internal theft.

Again, I think this in some ways highlights part of the challenge. We ship to hospitals and pharmacies all over this country. There are things that may happen inside their watch.

If the volumes are not things that would normally hit our thresholds that are happening at a much lower level, and this can happen, that is something we probably would not somebody detect.

And so, again, this may or may not be the situation you're referring to. If it is, and I think it may be, that's essentially what the issue is.

But for us today, we are driven by strict thresholds, and those are limits on the amount of certain products, 120 categories of drugs that can go to certain pharmacies.

Mrs. WALTERS. OK. Thank you.

I'm out of time.

Mr. HARPER. The Chair now recognizes the gentleman from Georgia, Mr. Carter, for 5 minutes.

Mr. CARTER. Thank you, Mr. Chairman.

And thank all of you for being here today. We appreciate this very much.

I have to say that I'm pleased thus far that my colleagues have not made this a witch hunt. But instead, I think they've asked some great questions and very fair questions.

What I've heard, and I've been kind of in and out, but what I've heard is that you've acknowledged that you have a responsibility here and that you understand that. What I think I've also heard is that if you knew back then what you know now, you'd do things differently. And I think that's true for all of us in this profession. And I say that having practiced pharmacy for over 30 years.

I'm going to ask you all to be very, very honest with me right now, because I'm concerned, as Dr. Burgess mentioned, about the role of the DEA.

Now, we've already had the DEA before this committee, and I think we had—I think we kind of had it backwards. I wish I could have another shot at them, to be quite honest with you, to ask them some questions.

But let me—I just ask any of you. I assume all of you are compliant to ARCOS, that you're reporting. What does DEA do with that information? Do you know? And if you can be brief, because I've got a bunch of questions.

I ask you, Mr. Hambergren. Do you have any idea what DEA does with that information?

Mr. HAMBERGREN. No, I don't, sir.

I would also say, Congressman, some of this testimony, you see these pharmacies switch wholesalers back and forth.

Mr. CARTER. Absolutely.

Mr. HAMBERGREN. We don't see it before that happens.

Mr. CARTER. OK.

Mr. Collis, do you have any idea what the DEA does with this?

Mr. COLLIS. No. No. We would like more feedback. We'd also like [off mic] the rules, for example, on what constitutes a suspicious order.

Mr. CARTER. OK.

Mr. COLLIS. Very, very helpful. I know one of the gentlemen and I think we would be very interested in complying with the rules.

Mr. CARTER. Let me ask any of you. Has the DEA ever come to you and said do not send opioids to that pharmacy or to that clinic or to that hospital? Has anybody ever been told that by the DEA?

Mr. COLLIS. Not to my knowledge.

Mr. CARTER. Have they ever given you any kind of directions or guidelines? You know, I get it if they're outside of the rim, you know, and obviously there's something going on. But, I mean, aside from that.

Mr. Collis.

Mr. COLLIS. Well in 2007, we had a lot of discussion with them, and we developed our current controlled substance order monitoring program and with the understanding that this was where they wanted the industry to go to.

So I would say we do have regular consultation with them. We have worked with them on training programs.

I wouldn't say it's—I would say, like all relationships, it can be improved and worked upon.

Mr. CARTER. Right. Right.

Mr. COLLIS. But it's not totally without communication and collaboration.

Mr. CARTER. Let me ask you this. Obviously, you know the difference in a schedule two drug and a schedule three drug. The DEA schedules those depending on the tendency for addiction.

When did hydrocodone become a C two drug?

Mr. COLLIS. I do not know.

Mr. CARTER. I will tell you. It became a C two drug in 2014.

Why did it take so long, do you think, for the DEA to reclassify hydrocodone from a C three to a C two drug? Do you treat C two drugs differently from C three drugs?

I know you do, because when I get them from you, or when I used to get them from you, I had to sign different documents that came in a different box. They came sealed.

Now, we're talking about all these pills that came here, and they weren't sealed, they weren't on a different invoice or anything else.

I'm just wondering, and, again, I wish I could ask the DEA this, why did it take so long to reschedule hydrocodone?

The last thing I will say is this. Mr. Smith, you were involved in the situation in West Virginia. And I'm not taking up for you guys. You guys have a responsibility, and I believe you take that responsibility very seriously. And what I said earlier, I believe. I believe that if you had it to do to over again, you'd do some things differently.

Mr. Smith, there was a doctor, a Dr. Katherine Hoover, who accounted for 69 percent of all the prescriptions that were written during that timeframe in this town in West Virginia. Do you know whatever came about with Dr. Hoover? Do you know where she is today?

Mr. SMITH. I believe they referred to her earlier, and that she's either—oh, I'm sorry.

Thanks, Steve.

I believe she was referred to earlier and that there's either been disciplinary action taken with her or she's left—

Mr. CARTER. She fled to the Bahamas. She bought an island. Twenty-one doctors, Dr. Burgess pointed out, 21 doctors in the whole Nation.

Now, when you're sending drugs to a pharmacy, and it's out of control, there's one of two things happening. Either that pharmacy is out of control and they're selling drugs out the back door, or there's a doctor who's out of control in that area.

Has the DEA ever come to you asking you about a particular doctor?

Mr. COLLIS. Not to the best of my knowledge.

Mr. CARTER. Nobody has.

Dr. MASTANDREA. We have received subpoenas regarding physicians.

Mr. CARTER. Good. Thank you. I'm glad to hear that. And I hope that we will hear that.

I'm sorry. I'm out of time. But, again, we all have responsibility in this. All of us. There is no one solution to the opioid epidemic. All of us. Pharmacists, distributors, manufacturers, physicians, all of us have a responsibility.

And I appreciate your role in that responsibility and you accepting that role in that responsibility. This is very important. You can help, and I hope that you are committed to helping. I believe that you are.

Thank you, Mr. Chairman, and I yield back.

Mr. HARPER. The gentleman yields back.

The Chair will now recognize the gentleman from Pennsylvania, Mr. Costello, for 5 minutes.

Mr. COSTELLO. Thank you, Mr. Chairman.

Mr. Barrett, the committee asked Cardinal Health how it assessed whether the 6.5 million opioid pills distributed to Family Discount Pharmacy over a 5-year period was an appropriate number to send to a town of less than 2,000 people. The company's response was that Family Discount in Mount Gay-Shamrock was a large pharmacy that served the broader Logan County, which has a population of 35,000 people.

When Cardinal investigators reviewed several high-volume purchases of controlled substances in 2008, they did not cite the county population in their investigation. They instead cited the population within a 35-mile radius of the pharmacy as 2,600 people. I know which figure looks better for the company, but why is the company now relying on the county population data when it cited a more limited area in its investigation of this pharmacy?

Mr. BARRETT. Mr. Congressman, let me start by saying, and I have mentioned earlier, if we looked at that pharmacy today and those patterns, we would have come to different conclusions. So I can only observe what I see in the documents back then.

I think the pharmacy is—its volumes are not necessarily dictated by the size of the community. It's dictated by the nature of the cus-

tomers that it serves: hospitals, clinics, surgery centers, regional centers.

So in some cases, rural centers—excuse me—rural pharmacies, which have small populations, search a large area. So I think that may have been part of the judgment.

What is important for me today is looking at it with today's eyes. And with today's eyes, I still think we would have made a different decision.

Mr. COSTELLO. Thank you.

Cardinal also told the committee that when assessing pharmacy drug orders it doesn't have the full picture of how many pills are being sent to a pharmacy or the surrounding area by other distributors. That's because the company does not have the ARCOS data collected by the DEA. But this argument that the distributor has to see the full picture to recognize issues with its own distribution is nevertheless problematic, I think.

Using ARCOS data, the committee was able to determine how many opioids Cardinal alone dispensed to pharmacies in ZIP Codes surrounding Family Discount. The company sent over 16 million hydrocodone and oxycodone pills to that West Virginia region between 2006 and 2016. Family Discount received 6.7 million of those pills and its Stollings location received another 1 million.

Mr. McKinley, I apologize if I pronounced Stollings wrong. I think I got it right, but if I did.

Cardinal could see that 46 percent of its own distribution of opiates to the region was going to two related pharmacies.

Mr. Barrett, can you really tell me that Cardinal needed to know what other companies were distributing in order to raise a red flag? I understand what you just said about hospitals in the region, but I'm trying to dig a little bit deeper here.

Mr. BARRETT. So again, I can only repeat what I've said about this. I've seen enough in reviewing this file to say that we should have seen patterns earlier. But I think the comment that was in our document is generally true about how we do assessment of pharmacies, that there are many factors that go beyond simply the size of the community.

Mr. COSTELLO. Right. But you did cut off Family Discount in 2012. Why is that?

Mr. BARRETT. Again, I think our team had enough data at that point in that moment at that time to say we are not comfortable with these levels of hydrocodone and oxycodone and at that point made a decision to cut off those pharmacies.

Mr. COSTELLO. But that data did not yield conclusions as to other pharmacies at that moment in time? Presumably not if you didn't stop.

Mr. BARRETT. I really can't answer that. I'm sorry. I just don't know the answer to that, sir.

Mr. COSTELLO. In addition to knowing what Cardinal itself distributes to a pharmacy, the company can also ask a pharmacy to produce a drug dispensing report. Is that correct?

Mr. BARRETT. I'm sorry. Could you repeat one more time

Mr. COSTELLO. In addition to knowing what Cardinal itself distributes to a pharmacy, the company can also ask a pharmacy to produce a drug dispensing report. Is that correct?



Mr. BARRETT. I think that may occur from time to time, yes.

Mr. COSTELLO. In the case of Family Discount, Cardinal asked for and received drug dispensing reports, an example of which can be found on tab 55, tab 55 in the document binder. Dispensing reports contain information about all the prescriptions and drugs a pharmacy sends out the door, not just the drugs that Cardinal supplied. Is that correct?

Mr. BARRETT. I think that's correct, sir.

Mr. COSTELLO. And for Family Discount, investigators requested drug dispensing reports multiple times as they reviewed high orders for controlled substances. Isn't that right?

Mr. BARRETT. Sir, I believe all this is in the documents. But I believe that's correct.

Mr. COSTELLO. Very good.

I will yield back the balance of my time.

Mr. HARPER. The Chair will now recognize the gentlewoman from Tennessee, Mrs. Blackburn, for 5 minutes.

Mrs. BLACKBURN. Thank you, Mr. Chairman.

Thank you all for being here today. We appreciate this.

And I think probably what you're hearing from us on each side of this dais is enough is enough. And you all have faced penalties. You have had settlements. You have had memorandums. We have covered every bit of that.

And just as we are doing more at this committee to get our arms around this issue, legislation that we are moving forward with, we expect you all to do more also.

And I have spent a lot of my time since I was in the senate in Tennessee, the Tennessee State Senate, doing roundtables, visiting treatment centers, sitting down with families, law enforcement, hearing their stories. And what we know is that the opioid crisis is different. The detox, the treatment, the recovery is different. And this is going to have to be a concerted effort to end this crisis.

And Senator Portman has CARA 2.0 in the Senate. I have it along with Congressman Ryan here in the House. It's totally bipartisan. Another billion dollars to go toward addressing this crisis. So we do expect you all to work with us on this.

And I have got kind of a different set of questions I want to run through fairly quickly, and this will be a yes or no. And I'm going to start with you, Mr. Barrett, straight down the list.

Have any of you personally met with families who have lost loved ones or survivors, individuals who are in recovery? Just yes or no right down the line.

Mr. BARRETT. Yes, ma'am.

Dr. MASTANDREA. Yes.

Mr. HAMMERGREN. Yes.

Mr. SMITH. I have not.

Mrs. BLACKBURN. You have not?

Mr. COLLIS. Yes.

Mrs. BLACKBURN. OK. So four of you have.

Now, let me ask you this. Do you have employees who are in treatment or recovery for opioid addiction, and does your insurance cover that treatment for these employees? Because what I understand is it takes about a year to a year and a half for someone to rewire their brain. Yes or no, straight down the line.

Mr. BARRETT. I believe our coverage does cover behavioral health issues.

Dr. MASTANDREA. Yes, we do have employees who have had substance abuse problems, and we do cover substance abuse treatment.

Mr. HAMMERGREN. Sadly, Congresswoman, I've had employees as well that are in treatment. And in addition to the insurance, we've also got a fund that helps them anytime it's outside of the treatment from insurance to cover those costs.

Mr. SMITH. I was generally not told about any health conditions of any employees, so I can't speak to that. But I do believe that during my tenure that would have been covered.

Mrs. BLACKBURN. Yes or no is fine.

Mr. COLLIS.

Mr. COLLIS. I'm not aware. I do not know.

Mrs. BLACKBURN. You do not know.

Well, let me ask you this. When you started distributing the opioids, were you aware of the addictive nature of this drug? Yes or no, straight down the line.

Mr. BARRETT. Our company's been distributing opioids—

Mrs. BLACKBURN. Yes or no.

Mr. BARRETT [continuing]. For as long as it's been in business. I would assume that we know that all drugs have side effects.

Mrs. BLACKBURN. OK.

Yes or no.

Dr. MASTANDREA. Yes.

Mrs. BLACKBURN. You were.

Dr. MASTANDREA. We know the requirements of the DEA schedules.

Mrs. BLACKBURN. OK.

Mr. Smith.

Mr. SMITH. We know there's a tradeoff with every drug.

Mrs. BLACKBURN. OK. All right.

Mr. COLLIS. It's done in a pure clinical decision.

Mrs. BLACKBURN. All right.

OK. We've talked a little bit about your algorithms and the way you've changed your protocols, moving to more of an evidence-based database, a platform less subjective. And we hope that that helps with the distribution.

I want to know from each of you, how many pharmacies have you removed from your distribution list?

Straight down the line. You can say—give me the number or “I don't know.” And then you'll submit it for the record.

Mr. COLLIS. We have 800.

Mrs. BLACKBURN. I'll get to you in a minute.

Mr. Barrett.

Mr. BARRETT. We have cut off or refused to do business with a thousand or more.

Mrs. BLACKBURN. A thousand.

You don't know? Please submit for the record.

Mr. HAMMERGREN. Hundreds.

Mrs. BLACKBURN. Hundreds? I'd like an exact, please.

Mr. SMITH. What time period are you asking for?

Mrs. BLACKBURN. Well, through the history of your company. How many of—

Mr. SMITH. I wouldn't be able to give an exact number, but hundreds.

Mrs. BLACKBURN. OK, find a number and let us know.

Mr. COLLIS. We have a robust list that we have 800 pharmacies.

Mrs. BLACKBURN. I would to know—800. That you've cut off or that you distribute to?

Mr. COLLIS. That we do not ship to.

Mrs. BLACKBURN. Eight hundred. OK. That is wonderful.

And how often does your algorithm flag a—and you all can submit this, because I'm out of time and there are others who want questions.

I want to know, how often does your system flag a bad pharmacy? And then what is your threshold? You have mentioned thresholds several times, but you have not given a specific as to what that threshold is that kicks a pharmacy out. And if each of you will submit that in writing, I'd appreciate it.

Thank you. I yield back.

Mr. HARPER. The Chair will now recognize the gentleman from New Jersey, Mr. Lance, for 5 minutes.

Mr. LANCE. Thank you very much, Mr. Chairman.

Dr. Mastandrea, Miami-Luken noted that in June of 2015, following a review of Westside Pharmacy's dispensing data, the company identified concerns with two of the pharmacy's top prescribing physicians of oxycodone, Dr. David Morgan and Dr. Sanjay Mehta. The company has said that you expressed your concerns to the pharmacy's owner who assured you the pharmacy would no longer fill their prescriptions effective June 30 of 2015.

However, as I understand it, in October of that year, Miami-Luken learned that Drs. Morgan and Mehta continued to be among the pharmacy's top prescribing physicians.

When Miami-Luken learned that Westside pharmacy had not been truthful by continuing to fill prescriptions written by these doctors, did you drop the pharmacy as a customer?

Dr. MASTANDREA. We probably dropped that customer within 30 days of finding out that she was not cooperating with us.

Mr. LANCE. On November 4, 2015, your director of compliance performed a site evaluation at Westside Pharmacy. You will find this evaluation in the binder at tab 33. Shouldn't your site investigators have investigated the pharmacy's falsehoods instead of ignoring them?

Dr. MASTANDREA. I'm sorry. The question was shouldn't the investigators have done what?

Mr. LANCE. Shouldn't your site investigators have investigated the pharmacy's falsehoods instead of apparently ignoring them?

Dr. MASTANDREA. I think that they should have investigated the pharmacy in totality.

Mr. LANCE. After you knew the pharmacy wasn't telling you the truth by continuing to fill prescriptions written by Drs. Morgan and Mehta, did Miami-Luken agree to increase Westside Pharmacy's oxycodone threshold in November 2015?

Dr. MASTANDREA. I am not aware of that.

Mr. LANCE. I request that you review the situation and give the committee an answer, yes or no. Not being aware of that is not sufficient, and please report back to the committee with the answer.

Dr. MASTANDREA. My counsel will do so.

Mr. LANCE. Thank you.

Given that the DEA cited Miami-Luken's relationship with Westside Pharmacy in its order to show cause, doesn't that raise a question in your mind about your company's due diligent efforts with respect to this pharmacy?

Dr. MASTANDREA. Congressman, we were in the process of vetting that particular customer at the time we received the order to show cause. We had already terminated—I believe there were 13 different customers that were on the order to show cause and we terminated, prior to receiving the order to show cause, all of them with the exception of Westside Pharmacy, which we were in the process of vetting at the time. When we found that they were on the order to show cause, enough was enough, and we terminated the relationship.

Mr. LANCE. It's my belief that the relationship was terminated at a point well beyond when it should have been terminated.

I realize that monitoring for and reporting suspicious records is often complicated. Therefore, I take this opportunity to discuss a proposal that may enable distributors and the DEA to use the data that is available to them in a more effective way. And this is for the entire panel.

Technology today that didn't exist when ARCOS was put into place is able to deliver information that would allow the DEA to stop a suspicious order before it is filled. I, along with colleagues in the Senate, I am working on a proposal that would create a new data platform for the DEA to utilize moving forward so that this situation is ameliorated to the greatest extent possible.

To the entire panel, will you commit to working with me and other Members of Congress—and this will be completely bipartisan, I assure you—to create a system that can effectively ensure that we are ready to police suspicious orders in a way that is truly effective? And as Congresswoman Blackburn suggested, going down the line.

Gentlemen.

Mr. BARRETT. I would support any technology that would help us do this job better, yes.

Dr. MASTANDREA. Yes.

Mr. HAMMERGREN. I look forward to working with you.

Mr. SMITH. I am no longer employed in the industry, but I wish you the best of luck.

Mr. LANCE. Yes, we will need more than luck.

Mr. COLLIS. Yes. Absolutely.

Mr. LANCE. Thank you.

I yield back the balance of my time, Mr. Chairman.

Mr. HARPER. The gentleman yields back.

And I would like to clarify for the record that Miami-Luken did increase the threshold, as Mr. Lance described. The Chair will now—and also would like to put into the record a letter so signifying.

Without objection.<sup>1</sup>

Mr. HARPER. Now the Chair will recognize the gentleman from West Virginia, Mr. McKinley, for 5 minutes.

Mr. MCKINLEY. Thank you, Mr. Chairman. And thank you, because I'm not a member of this committee, for the opportunity to address the panel and carry on.

I'm from West Virginia we've been hearing about all day today. The fury inside me right now is bubbling over with how we're going to address this problem. And for several of you to say you had no role whatsoever in this, I find it particularly offensive when we've had over 900 people a year dying in West Virginia because of lack of attention on your algorithm and your operation. And deflecting responsibility saying, "I just had to fill the order," no, you had a role. You had a role.

So let me just—Mr. Hammergren, if I could focus on you. You said you have notified the DEA of suspicious activity—suspicious orders. But between years 2001 and 2014, did any of those suspicious orders involve West Virginia?

Mr. HAMMERGREN. I can't be certain, Congressman. We've reported between 2000—in that period of time, around a million orders to the DEA as suspicious.

Mr. MCKINLEY. Well, I just want to, for all of you, between 2001 and 2014, none of you were complying with State law. State law says if there is a suspicious order that you file with the DEA, you're supposed to send a copy of that order to the West Virginia Board of Pharmacy, and none of you have done it between those time periods. Not only a suspicious order, but at the end of every month, you're supposed to file a report that says, during the past month, they give you 15 to the end of—after 15 days, you're supposed to file a report with the Board of West Virginia Pharmacy saying no suspicious orders took place in West Virginia.

But you didn't do it. And that was some of the heart. That was the genesis. That's when this disease really took hold in West Virginia. And you weren't complying. But yet you said the same thing. You said: We're not responsible.

I think you very much were responsible.

So, Mr. Hammergren, again, do you agree that a person like Dr. Hoover should be held accountable for her actions and perhaps pay more than a fine for her actions?

Mr. HAMMERGREN. Congressman, I don't know Dr. Hoover, and I don't know the situation of her case.

Mr. MCKINLEY. Do you just think in general doctors that spread this poison, writing 40,000, 50,000, 100,000 of prescriptions on opioids, should pay a penalty?

Mr. HAMMERGREN. Absolutely, Congressman.

Mr. MCKINLEY. OK. What about pharmacies, pharmacies that are following that order? The one that we have in particular, Sav-Rite pharmacy. Should that pharmacy, should that pharmacist be held accountable for what he's done?

Mr. HAMMERGREN. In fact, I think that pharmacy was closed, per some earlier—

<sup>1</sup>The letter appears in the document binder, which has been retained in committee files and also is available at <https://docs.house.gov/Committee/Calendar/ByEvent.aspx?EventID=108260>.

Mr. MCKINLEY. What about—no, no. It may have been closed. He may have lost his job. But what about him or her who filled the order? Should she have been held accountable?

Mr. HAMMERGREN. I don't know the specifics. I can't comment on it.

Mr. MCKINLEY. OK. I'm coming back. I'm setting this up. I want to know whether you all should be held accountable. Because if the doctors and the pharmacies are being held accountable, I sure as the dickens would think you all have a role in this thing, too.

So if I could, I want to go back again, Mr. Hammergren, to you. Let me try again with another. Do you regret any role that your company has played in this crisis?

Mr. HAMMERGREN. Congressman, I don't know how you could look at this crisis and not feel terrible about what's going on in this country. And I certainly believe in situations like the Sav-Rite pharmacy and—

Mr. MCKINLEY. So you do regret—

Mr. HAMMERGREN. I feel terrible about this—

Mr. MCKINLEY [continuing]. That what McKesson did in participating in this scourge that's ravaged this country, you regret it?

Mr. HAMMERGREN. I feel terrible about this crisis.

Mr. MCKINLEY. So what's the proper accountability? What's the punishment? It's just a slap on the wrist of maybe 100th of 1 percent of the revenue? What's the accountability, what's the punishment that fits this crime when 900 people in West Virginia lose their life or 115 people lose their lives across this country? Just a slap on the wrist? A financial penalty? Or should there be time spent for participating in this?

So I just want you to feel shame about your roles, respectively, in all of this, how we're going to get through this.

So apparently I have run out of time, but—let me just leave it at that. I am so frustrated for the people in West Virginia and across this country that you all have not played and stepped up, took more responsibility for this.

I yield back my time.

Mr. HARPER. The Chair now recognizes the gentleman from Ohio, Mr. Johnson, for 5 minutes.

Mr. JOHNSON. Thank you, Mr. Chairman.

And, gentlemen, thank you for being here today.

I have listened with interest to today's testimony and the questions that you have responded to. It's a very tough subject. Eastern and southeastern Ohio sits at the epicenter of the opioid epidemic. I hear about it every day that I'm out and about in my district.

And I don't know if you've heard this yet today, but I'm glad you folks are at the table. And part of my questioning is going to be, where do we go from here? What are the solutions to this problem that you folks have been looking at and maybe some things that you're looking at down the road?

Let me start out with Dr. Mastandrea. Do I have that pronounced right? And I apologize

Dr. MASTANDREA. Yes, sir.

Mr. JOHNSON. OK.

As I mentioned, I represent eastern and southeastern Ohio. It includes the town of Wheelersburg in Scioto County. In 2008 Scioto

County had an overdose death rate of more than 27 times the national average.

For several years, 2005 through 2011, Dr. Margy Temponeras owned and operated the Unique Pain Management Clinic there in Wheelersburg. This clinic was a pill mill. Temponeras saw more than 20 patients per day who paid cash, starting at \$200 for each appointment, and received monthly prescriptions for similar combinations of medications such as 120 to 150 pills of oxycodone and 90 pills of Xanax.

In April of 2017, Dr. Temponeras pleaded guilty in U.S. District Court to conspiracy to distribute a controlled substance, which she did through a pain clinic and dispensary.

Between November 2008 and August 2010, Miami-Luken supplied the Unique Pain Management Clinic with controlled substances, including oxycodone.

So my first question. According to the DEA, December of 2008 was the first full month that Miami-Luken began shipping to Dr. Temponeras. In that month's shipment, 97 percent of the total dosage units were controlled substances and 84 percent of the controlled substances ordered, totaling 71,100 dosage units, were oxycodone.

Do those numbers seem unusually high to you?

Dr. MASTANDREA. Congressman, I find it to be unusual that we would sell directly to a physician. I find it unusual that she would be a dispensing physician. By doing that, she bypassed all of the checks and balances that were in place.

Mr. JOHNSON. OK. But I'm not talking about what she did. I'm talking about what you guys did. Did those numbers—

Dr. MASTANDREA. That's right. And what we should not have done, we never should have supplied to a dispensing physician.

Mr. JOHNSON. All right. Given that, should those orders be investigated, do you think?

Dr. MASTANDREA. Those orders should have never been shipped.

Mr. JOHNSON. But should they be investigated?

Dr. MASTANDREA. How so?

Mr. JOHNSON. Well, I think, if my facts are correct, Miami-Luken claims to have investigated Dr. Temponeras and the clinic. You, yourself, stated that in November 2008 one of the company's salesmen conducted an inspection. However, according to the DEA, that inspection was cursory at best and it failed to take into account the area's prescription drug problem.

Then, in 2009, Miami-Luken CEO Tony Rattini and compliance manager Jim Barclay showed up to investigate on a day when the facility was closed and never returned to visit when it was open.

So I guess my question to you is, looking back in retrospect, are those instances, in your opinion, adequate due diligence? I mean, you express outrage now that it never should have happened. But was due diligence supplied, do you think, when the opportunity presented itself?

Dr. MASTANDREA. Due diligence was attempted in that particular situation.

Mr. JOHNSON. When they showed up and didn't show back up, the alarm bells didn't go off?

Dr. MASTANDREA. I said it was attempted.

Mr. JOHNSON. OK. All right.

My time has expired. But I do appreciate you folks being here. And I know that—I know there's a lot of emotion around this issue. There certainly is in my district. And I want to thank you for any work that you are doing and continue to do to help us get a handle on this, 115 people dying per day. We need your engagement at your level to get this problem resolved.

Mr. Chair, I yield back.

Mr. HARPER. The Chair now recognizes the gentleman from Florida, Mr. Bilirakis, for 5 minutes.

Mr. BILIRAKIS. Thank you, Mr. Chairman.

And I appreciate you all being here. This is something we need to focus on. It's an epidemic, and we need your engagement, as my colleagues said.

So I'm glad to hear that the drug distributors acted in recent years to reform the policies and tighten controls on the distribution of opioid pain pills. But I'm surprised to hear, why did it take so long?

And Florida was awash in pain—I represent the State of Florida, the Tampa Bay area, as you know, and the Tampa Bay area, in particular, but the whole State of Florida was awash in pain pills back in 2010. And it's taken significant efforts by law enforcement and Florida lawmakers, the local lawmakers, to battle the prescription drug epidemic in recent years.

On the part of the distributors, I'm concerned that you may not be on the same page. For instance, Mr. Barrett, Cardinal was the subject of a DEA administration action in Florida several times over the years. The DEA took enforcement action against Cardinal's Lakeland, Florida, distribution center in 2007 for failure to maintain effective controls against the diversion of hydrocodone and again for similar allegations involving oxycodone in 2012.

In court documents involving the 2012 action, the company made an interesting point. Cardinal said between 2009 and 2012 it stopped distributing controlled substances to 149 Florida pharmacies. But the company noted that 113 of those Florida pharmacies still had DEA registrations as of 2012. That means even though Cardinal had cut off pharmacies it suspected of drug diversion, other drug distributors were still doing business with them.

I understand the committee's investigation turned up numerous examples in West Virginia of one distributor dropping a pharmacy due to diversion concerns only for another distributor to immediately start doing business with the pharmacy. I mean, that's very concerning again.

So for all the witnesses, starting over here, I'd like all your companies to address two questions, please.

First, when your company is considering bringing on a new pharmacy as a customer, do you verify whether that particular pharmacy was cut off from another distributor for suspected diversion?

Please begin.

Mr. BARRETT. Congressman, I don't think we can know for sure. Actually, we don't have access to that information that another company has necessarily cut off a pharmacy. We may, but there's nothing in the mechanics of the regulatory process that makes that happen.



Mr. BILIRAKIS. All right. Next, please.

Dr. MASTANDREA. We ask them whether or not—why they are coming to us and whether or not they were with another distributor and why they left that distributor.

Mr. BILIRAKIS. And you take their word for it?

Dr. MASTANDREA. We do as much due diligence investigation as we possibly can, but it's, unfortunately, a trade.

Mr. BILIRAKIS. Next, please.

Mr. HAMMERGREN. It's difficult for us to get accurate information on that.

Mr. BILIRAKIS. Next, please.

Mr. SMITH. In my experience at H.D. Smith, that was something that we sought from the customer, an explanation, if they were leaving another wholesaler. But, no, we didn't talk to the other wholesaler about it.

Mr. BILIRAKIS. Next.

Mr. COLLIS. I agree with the previous comments. That information would be very helpful, Congressman.

Mr. BILIRAKIS. OK. Next question. And second, what safeguards do you have in place to ensure your company is not bringing on a bad actor as a customer after they were dropped by one of your competitors?

Let's start again from you.

Mr. BARRETT. So, Congressman, given the observation I made earlier, which is you don't know for certain, we try to take, in this know-your-customer program of ours, any information that will help us dictate the nature of that pharmacy, who it serves, what its customers are, and whether or not there are any red flags.

Mr. BILIRAKIS. So what safeguards do you have?

Mr. BARRETT. I'm sorry?

Mr. BILIRAKIS. What safeguards do you have in place, any particular safeguards? Name a few safeguards.

Mr. BARRETT. Well, as I mentioned today, we have either not taken on or shut off a thousand pharmacies over these last 7 or 8 years. So we literally put in place—

Mr. BILIRAKIS. What kind of process?

Mr. BARRETT. If they won't qualify, they don't get products from us.

Mr. BILIRAKIS. Do you have any kind of a process that you go through?

Mr. BARRETT. Yes, a very rigorous process, sir.

Mr. BILIRAKIS. All right. Go next, because I don't have a lot of time. Next, sir, please.

Dr. MASTANDREA. We ask for drug utilization reviews from every new customer.

Mr. BILIRAKIS. All right. Next, please.

Mr. HAMMERGREN. We certainly—first, we'll check with the regulatory agencies, the DEA and the State boards of pharmacy, make sure the licensing is all done. That would be a baseline check.

So certainly if there was a problem that was reported to the DEA and the DEA reported it to us, or a State pharmacy board, that would be the end of the decision relative to that pharmacy.

Mr. BILIRAKIS. Do you do that as well, sir?

Mr. SMITH. We had a due diligence process that included all the elements I think that you've heard from the other wholesalers.

Mr. BILIRAKIS. OK. Yes, please.

Mr. COLLIS. If we did bring on a new customer, we would have extensive monitoring requirements and look at—in our suspicious order program, we'd be looking at what is the content of the orders that we receive from that pharmacy.

Mr. BILIRAKIS. Would you also—for the first two—would you also check with the regulatory agencies as well.

Mr. BARRETT. Yes. We can't onboard a pharmacy without the proper authorization from the regulatory agencies.

Mr. BILIRAKIS. That's a common practice for you as well?

Mr. BARRETT. It's a standard practice.

Mr. BILIRAKIS. OK. Standard practice.

OK. Thank you very much. I appreciate it.

I yield back, Mr. Chairman.

Mr. HARPER. The gentleman yields back.

Certainly, I think each of you recognize and would agree that the distributors are the first line of defense against diversion of opioids.

And I know we've spent a lot of time on West Virginia. Is it been on the front line of the opioid epidemic. That's why we use apporitions of the State as a case study in this investigation. But it leads us to wonder are there other hot spots across the country that there are problems that maybe we haven't really seen enough of that information yet.

So given what you've heard today, will each of you commit to look for communities across the country where the volume of opioids that your company distributed appear far in excess of what the community can sustain?

Mr. BARRETT. Sir, we will and we do.

Dr. MASTANDREA. Absolutely.

Mr. HAMMERGREN. Absolutely.

Mr. SMITH. I'm not in a position to do that.

Mr. COLLIS. We will. And, unfortunately, you know, opioids seem to thrive in communities where there often is, you know, hardship. And so we feel particularly concerned about that.

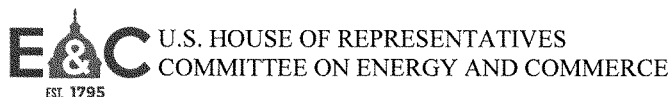
Mr. HARPER. I want to thank each of you for taking your valuable time to help us on this very important matter. I know everyone recognizes the seriousness of this. We're going to have to look at every aspect of what goes on. But we do appreciate the time.

I want to remind Members that they have 10 business days to submit questions for the record. And I ask that the witnesses agree to respond promptly to those questions.

Mr. HARPER. With that, the subcommittee is adjourned.

[Whereupon, at 12:50 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]



May 4, 2018

TO: Members, Subcommittee on Oversight and Investigations

FROM: Committee Majority Staff

RE: Hearing entitled "Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion."

The Subcommittee on Oversight and Investigations will hold a hearing on Tuesday, May 8, 2018, at 10:00 a.m. in 2123 Rayburn House Office Building. The hearing is entitled "Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion."

The purpose of this hearing is to investigate the role of wholesale drug distribution and diversion in the opioid epidemic in the U.S. Specifically, the hearing will examine whether any breakdowns occurred in the closed system for controlled substance distribution, established under the Controlled Substances Act (CSA), resulting in massive amounts of prescription opioids being shipped to small-town pharmacies in rural West Virginia while the opioid crisis continued to worsen throughout the U.S., but particularly in West Virginia.

## I. WITNESSES

- George S. Barrett, Executive Chairman of the Board, Cardinal Health, Inc.;
- Steven H. Collis, Chairman, President and Chief Executive Officer, AmerisourceBergen Corporation;
- John H. Hammergren, Chairman, President and Chief Executive Officer, McKesson Corporation;
- Dr. Joseph Mastandrea, Chairman of the Board, Miami-Luken, Inc.; and
- J. Christopher Smith, Former President and Chief Executive Officer, H.D. Smith Wholesale Drug Co.

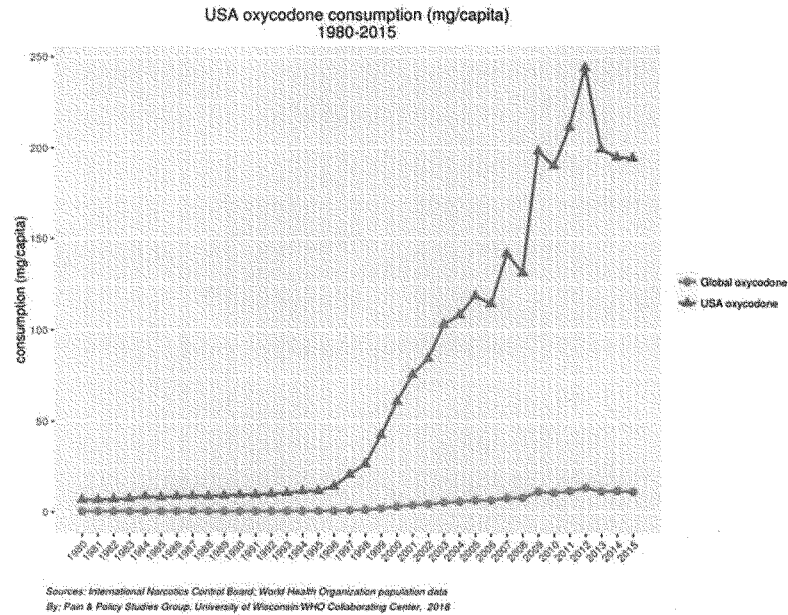
## II. BACKGROUND

Opioid prescription drugs are used for pain management. In the U.S., about 6.9 percent of all adults have used an opioid analgesic during the last 30 days.<sup>1</sup> Opioid prescribing rates

<sup>1</sup> Kristen Kenan, Karin Mack, and Leonard Paulozzi, *Trends in prescriptions for oxycodone and other commonly used opioids in the United States, 2000-2010*, 6 Open Med.e41 (2012) available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3659213/>.

Majority Memorandum for May 8, 2018, Subcommittee on Oversight and Investigations Hearing  
Page 2

peaked in 2012 with more than 255 million prescriptions written in that year. In 2016, the number decreased to slightly more than 214 million.<sup>2</sup>



The U.S. continues to experience an opioid epidemic, which has worsened over the last two decades. Opioid-involved overdose deaths are the leading cause of injury death in the U.S. and take the lives of 115 Americans per day.<sup>3</sup> According to a recent report issued by the Centers for Disease Control and Prevention (CDC), prescription or illicit opioids were involved in nearly two-thirds of all drug overdose deaths in the U.S. during 2016 – a 27.7 percent increase from 2015.<sup>4</sup> In total, more than 351,000 people have died since 1999 due to an opioid-involved

<sup>2</sup> Centers for Disease Control and Prevention, U.S. prescribing rate maps. Opioid overdose, updated July 31, 2017, available at <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html>.

<sup>3</sup> Centers for Disease Control and Prevention, Understanding the Epidemic, Opioid Overdose, Aug. 30, 2017, available at <https://www.cdc.gov/drugoverdose/epidemic/index.html>.

<sup>4</sup> Centers for Disease Control and Prevention, Vital Signs: Trends in Emergency Department Visits for Suspected Overdoses – United States, July 2016–September 2017, Mar. 9, 2018, available at <https://www.cdc.gov/mmwr/volumes/67/wr/mm6709e1.htm>.

Majority Memorandum for May 8, 2018, Subcommittee on Oversight and Investigations Hearing  
Page 3

overdose.<sup>5</sup> The crisis has become so severe that the average life expectancy declined in 2016 from the previous year, largely because of opioid overdoses.<sup>6</sup>

Beginning in April 2014, through numerous hearings, the Subcommittee on Oversight and Investigations has undertaken a comprehensive examination into the root causes of the opioid epidemic and explored possible solutions to enable greater access to effective, evidence-based treatment for substance use disorders. On May 8, 2017, the Committee launched an investigation into the distribution of prescription opioids, initially sending letters to the Drug Enforcement Administration (DEA) and the three largest wholesale drug distributors in the U.S., AmerisourceBergen, Cardinal Health, and McKesson.<sup>7</sup> The Committee has since expanded its investigation to include regional wholesale distributors, H.D. Smith Drug Co.,<sup>8</sup> and Miami-Luken, Inc.<sup>9</sup> The Committee also sent follow-up letters to the three national distributors on February 15, 2018.<sup>10</sup> The Committee sent a second letter to the DEA on October 13, 2017,<sup>11</sup> and held a hearing with the DEA's Acting Administrator Robert Patterson on March 20, 2018, which examined DEA's efforts to combat prescription drug diversion and the agency's response to the opioid epidemic.<sup>12</sup>

#### Role of the Wholesale Drug Distributors

In general, the role that wholesale drug distributors play in the pharmaceutical supply chain is to purchase pharmaceuticals from manufacturers and distribute the drugs to downstream

<sup>5</sup> Centers for Disease Control and Prevention, Data Brief 294. Drug Overdose Deaths in the United States, 1999-2016, available at [https://www.cdc.gov/nchs/data/databriefs/db294\\_table.pdf#page=4](https://www.cdc.gov/nchs/data/databriefs/db294_table.pdf#page=4).

<sup>6</sup> Catherine Roberts, *Opioid Overdoses Are Major Cause Behind Life Expectancy Decline, CDC Report Says*, Consumer Reports, Dec. 21, 2017, available at <https://www.consumerreports.org/drug-use/opioid-overdoses-life-expectancy-decline/>.

<sup>7</sup> See H. Comm. on Energy & Commerce, *Letters to Distributors and the DEA Regarding Alleged Pill Dumping in West Virginia*, May 9, 2017, available at <https://energycommerce.house.gov/news/letter/letters-distributors-and-dea-regarding-alleged-pill-dumping-west-virginia/>.

<sup>8</sup> On Nov. 21, 2017 AmerisourceBergen announced its intention to acquire H.D. Smith for \$815 million. See Press Release, AmerisourceBergen Corporation, AmerisourceBergen to Acquire HD Smith, Nov. 21, 2017, available at <https://www.amerisourcebergen.com/abcnew/newsroom/press-releases/amerisourcebergen-to-acquire-hd-smith>. AmerisourceBergen announced that it had completed its acquisition of H.D. Smith on Jan. 3, 2018. See Press Release, AmerisourceBergen Corporation, AmerisourceBergen Completes Acquisition of HD Smith, Jan. 3, 2018, available at <https://www.amerisourcebergen.com/abcnew/newsroom/press-releases/amerisourcebergen-completes-acquisition-of-hd-smith>.

<sup>9</sup> See H. Comm. on Energy & Commerce, *Letters to Regional Distributors Expanding Alleged Pill Dumping Investigation*, Jan 30, 2018, available at <https://energycommerce.house.gov/news/letter/letters-regional-distributors-expanding-alleged-pill-dumping-investigation/> and H. Comm. on Energy & Commerce, *Letter to Miami-Luken Regarding Alleged Pill Dumping in West Virginia*, Sept. 26, 2017 available at <https://energycommerce.house.gov/news/letter-miami-luken-regarding-alleged-pill-dumping-west-virginia/>.

<sup>10</sup> See H. Comm. on Energy & Commerce, *Follow-Up Letters to Distributors Regarding Ongoing Pill Dumping Investigation*, Feb. 15, 2018, available at <https://energycommerce.house.gov/news/follow-letters-distributors-regarding-ongoing-pill-dumping-investigation/>.

<sup>11</sup> Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy & Commerce, et al. to Robert W. Patterson, Acting Adm'r, U.S. Drug Enforcement Admin., Oct. 13, 2017, available at <https://energycommerce.house.gov/wp-content/uploads/2017/10/20171013DEA.pdf>.

<sup>12</sup> *The Drug Enforcement Administration's Role in Combating the Opioid Epidemic: Hearing Before the H. Comm. on Energy & Commerce, Subcomm. on Oversight and Investigations*, 115th Cong., Mar. 20, 2018.

Majority Memorandum for May 8, 2018, Subcommittee on Oversight and Investigations Hearing  
Page 4

customers, such as pharmacies, where they are dispensed to patients.<sup>13</sup> Wholesale drug distributors engaged in interstate commerce are required, pursuant to regulations issued by U.S. Food and Drug Administration (FDA) and authorized under the Prescription Drug Marketing Act of 1987,<sup>14</sup> to be licensed by a state where the distributor has a presence.<sup>15</sup> FDA's regulations also established minimum federal requirements necessary for state licensure.<sup>16</sup> In addition, Title II of the Drug Quality and Security Act, also referred to as the Drug Supply Chain Security Act, which was enacted on November 27, 2013, directed FDA to develop federal licensure standards for wholesale pharmaceutical distributors.<sup>17</sup>

It is common for wholesale drug distributors to purchase and distribute both controlled and non-controlled substances as part of their general course of business. However, distributors who engage in the purchase and distribution of controlled substances are subject to additional legal obligations under the Controlled Substances Act (CSA). Wholesale drug distributors that distribute controlled substances must be registered with the DEA<sup>18</sup> and such registrations shall be granted so long as the DEA determines they are in the public interest.<sup>19</sup> Currently, 947 entities are registered with the DEA to distribute controlled substances in the U.S.<sup>20</sup> While there are a large number of registrants, McKesson, Cardinal Health, and AmerisourceBergen are the predominant wholesale drug distributors in the U.S., accounting for approximately 85 percent to 90 percent of domestic pharmaceutical wholesaling revenue.<sup>21</sup>

The CSA was designed to combat diversion by providing for a closed system of drug distribution, in which all legitimate handlers of controlled substances must obtain a DEA registration and, as a condition of maintaining such registration, must take reasonable steps to ensure their registration is not being used as a source of diversion. Prior to the establishment of the DEA, the Bureau of Narcotics and Dangerous Drugs issued regulations in 1971 in accordance with the objectives of the CSA.<sup>22</sup> These regulations, among other things, require distributors to "design and operate a system to disclose . . . suspicious orders of controlled substances."<sup>23</sup> The regulations also require distributors to report suspicious orders of controlled substances to the DEA when they are discovered.<sup>24</sup> According to the regulations, suspicious

<sup>13</sup> 21 C.F.R. § 203.3(cc).

<sup>14</sup> Prescription Drug Marketing Act of 1987, Pub. L. No. 100-293, 102 Stat. 98 (1988).

<sup>15</sup> 21 C.F.R. § 205.4.

<sup>16</sup> 21 C.F.R. § 205.5.

<sup>17</sup> 21 U.S.C. § 360eee-2.

<sup>18</sup> 21 U.S.C. § 822.

<sup>19</sup> 21 U.S.C. § 823.

<sup>20</sup> *Registrant Population by Business Activity*, U.S. Drug Enforcement Admin., available at <https://apps.deadiversion.usdoj.gov/webforms/odrBusActReportSelect.do?jsessionid=EA9E06C5D86689DF265FE8B8CCB8C39B>, last visited May 1, 2018.

<sup>21</sup> Scott Higham and Lenny Bernstein and Scott Higham, *The Drug Industry's Triumph Over the DEA*, WASH. POST, Oct. 15, 2017, available at [https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm\\_term=.2608027cefa6](https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm_term=.2608027cefa6).

<sup>22</sup> The DEA was established within the Department of Justice by Executive Order on July 1, 1973, when various Executive Branch agencies were merged and the Attorney General was granted additional authority to coordinate federal efforts to combat illicit drug abuse. See Reorganization Plan No. 2 of 1973, 3 C.F.R. 785 (1971 – 1975 Comp.) reprinted at 21 U.S.C. § 801.

<sup>23</sup> 21 C.F.R. 1301.74(b).

<sup>24</sup> *Id.*

Majority Memorandum for May 8, 2018, Subcommittee on Oversight and Investigations Hearing  
Page 5

orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.<sup>25</sup>

In addition to the regulatory requirements incumbent upon controlled substance distributors, the distributors also have a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted to non-medical, scientific, or industrial channels.<sup>26</sup> The CSA also provides DEA with authority to deny, revoke, or suspend a distributor's registration if it determines the distributor's actions to be in violation of the mandates of the CSA or inconsistent with the public interest.<sup>27</sup> A distributor's failure to exercise adequate due diligence could provide a statutory basis for revocation or suspension of the distributor's DEA registration.<sup>28</sup>

#### Federal Efforts to Combat Illicit Prescription Drug Diversion

Over the last 13 years, the DEA has undertaken numerous efforts to educate drug distributors, pharmacies, and doctors about their roles and responsibilities to prevent drug diversion. Amid a dramatic increase in the trafficking and abuse of prescription controlled substances, the DEA identified distributors as a chokepoint in the drug supply chain that could monitor and analyze orders of controlled substances and report orders as suspicious as defined in 21 CFR 1301.74. Recognizing that wholesale distributors played a key role in the pharmaceutical supply chain, the DEA launched an industry-specific anti-diversion initiative in 2005, called the "Distributor Initiative Program." According to the DEA, the goal of the initiative is to "educate registrants on maintaining effective controls against diversion, and monitoring for and reporting suspicious orders."<sup>29</sup> DEA initially designed this program to educate drug distributors who were supplying controlled substances to rogue Internet pharmacies and, more recently, to diverting pain clinics and pharmacies. Through the program, the DEA "educates distributors about their obligations under the CSA, as well as provides registrants with current trends and 'red flags' that might indicate that an order is suspicious."<sup>30</sup> The initiative remains active and as of September 2017, the DEA has briefed at least 99 firms that hold 309 separate distributor registrations about concerns regarding illegal Internet pharmacy operations and rogue pain clinics.<sup>31</sup>

In addition to the briefings, the DEA also sent letters in 2006 and 2007 to every DEA-registered distributor to spell out their legal obligations. The initial letter, sent on September 27, 2006, emphasized that, under the CSA, distributors have a responsibility not just to report all

<sup>25</sup> *Id.*

<sup>26</sup> 21 U.S.C. § 823(b) and 21 U.S.C. § 823(e).

<sup>27</sup> 21 U.S.C. § 824.

<sup>28</sup> 21 U.S.C. § 823(b), 21 U.S.C. § 823(e), and 21 U.S.C. § 824(a).

<sup>29</sup> *Improving Predictability and Transparency in DEA and FDA Regulation: Hearing Before H. Comm on Energy & Commerce, Subcomm. on Health*, 113th Cong., 2014, Statement of Joseph T. Rannazzisi, Deputy Assistant Admin'r, Office of Diversion Control, U.S. Drug Enforcement Admin.

<sup>30</sup> *Id.*

<sup>31</sup> *DEA Trends & Updates – Connecticut/Rhode Island Pharmacy Diversion Awareness Conference*, U.S. Drug Enforcement Admin., Sept. 24-25, 2017, available at [https://www.deadiversion.usdoj.gov/mtgs/pharm\\_awareness/conf\\_2017/sept\\_2017/carrion.pdf#search=distributor%20initiative](https://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/conf_2017/sept_2017/carrion.pdf#search=distributor%20initiative).

suspicious orders to the DEA but also to exercise due diligence to avoid filling suspicious orders that might be diverted. In the letter, the DEA also provided examples of circumstances that might be indicative of controlled substance diversion and offered several suggested questions that distributors could ask pharmacy customers as they try to determine whether or not the customer is engaged in drug diversion.<sup>32</sup> These points were largely reiterated in the letter the DEA sent to distributors on February 7, 2007.<sup>33</sup>

The letter the DEA sent to distributors on, December 20, 2007, however, provided more specific guidance to wholesale distributors about their obligation to report suspicious orders under the CSA. The letter warned that it is the responsibility of the registrant to design and operate a suspicious order monitoring system and that suspicious orders must be reported to local DEA officers “when discovered by the registrant.”<sup>34</sup> Monthly reports submitted after orders were already filled and sent to customers would not meet the regulatory requirement, according to the DEA. Nor would providing daily, weekly, or monthly “excessive purchases” reports.<sup>35</sup> In the same letter, the DEA also specifically referred distributors to a July 3, 2007, final order issued by the DEA’s Deputy Administrator that revoked the DEA registration of Southwood Pharmaceuticals Inc.<sup>36</sup> The final order included discussion of distributors’ obligations to maintain effective controls against diversion and required action when distributors discover a suspicious order.

The DEA has also hosted several distributor conferences in the past, most recently in 2016, that had the purpose of providing distributors with “an overview of federal laws and regulations that affect pharmaceutical and chemical distributors, such as recordkeeping, Automation of Reports and Consolidated Orders System (ARCOS), and suspicious order reporting.”<sup>37</sup> Despite receiving significant guidance from the agency, some wholesale distributors have been subject to enforcement actions initiated by the DEA, alleging the distributors failed to adhere to their legal obligations under the CSA. Some of the enforcement actions taken against wholesale distributors, and related settlement agreements, include:

- April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order<sup>38</sup> against the AmerisourceBergen Orlando, Florida distribution center alleging

<sup>32</sup> Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, U.S. Drug Enforcement Admin. to DEA Registrants, Sept. 27, 2006, (On file with the Committee).

<sup>33</sup> Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, U.S. Drug Enforcement Admin. to DEA Registrants, Feb. 7, 2007, (On file with the Committee).

<sup>34</sup> Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, U.S. Drug Enforcement Admin. to DEA Registrants, Dec. 20, 2007, (On file with the Committee).

<sup>35</sup> *Id.*

<sup>36</sup> See 72 Fed. Reg. 36,487, July 3, 2007.

<sup>37</sup> *Distributor Conference – May 10 & 11, 2016; Indianapolis, Indiana*, U.S. Drug Enforcement Admin., [https://www.deadiversion.usdoj.gov/mtgs/distributor/conf\\_2016/index.html](https://www.deadiversion.usdoj.gov/mtgs/distributor/conf_2016/index.html).

<sup>38</sup> Immediate Suspension Orders (ISOs) and Orders to Show Cause (OTSCs) are administrative tools available to DEA to ensure compliance with the CSA, and to protect the public health and welfare. An OTSC requires a registrant to prove to the DEA Administrator why the registrant’s DEA registration should not be revoked or suspended. See 21 U.S.C. § 824(c) and 21 C.F.R. § 1301.37(b). If, however, the DEA Administrator determines that a DEA registrant’s activities constitute an imminent danger to the public health or safety, the Administrator may issue an ISO, which requires the immediate surrender of the registrant’s DEA registration, pending the final resolution of an accompanying OTSC. See 21 U.S.C. § 824(d) and 21 C.F.R. § 1301.36(e)(f).



failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement and release agreement with the DEA related to the allegations made by the agency;<sup>39</sup>

- November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center for failure to maintain effective controls against diversion of hydrocodone;<sup>40</sup>
- December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion of hydrocodone;<sup>41</sup>
- December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center for failure to maintain effective controls against diversion of hydrocodone;<sup>42</sup>
- January 30, 2008, the DEA issued an Order to Show Cause against the Cardinal Health Stafford, Texas Distribution Center for failure to maintain effective controls against diversion of hydrocodone;<sup>43</sup>
- On September 30, 2008, Cardinal Health agreed to pay a \$34 million civil penalty and entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement (MOA) with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The MOA also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia, Valencia, California, and Denver, Colorado;<sup>44</sup>
- May 2, 2008, McKesson Corporation agree to pay a \$13 million civil penalty and entered into an Administrative MOA with the DEA which provided that McKesson would “maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program;”<sup>45</sup>

<sup>39</sup> *In re AmerisourceBergen*, Settlement and Release Agreement (June 22, 2007) (On file with the Committee).

<sup>40</sup> *In re Cardinal Health*, Order to Show Cause and Immediate Suspension of Registration, Nov. 28, 2007, (On file with the Committee).

<sup>41</sup> *In re Cardinal Health*, Order to Show Cause and Immediate Suspension of Registration, Dec. 5, 2007, (On file with the Committee).

<sup>42</sup> *In re Cardinal Health*, Order to Show Cause and Immediate Suspension of Registration, Dec. 7, 2007, (On file with the Committee).

<sup>43</sup> *In re Cardinal Health*, Order to Show Cause, Jan. 30, 2008, (On file with the Committee).

<sup>44</sup> *In re Cardinal Health*, Settlement and Release Agreement, Sept. 30, 2008, (On file with the Committee).

<sup>45</sup> *In re McKesson*, Settlement and Release Agreement and Administrative Memorandum of Agreement, May 2, 2008, (On file with the Committee).

Majority Memorandum for May 8, 2018, Subcommittee on Oversight and Investigations Hearing  
Page 8

- February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion of oxycodone;<sup>46</sup>
- May 14, 2012, Cardinal Health entered into an Administrative MOA with the DEA, which, among other things, stipulated that its compliance with the terms of the 2008 MOA were inadequate in certain respects and that its Lakeland, Florida Distribution Center's DEA registration would be suspended for two years;<sup>47</sup>
- November 23, 2015, DEA Issued an Order to Show Cause against Miami-Luken for failure to maintain effective controls against the diversion of controlled substances, particularly hydrocodone and oxycodone, between 2007 and 2015. This enforcement action remains pending with DEA;<sup>48</sup>
- December 23, 2016, Cardinal Health agreed to pay a \$34 million civil penalty to the DEA to resolve allegations that it failed to report suspicious orders and meet its obligations under the CSA in Florida, Maryland, New York, and Washington;<sup>49</sup> and
- January 5, 2017, McKesson Corporation entered into an Administrative MOA with the DEA wherein it agreed to pay a \$150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora, Colorado; Aurora, Illinois; Delran, New Jersey; LaCrosse, Wisconsin; Lakeland, Florida; Landover, Maryland; La Vista, Nebraska; Livonia, Michigan; Methuen, Massachusetts; Santa Fe Springs, California; Washington Courthouse, Ohio; and West Sacramento, California.<sup>50</sup>

#### Prescription Opioid Distribution Investigation

As noted, in May 2017, the Committee opened an investigation into the distribution of prescription opioids by wholesale drug distributors, with a specific focus on unusually large opioid shipments to small pharmacies in West Virginia. Between 2007 and 2012, distributors sent more than 780 million hydrocodone and oxycodone pills to the state – or 433 doses per person. AmerisourceBergen, Cardinal Health, and McKesson delivered more than half of that amount, about 423 million pills.<sup>51</sup> In that timeframe, 1,728 West Virginians fatally overdosed on those two drugs.<sup>52</sup>

<sup>46</sup> *In re Cardinal Health*, Order to Show Cause and Immediate Suspension of Registration, Feb 2, 2012, (On file with the Committee).

<sup>47</sup> *In re Cardinal Health*, Administrative Memorandum of Agreement, May 14, 2012, (On file with the Committee).

<sup>48</sup> *In re Miami-Luken*, Order to Show Cause, Nov. 23, 2015, (On file with the Committee).

<sup>49</sup> Press Release, U.S. Dep't of Justice, United States Reaches \$34 Million Settlement With Cardinal Health For Civil Penalties Under the Controlled Substances Act, Dec. 23, 2016, *available at* <https://www.justice.gov/usao-mdfl/pr/united-states-reaches-34-million-settlement-cardinal-health-civil-penalties-under>.

<sup>50</sup> *In re McKesson*, Administrative Memorandum of Agreement, Jan. 5, 2017, (On file with the Committee).

<sup>51</sup> Eric Eyre, *Drug firms poured 780M painkillers into WV amid rise of overdoses*, Charleston Gazette-Mail, Dec. 17, 2016, *available at* [https://www.wvgazettemail.com/news/cops\\_and\\_courts/drug-firms-poured-m-painkillers-into-wv-amid-rise-of/article\\_99026dad-8ed5-5075-90fa-adb906a36214.html](https://www.wvgazettemail.com/news/cops_and_courts/drug-firms-poured-m-painkillers-into-wv-amid-rise-of/article_99026dad-8ed5-5075-90fa-adb906a36214.html).

<sup>52</sup> *Id.*

While the investigation is still ongoing, the Committee has uncovered additional information that raises questions about the adequacy of due diligence performed by wholesale drug distributors, and the companies' adherence to the CSA's requirement that they implement a suspicious order monitoring program and report any suspicious orders to DEA.<sup>53</sup> The information also raises questions about the DEA's oversight of its registrants in West Virginia as the opioid crisis continued to worsen.

Among the Committee's findings: a single pharmacy in Mount Gay-Shamrock, West Virginia—population 1,779—received more than 16.5 million hydrocodone and oxycodone pills between 2006 and 2016; distributors sent 20.8 million opioid pills to Williamson, West Virginia—population 2,900—during the same period; a pharmacy in Kermit, West Virginia—population 406—ranked 22nd in the entire country in 2006 in the overall number of hydrocodone pills it received, with a single distributor supplying 76 percent of its hydrocodone pills that year. Over a two-year period, distributors shipped approximately 9 million opioids to Kermit, West Virginia.

### III. ISSUES

The following issues may be examined at the hearing:

- The policies and procedures wholesale distributors had in place to mitigate controlled substance diversion amid the opioid epidemic and whether such policies and procedures were followed;
- The actions taken by wholesale distributors when presented with “red flags” for possible diversion; and
- The lessons wholesale distributors learned from past experiences in West Virginia that will enable them to safeguard against controlled substance diversion more effectively.

### IV. STAFF CONTACTS

If you have any questions regarding this hearing, please contact Alan Slobodin, Christopher Santini, Brittany Havens, or Andrea Noble of the Committee staff at (202) 225-2927.

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<sup>53</sup> See 21 C.F.R. § 1301.74.

### Salary of Big 3 Distributor CEOs

- John Hammergren, McKesson: \$131 million, including \$692 million in the ten years leading up to 2017
- Steve Collis, AmerisourceBergen: \$9.9 million total compensation for 2017.
- George Barrett, Cardinal: \$11 million compensation for 2017.

Steven H. Collis, Chairman, President, and CEO AmerisourceBergen Corporation

- \$9.9 million total compensation in 2017
- \$4,199,984 stock award value and \$2.8 option award value in 2017

George Barrett, Chairman of the Board, Cardinal Health Inc.

- \$11 million compensation in 2017
- \$6.33 million stock award value and \$3.166 million option award value in 2017
- Overall \$64 million in stock options value

5/8/2018

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ABC on New York Consolidated	Change (% chg)	Prev Close	Day's High	Volume	52-wk High
<b>85.16USD</b>	<b>\$0.47</b> (+0.55%)	<b>\$84.69</b>	<b>\$85.34</b>	<b>185,630</b>	<b>\$106.27</b>
8 May 2018		Open	Day's Low	Avg. Vol	52-wk Low
		<b>\$84.58</b>	<b>\$84.00</b>	<b>1,921,331</b>	<b>\$71.90</b>

**Collis, Steven**

Mr. Steven H. Collis is Chairman of the Board, President, Chief Executive Officer of the Company. He has been a member of our Board since 2011 and has served as our Board's Chairman since March 2016. From November 2010 to July 2011, Mr. Collis served as President and Chief Operating Officer of AmerisourceBergen Corporation. He served as Executive Vice President and President of AmerisourceBergen Drug Corporation from September 2008 to November 2010, as Executive Vice President and President of AmerisourceBergen Specialty Group from September 2007 to September 2009 and as Senior Vice President of AmerisourceBergen Corporation and President of AmerisourceBergen Specialty Group from August 2001 to September 2007. Mr. Collis has held a variety of other positions with AmerisourceBergen Corporation and its predecessors since 1994. Mr. Collis is a member of the Board of the International Federation of Pharmaceutical Wholesalers, Inc. and CEOs Against Cancer (PAC), and is a member of the American Red Cross Board of Governors. He previously served as a Member of the Board of Thorntec Corporation from 2008 to 2015.

**BASIC COMPENSATION**

Total Annual Compensation, USD	2,579,880
Restricted Stock Awards, USD	4,199,980
Long-Term Incentive Plans, USD	--
All Other, USD	3,127,410
Fiscal Year Total, USD	9,907,270

**OPTIONS COMPENSATION**

	Quantity	Market Value
Exercisable	332,351	4,958,760.00
Unexercisable	161,250	1,398,840.00
Exercised	180,000	8,718,860.00

**BASIC COMPENSATION**

Name	Fiscal Year Total
Steven Collis	9,907,270
Tim Guttman	3,842,990
Kathy Gaddes	--
Gina Clark	--
Dale Danilewitz	--
John Chou	3,184,360

As Of 29 Sep 2017

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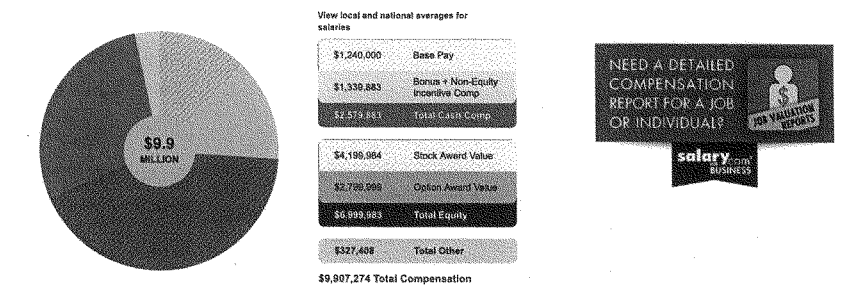
1/2

Steven H. Collis

Executive Compensation

As Chairman, President and Chief Executive Officer at AMERISOURCEBERGEN CORP, Steven H. Collis made \$9,907,274 in total compensation. Of this total \$1,240,000 was received as a salary, \$1,339,883 was received as a bonus, \$2,799,999 was received in stock options, \$4,199,984 was awarded as stock and \$327,408 came from other types of compensation. This information is according to proxy statements filed for the 2017 fiscal year.

Chairman, President and Chief Executive Officer  
AMERISOURCEBERGEN CORP



Fiscal Year Ended in 2017

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The chart on this page features a breakdown of the total annual pay for Steven H. Collis , Chairman, President and Chief Executive Officer at AMERISOURCEBERGEN CORP as reported in their proxy statements.

Total Cash Compensation information is compiled of yearly Base Pay and Bonuses. AMERISOURCEBERGEN CORP income statements for executive base pay and bonus are filed yearly with the SEC in the edgar filing system. AMERISOURCEBERGEN CORP annual reports of executive compensation and pay are most commonly found in the Def 14a documents.

Total Equity aggregates grant date fair value of stock and option awards and long term incentives granted during the fiscal year.

Other Compensation covers all compensation-like awards that don't fit in any of these other standard categories. Numbers reported do not include change in pension value and non-qualified deferred compensation earnings.

Other Executives at this Company			
John G. Chou	James D. Frary	Peyton R. Howell	Tim G. Guttman
Robert P. Mauch			

Steven H. Collis			
Enterprise   Small Business   Personal	Bonus + Incentive Comp	Total Cash Compensation	
Base Pay	\$1,339,883	\$2,579,883	
\$1,240,000			
	Job title or Keyword	Location	
Stock Award Value	Op		
\$4,199,984	\$2,799,999	\$6,999,983	
		Total Other	
		\$327,408	
		Total Compensation	
		\$9,907,274	

Browse Executives by First Name  
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5/8/2018

George S. Barrett: Executive Profile &amp; Biography - Bloomberg

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**Cardinal Health Inc (CAH:New York)**

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**Executive Profile\*****George S. Barrett**

Executive Chairman, Cardinal Health, Inc.

Age **62** Total Calculated Compensation **\$10,985,177** This person is connected to **82** board members in **5** different organizations across **9** different industries.

As of Fiscal Year 2017 See Board Relationships

**Background\***

Mr. George S. Barrett has been the Executive Chairman of Cardinal Health, Inc. since January 1, 2018. Mr. Barrett served as the Chairman and Chief Executive Officer of Cardinal Health, Inc., the holding company of Cardinal Health 414, LLC from August 31, 2009 to January 1, 2018. Mr. Barrett served as the Vice Chairman and Chief Executive Officer of Healthcare Supply Chain Services at Cardinal Health Inc. from January 2008 to September 2009. He served as the President ...

[Read Full Background](#)**Corporate Headquarters\***

7000 Cardinal Place  
Dublin, Ohio 43017

United States

Phone: 614-757-5000

Fax: --

**Board Members Memberships\***

**Chairman of Cardinal Health Inc and Chief Executive Officer of Cardinal Health Inc**  
Cardinal Health 414, LLC

**Trustee**

The Conference Board, Inc.

**Director**

Nationwide Children's Hospital, Inc.

2009-Present

**Executive Chairman**  
Cardinal Health, Inc.

**Education\*****Bachelor's Degree** 1977**Annual Compensation\***

Salary	\$1,320,000
<b>Total Annual Compensation</b>	<b>\$1,320,000</b>

**Stock Options\***

Restricted Stock Awards	\$5,333,255
All Other Compensation	\$165,488
Exercised Options	685,989
Exercised Options Value	\$32,061,337
Exercisable Options	1,123,387
Exercisable Options Value	\$32,113,610
Unexercisable Options	386,518
Unexercisable Options Value	\$458,674
Total Value of Options	\$64,633,621
<b>Total Number of Options</b>	<b>2,195,894</b>

**Total Compensation\***

Total Annual Cash Compensation	\$1,485,488
Total Short Term Compensation	\$1,320,000
Other Long Term Compensation	\$6,498,743
<b>Total Calculated Compensation</b>	<b>\$10,985,177</b>

<https://www.bloomberg.com/research/stocks/people/person.asp?personId=4950498&privcapId=172207>

1/2



5/8/2018

Compensation Information for George S. Barrett , Chairman and Chief Executive Officer of CARDINAL HEALTH INC | Salary.com

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Job title or Keyword

Location

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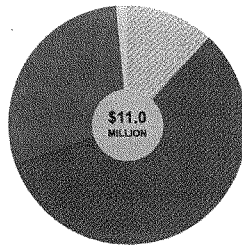
Education

Advice

**George S. Barrett****Executive Compensation**

As Chairman and Chief Executive Officer at CARDINAL HEALTH INC, George S. Barrett made \$10,985,177 in total compensation. Of this total \$1,320,000 was received as a salary, \$0 was received as a bonus, \$3,166,434 was received in stock options, \$6,333,255 was awarded as stock and \$165,488 came from other types of compensation. This information is according to proxy statements filed for the 2017 fiscal year.

Chairman and Chief Executive Officer  
CARDINAL HEALTH INC



View local and national averages for salaries

\$1,320,000	Base Pay
\$0	Bonus + Non-Equity Incentive Comp
\$1,320,000	Total Cash Comp
\$6,333,255	Stock Award Value
\$3,166,434	Option Award Value
\$9,499,689	Total Equity
\$165,488	Total Other

**\$10,985,177 Total Compensation**

Fiscal Year Ended in 2017

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The chart on this page features a breakdown of the total annual pay for George S. Barrett , Chairman and Chief Executive Officer at CARDINAL HEALTH INC as reported in their proxy statements.

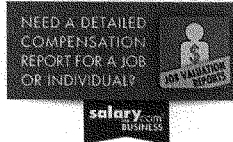
**Total Cash Compensation** information is comprised of yearly Base Pay and Bonuses. CARDINAL HEALTH INC income statements for executive base pay and bonus are filed yearly with the SEC in the Edgar filing system. CARDINAL HEALTH INC annual reports of executive compensation and pay are most commonly found in the Def 14a documents.

**Total Equity** aggregates grant date fair value of stock and option awards and long term incentives granted during the fiscal year.

**Other Compensation** covers all compensation-like awards that don't fit in any of these other standard categories. Numbers reported do not include change in pension value and non-qualified deferred compensation earnings.

Other Executives at this Company			
Craig S. Morford	Michael C. Kaufmann	Donald M. Casey Jr.	Jon L. Giacomini

George S. Barrett		
Base Pay \$1,320,000	Bonus + Incentive Comp \$0	Total Cash Compensation \$1,320,000
Stock Award Value \$6,333,255	Option Award Value \$3,166,434	Total Equity \$9,499,689
		Total Other \$165,488
		Total Compensation \$10,985,177



https://www1.salary.com/George-S-Barrett-Salary-Bonus-Stock-Options-for-CARDINAL-HEALTH-INC.html

1/2

5/8/2018

CEO's pay is under fire amid opioid epidemic

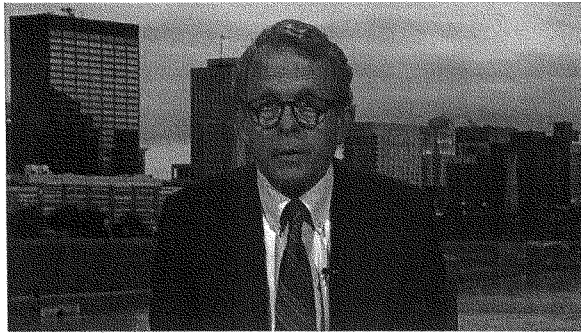
2017-07-25

# CEO's pay is under fire amid opioid epidemic

by Julia Horowitz @juliahorowitz

July 25, 2017: 9:03 PM ET

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Allegations against Junot Díaz lead world asking questions

McKesson CEO John Hammergren has earned \$692 million in the past 10 years. The Teamsters think that's too much.

On Wednesday, the union plans to protest Hammergren's compensation at the drug distributor's annual shareholder meeting. They argue that McKesson, as a distributor of oxycodone and hydrocodone pills, has played a role in the U.S. opioid epidemic.

"For years, McKesson allowed opioids to flood into our communities, and despite the irreparable harm and growing reputational and financial risks, the company has continued to reward [Hammergren] with ballooning bonuses and some of the most lucrative pay packages in the country," Teamsters General Secretary-Treasurer Ken Hall said in a statement.

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The union, which holds more than \$30 million worth of McKesson shares, has also filed a shareholder proposal to install an independent board chairman who hasn't previously served as a top executive.

Hammergren, who has been CEO of McKesson since 2001, has served as chairman of the firm since 2002 as well.

"We can't afford another decade of business as usual at McKesson," Hall said.

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<http://money.cnn.com/2017/07/25/investing/mckesson-opioid-shareholder-meeting/index.html>

1/5

5/8/2018

CEO's pay is under fire amid opioid epidemic

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the nation's opioid epidemic."

In January, McKesson agreed to pay a \$150 million settlement and suspend sales of controlled substances from distribution centers in Colorado, Ohio, Michigan and Florida, according to Justice Department documents. The government said it concluded that the company had not properly identified pharmacy orders that should have been scrutinized due to their frequency and size. In 2008, McKesson was fined \$13.25 million for a similar problem, the department said.

Many Teamsters also come from areas afflicted by the opioid epidemic -- and for them, the subject of addiction hits home.

At the 2016 Teamsters International convention Travis Bornstein, president of the Local 24 group in Akron, Ohio, spoke about his son Tyler, who died of a heroin overdose in 2014 at age 23.

The Teamsters raised more than \$1.4 million to fight addiction after he spoke, according to a union statement about the event.

Hammergren's 10-year payout of \$692 million includes his salary and bonus, as well as the value of his vested shares and the money he made when he exercised his options, according to executive compensation data firm Equilar.

Much of that value comes from the dramatic rise in the company's stock price. The value of shares has nearly tripled since mid-2007, Equilar said.

McKesson says its board has appointed an independent committee to review the company's distribution of controlled substances, and that the company has invested millions of dollars to revamp its system for monitoring the distribution of controlled substances.

The Teamsters' efforts "do little to address the root causes of the opioid epidemic," the company

**CNN Money** Companies Markets Tech Media

For its part, McKesson is asking shareholders to approve Hammergren's compensation and oppose the Teamster's chairman proposal, and says it's working hard to address the opioid crisis.

"We take our responsibility to help manage the safety and integrity of the pharmaceutical supply chain extremely seriously and are committed to maintaining -- and continuously improving -- strong programs designed to detect and prevent opioid diversion," the company said in a statement to CNNMoney.

### Related: The opioid epidemic is draining America of workers

The state treasurers of West Virginia, Illinois and Pennsylvania backed the idea of an independent board chairman in a letter sent to McKesson on Monday. They also said McKesson should include a "metric for senior executive compensation related to progress towards the fight against the opioid epidemic."

McKesson shareholders, including the Teamsters, worry about the company's financial exposure.

In its petition, the union cites the "potential reputational, legal and regulatory risks McKesson faces over its role in

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WASHINGTON, DC 20515-6115  
Majority (201) 225-2927  
Minority (202) 225-3641

May 31, 2018

Dr. Joseph Mastandrea  
Chairman of the Board  
Miami-Luken, Inc.  
265 South Pioneer Boulevard  
Springboro, OH 45066

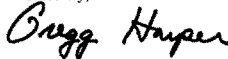
Dear Dr. Mastandrea:

Thank you for appearing before the Subcommittee on Oversight and Investigations on May 8, 2018, to testify at the hearing entitled "Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Thursday, June 14, 2018. Your responses should be mailed to Ali Fulling, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to [Ali.Fulling@mail.house.gov](mailto:Ali.Fulling@mail.house.gov).

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



Gregg Harper  
Chairman  
Subcommittee on Oversight and Investigations

cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachment



Direct Dial: 216.348.5839  
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600 Superior Avenue, East  
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Cleveland, OH 44114  
P 1.216.348.5400  
F 1.216.348.5474

June 19, 2018

(Sent via Regular and Electronic Mail)  
Ali Fulling  
Legislative Clerk  
Committee on Energy and Commerce  
2125 Rayburn House Office Building  
Washington, DC 20515-6115  
[Ali.Fulling@mail.house.gov](mailto:Ali.Fulling@mail.house.gov)

**Re: Dr. Joseph Mastandrea – Miami-Luken, Inc.**

Dear Ms. Fulling:

Please accept these responses pursuant to Congressman Harper's letter dated May 31, 2018. Should you have additional questions, please direct them to my attention.

**The Honorable Gregg Harper**

1. Does your company request dispensing data from both prospective and existing pharmacy customers as part of its due diligence efforts to mitigate controlled substance diversion? If so, at what frequency does your company request this information and how is the dispensing data utilized? If no, why not?

**Response: Miami-Luken no longer sells any controlled substances to retail customers.**

2. In its contracts with pharmacy customers, is your company able to require that a pharmacy produce dispensing data upon request? If so, does your company include such a requirement in the contracts it enters into with its pharmacy customers? If your company doesn't include such a requirement in its contracts, why not?

**Response: Miami-Luken no longer sells any controlled substances to retail customers.**

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{7492688: }

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3. As part of your company's due diligence efforts related to prospective and existing customers, does your company review and maintain a list of the number of pharmacies that are located in the prospective/existing customer's service region? If so, how long has that been your company's practice and how does your company determine what a pharmacy's potential service region is?

**Response: Miami-Luken no longer sells any controlled substances to retail customers.**

4. Does your company request dispensing data from both prospective and existing pharmacy customers as part of its due diligence efforts to mitigate controlled substance diversion? If so, at what frequency does your company request this information and how is the dispensing data utilized? If no, why not?

**Response: Miami-Luken no longer sells any controlled substances to retail customers.**

5. In its contracts with pharmacy customers, is your company able to require that a pharmacy produce dispensing data upon request? If so, does your company include such a requirement in the contracts it enters into with its pharmacy customers? If your company doesn't include such a requirement in its contracts, why not?

**Response: Miami-Luken no longer sells any controlled substances to retail customers.**

6. As part of your company's due diligence efforts related to prospective and existing customers, does your company review and maintain a list of the number of pharmacies that are located in the prospective/existing customer's service region? If so, how long has that been your company's practice and how does your company determine what a pharmacy's potential service region is?

**Response: Miami-Luken no longer sells any controlled substances to retail customers.**

#### **The Honorable Michael C. Burgess**

1. While your companies seem to have put forth effort to improve your system of flagging possible drug diversion, there remains work to be done. In February, the Drug Enforcement Administration announced that it would begin sharing select data it collects on controlled substance prescriptions with drug distributors. Have your companies been able to access that data, and if so, has it been useful?

**Response: We have not been provided access to any data from the DEA.**

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2. What is the largest hurdle you face as your companies scale up your diversion prevention on activities? Is data-sharing, or lack thereof, the primary challenge?

**Response: Miami-Luken no longer sells any controlled substances to retail customers.**

3. Throughout each of your written testimonies, you mentioned your efforts to report suspicious orders to the DEA, and in cases that exceed the volume threshold, you stop the orders entirely. Where is the line drawn between drug manufacturers and the DEA in responding to suspicious orders? Does the DEA take enforcement action after you report the suspicious order?

**Response: The DEA does not share its enforcement actions with us and therefore we are not privy to this information.**

4. Distributors and other pieces of the drug supply chain have a responsibility to help prevent diversion. What can Congress do legislatively to strengthen oversight of that supply chain?

**Response: Federal and state agencies need to work better with industry. We also need laws that are consistent from state to state and uniform enforcement of those laws. There also needs to be sharing of data in all states across the full supply chain.**

**The Honorable David B. McKinley**

1. As a Wholesale Distributor of prescription opiates, do you agree that you owe a duty under federal law to monitor, detect, investigate, refuse and report suspicious orders? 21 U.S.C. § 823, 21 CFR 1301.74

**Response: Yes.**

2. Do you agree that the foreseeable harm of a breach of this duty is the diversion of prescription opiates for nonmedical purposes?

**Response: Not necessarily.**

3. In other words, if you ship a suspicious order, it is likely that prescription opiates will be diverted into the illicit market. Agree?

**Response: Not necessarily.**

4. Do you concur that filling suspicious orders is a direct and proximate cause of prescription opiate abuse, addiction, morbidity and mortality?

**Response: Not necessarily.**

5. Do you agree the United States is in the midst of a prescription opiate epidemic?

**Response: Yes.**

6. Do you concur that filling suspicious orders is a direct and proximate cause of the prescription opiate epidemic plaguing our country?

**Response: It is a contributing factor.**

7. Do you believe the prescription opiate epidemic is an immediate hazard to public health and safety?

**Response: Yes.**

8. Do you believe the prescription opiate epidemic is a public nuisance?

**Response: Yes.**

9. Are you aware of your company's efforts to detect, address, and report suspiciously large orders in West Virginia?

**Response: Miami-Luken no longer sells any controlled substances to retail customers.**

10. Are you aware that for years your company never followed West Virginia's law by reporting all suspicious orders to the West Virginia Board of Pharmacy?

**Response: No, we are unaware of this.**

11. Did your company have a policy that orders had to be less than 50% controlled substances to be filled?

**Response: No, such a policy did not exist.**



**The Honorable Frank Pallone, Jr.**

1. The Committee asked Miami-Luken for copies of all suspicious order reports that MiamiLuken submitted to DEA since 2008. According to what your company provided, it does not appear that Miami-Luken submitted any suspicious order reports to DEA earlier than 2015. Miami-Luken also provided the Committee with its due diligence files for several pharmacies. These files show that Miami-Luken supplied the Sav-Rite pharmacy in Kermit, WV, population 400, with over 5.7 million opioids between 2005 and 2011. Why did Miami-Luken not submit any suspicious order reports for any of its sales to SavRite?

**Response:** As Miami-Luken has previously informed the DEA and this Subcommittee, the company's prior management did not maintain an effective suspicious order monitoring system at that time. Although prior management did take steps to address suspicious orders and were instructed by the Board to do so, its efforts were not effective.

2. You told the Committee that you wished Miami-Luken had had a suspicious order monitoring system in place sooner, and that your failure to do so resulted in high distribution to at least one pharmacy. However, DEA sent letters to all distributors in 2006 and 2007 reminding them that federal regulations expressly require distributors to identify and report suspicious orders of controlled substances, and laying out examples about how to do so. After receiving letters from the DEA advising you to report suspicious orders, why did your company not have a robust program in place to make this happen, especially when it was well known that the opioid crisis was growing?

**Response:** As Miami-Luken has previously informed the DEA and this Subcommittee, the company's prior management did not maintain an effective suspicious order monitoring system at that time. Although prior management did take steps to address suspicious orders and were instructed by the Board to do so, its efforts were not effective.

**The Honorable Jan Schakowsky**

1. Does your company buy the drugs from the manufacturers, take title and move pallets to and from your warehouse? Or are you like brokers, working on consignment, arranging sales to pharmacies and then taking a percentage of the sale price?

**Response:** Miami-Luken purchases product from manufacturers and such product is moved to and from its warehouse.

2. In setting prices to pharmacies, is your markup more like a flat rate (for example, selling \$5 more than the price at which you bought), or is your markup more like a percentage (for example, selling for 5% higher than the price at which you bought)?

**Response: Branded products are generally sold at a discounted percentage to Wholesale Acquisition Cost, while generics are priced to market.**

3. Is it possible that even if your company pays a higher price to get those drugs in stock, you end up making more money on those sales where your acquisition prices are higher? And would the same be true for your consignment/broker sales?

**Response: No. Miami-Luken is a market price taker, not a market price setter.**

Thank you again.

Very truly yours,

A black rectangular box redacting the signature of Richard H. Blake.

Richard H. Blake

GREG WALDEN, OREGON  
CHAIRMAN

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RANKING MEMBER

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May 31, 2018

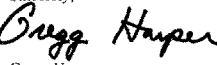
Mr. John H. Hammergren  
Chairman, President, and CEO  
McKesson Corporation  
One Post Street  
San Francisco, CA, 94104

Dear Mr. Hammergren:

Thank you for appearing before the Subcommittee on Oversight and Investigations on May 8, 2018, to testify at the hearing entitled "Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Thursday, June 14, 2018. Your responses should be mailed to Ali Fulling, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to [Ali.Fulling@mail.house.gov](mailto:Ali.Fulling@mail.house.gov).

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,  
  
Gregg Harper  
Chairman  
Subcommittee on Oversight and Investigations

cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachment

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June 14, 2018

The Honorable Gregg Harper  
Chairman  
Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations  
U.S. House of Representatives  
2125 Rayburn House Office Building  
Washington, D.C. 20515-6115

The Honorable Diana DeGette  
Ranking Member  
Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations  
U.S. House of Representatives  
2125 Rayburn House Office Building  
Washington, D.C. 20515-6115

### Re: McKesson Corporation

Dear Chairman Harper and Representative DeGette:

On behalf of the McKesson Corporation,<sup>1</sup> please find below responses to the Committee's May 31, 2018 questions for the record related to the Committee's May 8, 2018 hearing regarding opioid distribution.

### The Honorable Gregg Harper

1. Does your company request dispensing data from both prospective and existing pharmacy customers as part of its due diligence efforts to mitigate controlled substance diversion? If so, at what frequency does your company request this information and how is the dispensing data utilized? If no, why not?

---

<sup>1</sup> McKesson U.S. Pharmaceutical is the business unit of McKesson Corporation that is relevant to the requests contained in the Committee's letter. Accordingly, the responses contained in this letter are based on information provided by McKesson U.S. Pharmaceutical. Throughout the letter, McKesson U.S. Pharmaceutical is referred to as "McKesson" or the "Company."

**COVINGTON**

The Honorable Gregg Harper  
 The Honorable Diana DeGette  
 June 14, 2018  
 Page 2

McKesson requests dispensing data from both prospective and existing pharmacy customers, and this information is an integral part of the company's due diligence efforts to mitigate controlled substance diversion. The company normally reviews a prospective customer's dispensing data as part of its due diligence before bringing on the new customer. The company requests and analyzes dispensing data from current customers when the customer requests to modify its controlled substance ordering thresholds. The company may also request dispensing data when it conducts a proactive or reactive review of an existing customer. This information allows McKesson to, for example, compare a customer's dispensing levels against its purchasing data, or to better understand a customer's business model.

- 2. In its contracts with pharmacy customers, is your company able to require that a pharmacy produce dispensing data upon request? If so, does your company include such a requirement in the contracts it enters into with its pharmacy customers? If your company doesn't include such a requirement in its contracts, why not?**

As noted above, McKesson requires dispensing data of new customers as part of the onboarding process, and from current customers as part of various due diligence reviews. If a current customer refuses to provide dispensing data upon request, McKesson will generally not continue to supply the customer with controlled substances. If a prospective customer with a history of dispensing controlled substances refuses to provide dispensing data upon request, McKesson will generally not onboard the prospective customer until the data has been provided. McKesson's standard contract with independent and small- and medium-chain pharmacy customers reserves McKesson's right to terminate the relationship if the customer puts McKesson at risk of noncompliance with any law, regulation, or requirement involving controlled substances. McKesson can exercise that right when a customer refuses to provide dispensing data upon request. McKesson also may require those pharmacy customers to consent to sharing dispensing data in order to receive certain rebates based on purchasing.

- 3. As part of your company's due diligence efforts related to prospective and existing customers, does your company review and maintain a list of the number of pharmacies that are located in the prospective/existing customer's service region? If so, how long has that been your company's practice and how does your company determine what a pharmacy's potential service region is?**

McKesson has a tool that allows it to review a list of its current customers in the same city, state, zip code, or geographic radius as another of its customers. This tool also allows McKesson to compare available purchasing data for those customers. McKesson's onboarding process also asks prospective customers to define their service area. All of this information is available to McKesson when it conducts a review of a current or prospective customer. McKesson does not, however, assign its customers a set "service area." The retail pharmacy market is highly dynamic, with pharmacies opening, closing, and/or changing business models regularly. As a result, the "service region" of a pharmacy is an imprecise measurement that can expand and contract due to market factors. Additionally, a pharmacy's service area can be quite different than that of a neighboring pharmacy.

**COVINGTON**

The Honorable Gregg Harper  
 The Honorable Diana DeGette  
 June 14, 2018  
 Page 3

- 4. Does your company request dispensing data from both prospective and existing pharmacy customers as part of its due diligence efforts to mitigate controlled substance diversion? If so, at what frequency does your company request this information and how is the dispensing data utilized? If no, why not?**

This question is a duplicate of Rep. Harper's Question #1.

- 5. In its contracts with pharmacy customers, is your company able to require that a pharmacy produce dispensing data upon request? If so, does your company include such a requirement in the contracts it enters into with its pharmacy customers? If your company doesn't include such a requirement in its contracts, why not?**

This question is a duplicate of Rep. Harper's Question #2.

- 6. As part of your company's due diligence efforts related to prospective and existing customers, does your company review and maintain a list of the number of pharmacies that are located in the prospective/existing customer's service region? If so, how long has that been your company's practice and how does your company determine what a pharmacy's potential service region is?**

This question is a duplicate of Rep. Harper's Question #3.

**The Honorable Michael C. Burgess**

- 1. While your companies seem to have put forth effort to improve your system of flagging possible drug diversion, there remains work to be done. In February, the Drug Enforcement Administration announced that it would begin sharing select data it collects on controlled substance prescriptions with drug distributors. Have your companies been able to access that data, and if so, has it been useful?**

This question appears to reference the Drug Enforcement Administration's ("DEA's") move to share a limited amount of its ARCOS database information via the Buyer Statistics Lookup tool on the DEA website. McKesson has been able to access that data. McKesson believes that this tool represents a start towards better data-sharing, but that including additional information would enhance the usefulness of the tool.

The current tool allows McKesson to search for a DEA registrant to see whether the registrant has purchased certain broad "base codes" of controlled substances and, if so, how many distributors sold those base codes to the registrant within a limited timeframe. The tool does not allow McKesson to see the quantity of product purchased in that base code, nor does it identify the specific product purchased or the strength of the product purchased. The information also covers only a recent six-month period and has about a one-month lag period.

**COVINGTON**

The Honorable Gregg Harper  
 The Honorable Diana DeGette  
 June 14, 2018  
 Page 4

The usefulness of the data is also limited by what is contained in the ARCOS database and when data is reported to the DEA. ARCOS does not, as stated in the question, include data on "controlled substance prescriptions." It includes information on the sale and redistribution of select controlled substances. Whether and how the substances are eventually prescribed to consumers, and whether those prescriptions are filled, is not information contained in the ARCOS system. ARCOS also does not include information on every opioid product.

**2. What is the largest hurdle you face as your companies scale up your diversion prevention activities? Is data-sharing, or lack thereof, the primary challenge?**

Data-sharing is certainly one of the major challenges to anti-diversion efforts, but it also represents an opportunity. Anti-diversion efforts of Controlled Substance Act registrants all along the supply chain, from manufacturers to distributors, providers, and pharmacists, would benefit from increased data sharing among one another and with the DEA. Programs such as a prescription safety alert system could provide information about a patient's nationwide prescribing history to identify abuse or misuse. As described above, more complete access to the DEA's ARCOS data could also be a valuable anti-diversion tool. Clearer definition of the roles, responsibilities, and expectations of each registrant could also generate better results.

**3. Throughout each of your written testimonies, you mentioned your efforts to report suspicious orders to the DEA, and in cases that exceed the volume threshold, you stop the orders entirely. Where is the line drawn between drug manufacturers and the DEA in responding to suspicious orders? Does the DEA take enforcement action after you report the suspicious order?**

Each registrant under the Controlled Substances Act has a role to play in preventing diversion, as does the DEA. McKesson's Controlled Substance Monitoring Program ("CSMP") can help to identify potentially suspicious orders. However, McKesson does not have full visibility into the actions of prescribers, pharmacies, patients, or the other distributors. DEA has the most complete information, and only DEA has the ability to conduct law enforcement investigations of reported suspicious ordering activity. McKesson supports the DEA in those efforts when asked. McKesson respectfully defers to the DEA on what the DEA does with the suspicious order information the company reports.<sup>2</sup>

**4. Distributors and other pieces of the drug supply chain have a responsibility to help prevent diversion. What can Congress do legislatively to strengthen oversight of that supply chain?**

McKesson has released a comprehensive set of proposals that it believes would help address the opioid crisis. These are available at <http://www.mckesson.com/about-mckesson/fighting-opioid-abuse/opioid-policy-recommendations/>. Enclosed with this letter

<sup>2</sup> McKesson assumes for purposes of this response that the question was intended to read, "Where is the line drawn between drug *distributors* and the DEA in responding to suspicious orders?"

**COVINGTON**

The Honorable Gregg Harper  
 The Honorable Diana DeGette  
 June 14, 2018  
 Page 5

are copies of McKesson's 2017 white paper, *Combating the Opioid Abuse Epidemic: A Shared Responsibility that Requires Innovative Solutions*, and McKesson's 2018 white paper, *Call to Action: Execute Solutions Today to Combat the Opioid Crisis*.

**The Honorable David B. McKinley**

- 1. As a Wholesale Distributor of prescription opiates, do you agree that you owe a duty under federal law to monitor, detect, investigate, refuse and report suspicious orders? 21 U.S.C. § 823, 21 CFR 1301.74**

DEA regulations require registrants to identify and report suspicious orders when discovered. McKesson complies with this regulation using complex data analytics to set and manage customer thresholds for controlled substances. McKesson's model analyzes each customer order against its applicable threshold to determine whether the order should be filled. If a customer's order exceeds the applicable monthly threshold, that order is blocked and not filled. McKesson reports all such orders to DEA pursuant to 21 C.F.R. § 1301.74.

- 2. Do you agree that the foreseeable harm of a breach of this duty is the diversion of prescription opiates for nonmedical purposes?**

No. McKesson only ships controlled substances to pharmacies that are registered with the DEA and licensed by their respective state to receive such products. As a distributor, McKesson does not have visibility into or control over the doctor-patient or pharmacist-patient relationships and is not involved in the healthcare decisions made for a particular patient, the decision by a prescriber to write a prescription for a particular controlled substance, the decision by a pharmacist to fill a prescription for a controlled substance, or the decision by a patient to use, misuse, or divert a prescription medication. Moreover, McKesson has no visibility into the medical needs of the patient who is prescribed an opioid product.

- 3. In other words, if you ship a suspicious order, it is likely that prescription opiates will be diverted into the illicit market. Agree?**

No. As noted above, McKesson only ships controlled substances to pharmacies that are registered with the DEA and licensed by their respective state to receive such products. As a distributor, McKesson does not have visibility into or control over the doctor-patient or pharmacist-patient relationships and is not involved in the healthcare decisions made for a particular patient, the decision by a prescriber to write a prescription for a particular controlled substance, the decision by a pharmacist to fill a prescription for a controlled substance, or the decision by a patient to use, misuse, or divert a prescription medication. Moreover, McKesson has no visibility into the medical needs of the patient who is prescribed an opioid product.

- 4. Do you concur that filling suspicious orders is a direct and proximate cause of prescription opiate abuse, addiction, morbidity and mortality?**

No. As stated previously, McKesson supplies controlled substances only to those pharmacies that are registered with DEA and licensed by their respective states. As a



**COVINGTON**

The Honorable Gregg Harper  
 The Honorable Diana DeGette  
 June 14, 2018  
 Page 6

distributor, McKesson does not have visibility into or control over the doctor-patient or pharmacist-patient relationships and is not involved in the healthcare decisions made for a particular patient, the decision by a prescriber to write a prescription for a particular controlled substance, the decision by a pharmacist to fill a prescription for a controlled substance, or the decision by a patient to use, misuse, or divert a prescription medication. Moreover, McKesson has no visibility into the medical needs of the patient who is prescribed an opioid product.

**5. Do you agree the United States is in the midst of a prescription opiate epidemic?**

McKesson agrees and believes that many players in the pharmaceutical supply chain, medical community, and government will be needed to help bring an end to prescription drug abuse. To that end, beyond its various CSMP activities and anti-diversion efforts, McKesson has published multiple white papers containing proposals aimed at combatting drug diversion. In addition, McKesson has established and committed \$100 million to a new non-profit foundation dedicated to combatting the opioid crisis.

**6. Do you concur that filling suspicious orders is a direct and proximate cause of the prescription opiate epidemic plaguing our country?**

No. As stated previously, McKesson supplies controlled substances only to those pharmacies that are registered with DEA and licensed by their respective states. As a distributor, McKesson does not have visibility into or control over the doctor-patient or pharmacist-patient relationships and is not involved in the healthcare decisions made for a particular patient, the decision by a prescriber to write a prescription for a particular controlled substance, the decision by a pharmacist to fill a prescription for a controlled substance, or the decision by a patient to use, misuse, or divert a prescription medication. Moreover, McKesson has no visibility into the medical needs of the patient who is prescribed an opioid product.

**7. Do you believe the prescription opiate epidemic is an immediate hazard to public health and safety?**

The country is in the midst of a serious opioid abuse problem. It is a multi-faceted problem that must be addressed through a comprehensive approach. McKesson has published a range of public policy recommendations aimed at combatting the opioid abuse problem.

**8. Do you believe the prescription opiate epidemic is a public nuisance?**

The opioid epidemic is a terrible problem faced by many families and communities in this country. McKesson is committed to working with Congress and other stakeholders to find effective means to combat the problem of prescription drug abuse. But as a legal matter, the answer to your question is no.

**9. Are you aware of your company's efforts to detect, address, and report suspiciously large orders in West Virginia?**

**COVINGTON**

The Honorable Gregg Harper  
 The Honorable Diana DeGette  
 June 14, 2018  
 Page 7

McKesson has devoted significant resources to make key enhancements to its CSMP, including strengthening our compliance team, customer diligence efforts, ongoing oversight, suspicious order reporting, and customer education efforts. McKesson has also devoted significant resources to the development and implementation of advanced analytics to monitor orders for controlled substances, including those placed by pharmacies in West Virginia.

**10. Are you aware that for years your company never followed West Virginia's law by reporting all suspicious orders to the West Virginia Board of Pharmacy?**

McKesson has made a number of enhancements to its CSMP and reporting practices, including its reporting practices with respect to the West Virginia Board of Pharmacy. If a customer order for a controlled substance exceeds established monthly thresholds, the order is blocked and reported to DEA and to the West Virginia Board of Pharmacy.

**11. Did your company have a policy that orders had to be less than 50% controlled substances to be filled?**

McKesson's CSMP includes a tool that allows the company to analyze a pharmacy's controlled substance ordering ratio over time, and that information can be a data point in decisions about whether to bring on the pharmacy as a new customer or change the ordering thresholds for a current customer. Because each pharmacy's situation is unique, McKesson believes that the company's advanced analytics system is a more appropriate tool for identifying suspicious ordering activity than a fixed ratio.<sup>3</sup>

**The Honorable Frank Pallone, Jr.**

**1. Prior to August 2013, McKesson was not regularly reporting suspicious order reports to DEA as required. When DEA Administrator Robert Patterson testified before the Committee in March, he stated that when distributors fail to report suspicious orders to DEA, it is much harder for DEA to do its job. Do you agree that timely reporting of suspicious orders plays a key role in preventing diversion?**

McKesson has reported hundreds of thousands of controlled substance orders to DEA as suspicious pursuant to 21 C.F.R. § 1301.74. McKesson is not aware of evidence that those reports are used by DEA to generate investigative leads. McKesson has for many years reported orders to DEA through ARCOS. According to DEA's website, "ARCOS accumulates these transactions which are then summarized into reports which give investigators in Federal and

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<sup>3</sup> As for a ratio requiring individual orders to be less than 50% controlled substances, such a policy is not feasible. Federal regulations require that some orders containing controlled substances not include any non-controlled substances in the order.

## COVINGTON

The Honorable Gregg Harper  
 The Honorable Diana DeGette  
 June 14, 2018  
 Page 8

state government agencies information which can then be used to identify the diversion of controlled substances into illicit channels of distribution. The information on drug distribution is used throughout the United States (U.S.). [sic] by U.S. Attorneys and DEA investigators to strengthen criminal cases in the courts.”<sup>4</sup>

- 2. You testified that McKesson’s order monitoring systems “determine a suspicious order based primarily on quantities compared to average pharmacies, pharmacies that are similar.” However, McKesson shipped Sav-Rite pharmacy in Kermit, WV, population 400, 4.8 million hydrocodone pills in 2006 and 2007. According to data cited by DEA, that was approximately 8 times the amount of hydrocodone that an average rural pharmacy in West Virginia would have expected to receive. What failed in McKesson’s suspicious order monitoring system to allow such large quantities of opioids to ship to this pharmacy?**

McKesson’s current CSMP utilizes a threshold management system to monitor orders of controlled substances and block and report all orders exceeding that threshold. McKesson’s customer thresholds are set using complex analytics that take into account, among other factors, pharmacy size and a comparison to pharmacies of similar size. Orders that exceed monthly thresholds are blocked and not shipped. Those blocked orders are reported to DEA as suspicious pursuant to 21 C.F.R. § 1301.74.

- 3. Considering the opioid crisis in West Virginia, what more could McKesson have done to monitor the opioid shipments it was sending to these communities?**

As described above, McKesson is firmly committed to having in place effective policies and procedures to monitor its distribution of controlled substances across the country, including West Virginia, and has continued to enhance its program. Moving forward, McKesson hopes that there will be greater coordination, cooperation, data sharing, and knowledge sharing among the industry, DEA, and state boards of pharmacy.

- 4. When McKesson acquires a smaller wholesale distribution company, what type of due diligence does McKesson perform on the pharmacy customers previously served by the acquired distribution company? Is it McKesson’s practice to perform a new customer intake examination of each pharmacy that has elected to use McKesson as its new wholesaler? If so, for how long has this been McKesson’s policy? Does McKesson inspect the due diligence files maintained by the acquired wholesaler for each transferred pharmacy customer? If so, for how long has this been McKesson’s policy?**

While this type of acquisition is infrequent and atypical, when McKesson acquires customers through the acquisition of another distributor, it validates the registration and

<sup>4</sup> See <https://www.deadiversion.usdoj.gov/arcs/index.html> (last visited June 6, 2018).

**COVINGTON**

The Honorable Gregg Harper  
 The Honorable Diana DeGette  
 June 14, 2018  
 Page 9

licensure status of each of the target company's pharmacy customers that will be supplied controlled substances after the acquisition. To the extent the newly acquired pharmacy customers will be supplied controlled substances, such distribution will be subject to the applicable requirements of McKesson's Controlled Substance Monitoring Program, including its system of monthly thresholds limiting the amount of controlled substances the pharmacy customer can purchase.

**The Honorable Jan Schakowsky****1. How much does McKesson net annually for its distribution of Evzio?**

McKesson does not generally track profits by molecule for products in its branded and generic pharmaceutical units.

**2. McKesson also distributes Narcan. What does McKesson earn net per unit for Narcan?**

McKesson does not generally track profits by molecule for products in its branded and generic pharmaceutical units.

**3. How much does McKesson net annually for its distribution of Narcan?**

McKesson does not generally track profits by molecule for products in its branded and generic pharmaceutical units.

**4. As early as 2007, a CDC memorandum showed that West Virginia drug overdose deaths increased by 550 percent between 1999 and 2004. Despite these reports, McKesson was providing millions of opioid pills to a single pharmacy in Kermit, West Virginia. Did McKesson understand there was a serious diversion problem facing the state, and how could McKesson have improved its handling of controlled substances?**

As described in McKesson's written response to the Committee, in 2007 McKesson implemented a new controlled substance monitoring program, and further enhanced that program in 2008 following its settlement with DEA. McKesson is firmly committed to having in place effective policies and procedures to monitor its distributions of controlled substances across the country, including West Virginia. Moving forward, McKesson hopes that there will be greater coordination, cooperation, data sharing, and knowledge sharing among the industry, DEA, and state Boards of Pharmacy.

**5. Does your company buy the drugs from the manufacturers, take title and move pallets to and from your warehouse? Or are you like brokers, working on consignment, arranging sales to pharmacies and then taking a percentage of the sale price?**

**COVINGTON**

The Honorable Gregg Harper  
 The Honorable Diana DeGette  
 June 14, 2018  
 Page 10

In most instances, McKesson buys drugs from manufactures, takes title upon delivery to McKesson facilities, and transfers title upon delivery to the customer.

- 6. In setting prices to pharmacies, is your markup more like a flat rate (for example, selling \$5 more than the price at which you bought), or is your markup more like a percentage (for example, selling for 5% higher than the price at which you bought)?**

McKesson determines pricing for all pharmaceutical products, including controlled substances, on an individual customer basis determined by factors specific to that customer, including the customer's overall product mix. The system is not as simple as buying a product from a manufacturer and selling it to customers at a markup. Although the specifics vary by product, McKesson's business model involves purchasing product from the manufacturer; charging the manufacturer a fee for service on the product; earning rebates and similar benefits from the manufacturer based on product ordering; and charging the customer a percent of the original acquisition costs. Depending on the product, McKesson may charge the customer more or less than McKesson paid to acquire the product from the manufacturer.

- 7. Is it possible that even if your company pays a higher price to get those drugs in stock, you end up making more money on those sales where your acquisition prices are higher? And would the same be true for your consignment/broker sales?**

As described above, McKesson's sales model is not as simple as reselling products at a markup. McKesson may make either more or less when the acquisition price of a product increases. Put another way, McKesson does not benefit from every price increase by a manufacturer, and often is required to return to the manufacturer the benefit of the manufacturer's price increase.

\* \* \*

McKesson appreciates this opportunity to respond to the Committee's questions. Please let us know if you require additional information.

Respectfully submitted,



Robert K. Kelner

Encl.

## Combating the Opioid Abuse Epidemic: A Shared Responsibility that Requires Innovative Solutions

March 2017

Public Affairs  
McKesson Corporation  
PublicAffairs@McKesson.com

Every day, the opioid abuse epidemic affects communities across America. This white paper presents McKesson's recommendations to improve prescribing and dispensing practices towards our country's shared goal: to eliminate the detrimental impact of the opioid abuse epidemic. Our recommendations include the following:

- Require all payers and providers to use opioid management programs
- Require e-prescribing for all controlled substances
- Harness the Food and Drug Administration's Risk Evaluation and Mitigation Strategies Program
- Fully leverage data analytics to identify patients most at risk and integrate a National Patient Safety Network into the pharmacy dispensing process
- Improve information sharing among Prescription Drug Monitoring Programs
- Permit partial refills to reduce risks associated with an excess of unused pills

The white paper also highlights McKesson's efforts to promote a secure supply chain and educate and equip our customers, physicians and pharmacists. As healthcare reform and other issues capture headlines, we must continue to do all we can, together, to combat this public health challenge.

### ***The Crisis***

Our country is in the midst of a serious opioid abuse epidemic, which is affecting every community in America. It has claimed victims from all races, ages, and socio-economic groups. According to the Centers for Disease Control & Prevention (CDC), from 2000 to 2014, nearly half a million Americans died from drug overdoses.<sup>1</sup> In 2015, more than 15,000 people died from overdoses involving prescription opioids.<sup>2</sup> Additionally, each day over 1,000 people are treated in emergency departments for not using prescription opioids as directed.<sup>3</sup> The National Institute on Drug Abuse (NIDA) has cited the increased volume of opioid prescriptions as a driving factor for the severity of the current crisis.<sup>4</sup>

The opioid epidemic is a multi-faceted problem that cannot be solved by focusing on individual parts of the healthcare system. It must be addressed through a comprehensive approach that includes the doctors who write the prescriptions, the pharmacists who fill them, the distributors who fill and deliver pharmacies' orders, the manufacturers who make and promote the products, and the regulators who license the above activities and determine supply.

**McKesson is fully committed to working with all stakeholders to protect the supply chain and help prevent diversion while ensuring appropriate treatments are available to patients. With a 360-degree view of healthcare and customers across industry and government, McKesson is uniquely positioned to advocate for a comprehensive set of policy and business solutions that will harness the power of technology to promote improved prescribing and dispensing. The implementation of these policy and business solutions could significantly slow the abuse and diversion of opioids, to the benefit of patients and their families.**

### ***Current Initiatives and Proposals***

Policymakers, manufacturers, insurers, and other stakeholders have launched numerous initiatives and proposed a wide range of policies aimed at curbing misuse of opioids, including pill disposal requirements, product stewardship, enhanced provider and pharmacist education, Medicare beneficiary "lock in," and various pill limitation measures.

In January 2016, the **Centers for Medicare & Medicaid Services (CMS)** released its opioid management strategy, which outlines the agency's plan to address the national opioid epidemic. The strategy features four key policy areas: (1) implementing more effective person-centered and population-based strategies to reduce the risk of opioid use disorders, overdoses, inappropriate prescribing, and drug diversion; (2) expanding naloxone (an overdose reversal drug) use, distribution, and access, when clinically appropriate; (3) expanding screening, diagnosis, and treatment of opioid use disorders, with an emphasis on increasing access to medication-assisted treatment; and (4) increasing the use of evidence-based practices for acute and chronic pain management.

**The Department of Veterans Affairs (VA)** has engaged in a comprehensive approach aimed at reducing the use of opioids among veterans using VA healthcare.<sup>6</sup> The VA's Opioid Safety Initiative (OSI) is an effort to improve the quality of life for veterans suffering from chronic pain. The program features patient management initiatives including Pain Coach, which is a pain management application available for download by patients receiving pain management treatments, a Veterans' Health Library, a Patient/Family Management Toolkit, and resources for Pain Management on My HealtheVet. All of these applications allowed veterans to better manage their pain without the use of opioids.<sup>7</sup> The VA has also been on the leading edge of PDMP interoperability, naloxone distribution, drug take back and opioid management programs.

In July 2016, **Congress** passed the Comprehensive Addiction and Recovery Act of 2016 (CARA) with overwhelming bipartisan support. CARA focuses primarily on treatment, recovery, law enforcement, criminal justice reform, and access to overdose reversal drugs.

Also in July 2016, the **National Governors Association (NGA)**, released a resource for state governments to address the opioid epidemic, titled *Finding Solutions to the Prescription Opioid and Heroin Crisis: A Road Map for States*.<sup>8</sup> *A Road Map for States* is a thoughtful and comprehensive set of evidence-based public policy recommendations and public health strategies focused on prevention and response to opioid misuse and overdose.

These are all thoughtful steps in taking meaningful action to combat the scourge of opioid abuse and diversion; and yet, there is more work to be done.

### ***McKesson's Public Policy Recommendations***

Patients taking prescription opioids interact with the healthcare system at least twice in order to access their medications. The first interaction takes place when the prescriber writes a prescription, and the second interaction takes place at the pharmacy when the prescription is dispensed to the patient. There are significant opportunities to engage at both encounter points to ensure that opioids are being prescribed and dispensed in an appropriate manner.

The proposals outlined below are aimed at establishing mechanisms to improve clinical treatment decisions by providing better information at the point of prescribing. Also included are a complementary set of policies that would similarly deliver actionable information to dispensing pharmacists.

#### **Section 1: Improve Prescribing Practices for Opioids**

In some instances, patients can obtain inappropriate access to prescription opioid medication by manipulating the prescription process. For example, some patients are able to interact with multiple doctors or pharmacies to acquire opioids that may not be clinically necessary. Multiple strategies can be deployed to improve opioid prescribing practices. Implementing e-prescribing requirements can limit opportunities for individuals to forge paper prescriptions for opioids. Providing comprehensive, accurate, and up-to-date information about a patient's prescription utilization history would significantly improve a physician's ability to identify instances where prescribing an opioid may be inappropriate. Additionally, improving and enhancing provider education about when and how to prescribe opioids, as well as recognizing any potential abuse, and the ability to carefully review a patient's prescription history – all would enhance the safety of prescribing practices.

##### ***Recommendation 1: Require all payers and providers to use opioid management programs***

Many public and private health plans, pharmacy benefit managers (PBMs), and hospital and physician organizations have adopted opioid management programs to curb overprescribing, misuse, and abuse. These programs often combine multiple strategies to improve decision-making when prescribing opioids and incorporate evidence-based clinical guidelines. A number of payers have adopted the CDC clinical guidelines for prescribing opioids, released in March of 2016. By the end of 2017, 21 states will use these guidelines for Medicaid fee-for-service and 11 states will require that Medicaid managed care organizations adopt them.<sup>9</sup> McKesson supports broader awareness and adoption of the CDC and other evidence-based clinical practice guidelines. We believe embedding these guidelines at the point of care (e.g., integration into e-prescribing, electronic health records, or other care management processes) can improve prescribing practices both in workflow and at the right time along the care continuum.

Several opioid management programs have had promising results. The emerging model implemented by Blue Cross Blue Shield of Massachusetts (BCBS-MA) is reporting successful outcomes and can serve as a model for other stakeholders to consider. Over a three-year period, the BCBS-MA program reduced the risk of substance use disorders and other health issues related to long-term use of opioids. The program eliminated an estimated 21.5 million doses of opioid-based medications in the communities served by its plans and reduced claims for long-acting opioids by approximately 50 percent by switching patients to short-acting pain treatments.<sup>10</sup>

Key elements of the program include, but are not limited to: (1) a comprehensive treatment plan between doctor and patient that outlines the expectations of both parties and considers non-narcotic treatment options; (2) a clinical risk evaluation for addiction that is signed by the patient; (3) choosing a single pharmacy or pharmacy chain to be used for all opioid prescriptions; (4) a prior authorization requirement for all new short-acting opioid prescriptions for more than 30 days and for all new long-acting opioid prescriptions; and (5) a three-day supply of short-acting opioids if prior authorization isn't immediately available, allowing time for authorization.

The BCBS-MA program features effective patient safety measures while ensuring access to care for patients in need. Cancer patients and terminally-ill patients are exempt from many of the authorization requirements, which is important for every opioid management program to contemplate since it is estimated that pain occurs in up to 70 percent of patients with advanced cancer.<sup>11</sup> Requiring a broader adoption of the key elements of BCBS-MA's opioid management programs could have a significant impact on the national opioid epidemic.

##### ***Recommendation 2: Require e-prescribing for all controlled substances***

Traditional handwritten prescriptions can be forged, altered, or diverted and can enable illegal access to prescription opioids.<sup>12</sup> Electronic prescribing (e-prescribing) allows prescriptions to be transmitted to pharmacies



securely without risk of alteration or diversion, and prescribers can be authenticated before dispensing of controlled substances and prescriptions. The American Journal of Pharmacy Benefits (AJPB) has recommended e-prescribing to help address the misuse and diversion of opioid medications.<sup>13</sup> E-prescribing of controlled substances (EPCS) is currently permitted in all 50 states, yet is only required in New York, Maine, and Minnesota. There is significant variability across the states in terms of e-prescribing capabilities and behaviors, and not all pharmacies or physicians' offices are capable of transmitting prescriptions electronically.<sup>14</sup> For example, in 2015, 82% of pharmacies in Nebraska were EPCS-enabled, along with 15% of prescribers.<sup>15</sup> By contrast, for the same year in Florida, 74% of pharmacies were EPCS enabled along with only 2% of prescribers.<sup>16</sup> Nationally, just 8% of physicians serve in practices that allow for the use of this technology to prescribe controlled substances like opioids.<sup>17</sup> Research on EPCS has been scarce, but surveys have shown that prescribers are generally optimistic about the benefits of EPCS.<sup>18</sup> A nationwide e-prescribing requirement for opioids could be a promising solution for reducing forged prescriptions and strengthening the efficacy of state prescription drug monitoring programs (PDMPs) across the country.

***Recommendation 3: Harness FDA's Risk Evaluation and Mitigation Strategies (REMS) Program***

The Food and Drug Administration (FDA) recognizes that there are risks associated with the use of certain drugs or classes of drugs. In order to manage these risks, the FDA requires drug manufacturers to create risk evaluation and mitigation strategy programs, or REMS, which include activities such as creating a medication guide and communication plan for healthcare professionals and distributors. These initiatives can help identify potential risks, harmful drug interactions, and other guidelines for safe use and proper disposal of opioids. Given the potential safety risks associated with opioids, the FDA has a class-wide REMS policy for all extended release and long acting (ER/LA) opioids. However, not all long-acting opioids have been subject to REMS requirements. The FDA recently announced that it intends to require a REMS for all forms of opioids to "ensure the benefits of these drugs continue to outweigh the risks of misuse, abuse, addiction, overdose and death."<sup>19</sup> McKesson supports the FDA's initiative.

The impact of opioid REMS has been hindered by low awareness of, and limited participation in, the physician education programs offered by drug manufacturers. For example, the voluntary REMS for ER/LA opioids fell short of its targeted prescriber goal. In the first two years, 37,512 prescribers completed the training, accounting for just under half (47 percent) of the targeted 80,000 prescribers.<sup>20</sup> A recent PriMed study involving 441 healthcare providers that received REMS training and 4,669 providers that were not trained, found that those who had REMS training had a 10% drop in ER/LA prescribing compared with a 4% increase in the untrained population.<sup>21</sup>

To improve effectiveness of the opioid REMS program, McKesson recommends: (1) implementing REMS requirements for all long-acting opioids as soon as possible; (2) increasing provider participation in REMS educational activities; and (3) improving the educational programs associated with REMS requirements and beyond. An exemption should be granted for cases in which a physician cares for a patient with a terminal condition, since certain REMS requirements (e.g., requiring physicians to document that terminally-ill patients understand the risk of addiction and abuse) could contribute to the patient avoiding the medication due to fear of addiction.

**Section 2: Improve Dispensing Practices for Opioids**

Dispensing pharmacists are a strong second line of defense to detect potential opioid abuse or misuse. Unlike prescribers who often do not engage with patients during refills, pharmacists handle refill prescriptions and the interaction with patients. Therefore, they must be a part of the solution. To maximize a dispenser's ability to identify potential instances of fraud or opioid misuse, it is vital that pharmacists and their staff have easy access to reliable, up-to-date information about a patient's prescription history. Further, to minimize the risk of opioid misuse, patients must not be prescribed more medication than they will need to manage their medical conditions.

***Recommendation 4: Integrate a National Patient Safety Network into the pharmacy dispensing process***

Under the current system, which the National Council for Prescription Drug Programs (NCPDP) describes as "systematically burdensome," pharmacists must leave their workstations to check a PDMP.<sup>22</sup> Unsurprisingly, research indicates that pharmacists do not always consult PDMPs. For example, a survey of pharmacists in Maine found that, in 2014, only 56 percent were using the state's PDMP.<sup>23</sup> Delivering alerts through the very same system that pharmacists use as part of their dispensing process would save significant time and, most importantly, would increase the likelihood that pharmacists consult their PDMPs.

To make the most informed dispensing decisions, pharmacists need access to robust, real-time information that can access and analyze data across all 50 states. One tool that can be used to increase patient safety is an automated,

clinically-based system that notifies dispensers in real-time and in workflow when a drug may present a safety issue to a patient (e.g., non-medical use, miscalculated dosage, or drug interactions).

This tool, a National Patient Safety Network ("Network"), as envisioned by NCPDP would identify "red flags" and alert dispensers whenever patient safety issues are identified. For example, in instances where there may be non-medical use of opioids, the Network would notify the pharmacist who could *voluntarily* check the PDMP before dispensing. The Network would complement PDMPs in two significant ways by: (1) providing alerts to dispensing pharmacists that are based on real-time, comprehensive prescription history data for patients, regardless of setting of care, and (2) promoting more effective use of PDMP information since pharmacists would know when to consult the PDMP rather than having to check it for all patients.

The Network could also benefit physicians, who according to a 2014 survey cited the time-consuming nature of retrieving data from PDMPs as a barrier to their use.<sup>24</sup> The same survey found that while doctors prescribed opioids for an average of 35 patients a month, they retrieved data from a PDMP for an average of only eight patients a month.<sup>25</sup> The NCPDP solution proposes that all electronic prescriptions, as well as all pharmacy dispensing activity, are evaluated against the Network.

#### ***Recommendation 5: Improve information sharing among PDMPs***

PDMPs are an important tool for pharmacists who serve as a crucial line of defense in identifying and avoiding potential opioid misuse and abuse. However, the data in PDMPs are typically limited to the prescription data from within the state the pharmacist is operating in. This means that a pharmacist searching a PDMP in one state may not have access to data from another state's PDMP. The data collected by PDMPs vary by state<sup>26</sup> and, according to a December 2016 report by Pew Charitable Trusts, data sharing between PDMPs is often slow.<sup>27</sup> Establishing a mechanism to exchange opioid prescription data across all state PDMPs would enable standardized data to be shared on a real-time basis. For example, a system like the one envisioned by CommonWell® Health Alliance, a vendor-neutral platform that breaks down barriers that currently inhibit effective, interoperable exchange of health data, would enable prescribers and dispensers to access comprehensive data from PDMPs from across the country that captures all opioid prescription activity, regardless of setting of care. The Network described above can provide PDMPs more robust real-time data, if states elect for that data to be incorporated into their PDMPs.

#### ***Recommendation 6: Permit partial refills to reduce risks associated with an excess of unused pills***

Prior to 2016, as Schedule II products, opioid prescriptions were not permitted to be refilled. This may have led some prescribers who anticipate an increased need for pain management in patients with acute pain to prescribe a greater supply of medication than necessary. This practice has resulted in an excess of unused pills. According to a study by the Johns Hopkins Bloomberg School of Public Health, six out of 10 adults prescribed opioid painkillers have leftover pills.<sup>28</sup> Allowing patients to partially refill their prescriptions increases the chances that a patient will be prescribed the exact number of pills that he or she needs, thereby reducing the risk of these "extra" pills being improperly disposed, lost, stolen, sold or given to others.

States and federal lawmakers have begun to take action aimed at limiting the risks associated with excess pills. For example, New Jersey recently enacted a law that imposed a five-day limit on a patient's first opioid prescription.<sup>29</sup> At the federal level, CARA permits a prescription for a Schedule II controlled substance to be partially filled if: (1) it is not prohibited by state law; (2) the partial fill is requested by the patient or the practitioner who wrote the prescription; and (3) the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.<sup>30</sup> Providing flexibility to allow patients and prescribers to reduce the number of unused opioid pills limits opportunities for diversion or misuse of these medications. A swift and comprehensive implementation of this policy, along with proper coordination with the states, can reduce the volume of unused pills and the risk of diversion and misuse.

### **Section 3: Our Efforts**

McKesson understands that thoughtful and innovative public policy solutions alone are not enough. We are committed to working closely with our partners and customers to fight the opioid abuse epidemic.

#### ***Promoting a Secure Supply Chain***

McKesson plays an important role in the proper disposal of medication. We are committed to ensuring unused medications are properly collected from our customers and our distribution centers and safely processed out of the supply chain. Over the last three years, we have worked with reverse distributors to appropriately dispose of, and in many instances, recycle, an average of 7.2 million products a year. In addition, we leverage our unique relationship with our customers to educate pharmacists about medication disposal so they in turn can educate their patients.

McKesson provides its Health Mart® pharmacists with “Drug Take Back Solutions” information, which demonstrate how they can partner with local law enforcement in getting unwanted or expired medications off the street.

McKesson operates a robust Controlled Substances Monitoring Program (CSMP) to help us identify and report suspicious orders. We also are utilizing advanced analytical tools to closely monitor our customers' purchases. We are committed to continuing to make enhancements as needed to ensure our CSMP remains an effective contribution in our country's battle with opioid diversion and abuse.

#### ***Educating Our Customers***

An FDA advisory panel has endorsed mandatory training for doctors who prescribe opioids as part of the efforts to stem the national epidemic of deaths and addiction related to these drugs. McKesson supports improvements in both formal medical education and continuing medical education to better inform clinical practice in pain management. MedTrainer, a compliance and regulatory training tool offered to McKesson's provider customers, provides training opportunities focused on responsible opioid prescribing and on recognition of drug seeking behavior and substance abuse disorders.<sup>31</sup>

Similarly, McKesson provides its nearly 5,000 HealthMart® independent community pharmacies with relevant information, tools, and resources about prevention of opioid abuse. As independent business owners, Health Mart® members are empowered to become advocates for drug abuse prevention in their communities, starting with their own pharmacies. All HealthMart® pharmacies are equipped with the *Health Mart Operations Toolkit*, an online portal where pharmacists can access resources created specifically to help prevent drug abuse in their communities, including: (1) education and training courses available for the entire pharmacy's staff; (2) drug abuse prevention solutions, which contains news, drug take back solutions, education, and outreach ideas; (3) best practices and practical advice for pharmacists and technicians to prevent drug abuse when filling prescriptions; and (4) community outreach resources with strategies to promote drug abuse prevention at the local level.

#### ***Conclusion***

Absent thoughtful and innovative solutions, the disturbing impact of opioid abuse and misuse will continue unabated. Meaningful solutions require the partnership of a variety of stakeholders, including doctors, pharmacists, distributors, manufacturers, payers, policymakers, and regulators. We believe the innovative solutions presented above offer a practical and unique approach to both the improvement of prescribing and dispensing practices and processes.

As a company, we are committed to advancing impactful solutions and continuing to innovate in our own processes. We stand ready to collaborate with lawmakers and all stakeholders and partners in the pharmaceutical supply chain to address our nation's devastating opioid abuse epidemic. For more information or to partner with McKesson Public Affairs on these policy solutions, contact [PublicAffairs@McKesson.com](mailto:PublicAffairs@McKesson.com).

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## Call to Action: Execute Solutions Today to Combat the Opioid Crisis

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### McKesson's Recommendations to Combat the Opioid Crisis

The opioid epidemic continues to affect communities across America. Our prioritized set of recommendations focus on enhancing clinical knowledge and leveraging data and technology solutions across the care continuum to address overprescribing and dispensing and enable real-time solutions to identify at-risk patients.

Key recommendations include:

- Implement a prescription safety-alert system to provide pharmacists and ultimately doctors with real-time alerts to identify at-risk patients
- Incentivize implementation of opioid stewardship or similar clinical excellence programs
- Ensure patients receive education on risks and benefits of opioids, and clinically appropriate treatment alternatives
- Require electronic prescribing (eRx) of all controlled substances
- Require use of electronic prior authorization (ePA) to better align prescribing with best clinical practices, prevent misuse, and ensure access for patients with legitimate need
- Pilot pharmacist-led opioid care management programs

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## Introduction

Our country's opioid epidemic has continued to affect communities throughout the country. It has claimed victims from all races, ages, and socio-economic groups.

The opioid epidemic is a complex, multi-faceted problem that cannot be solved by focusing on one part of the system or stakeholder. Rather, solutions must be comprehensive and should include, among others:

- the doctors who write the prescriptions,
- the pharmacists who fill them,
- the distributors who deliver the pharmacists' orders,
- the manufacturers who make and promote the products,
- the payers who make reimbursement decisions,
- and the regulators who license the above activities and determine supply.

More must be done, starting with acting on the recommendations we've proposed in this paper.

Every day, our company and our people work hard to ensure that appropriate treatments are available to patients in need. We remain steadfast in our commitment to work with all stakeholders to protect the supply chain and prevent diversion while ensuring that patients who need their medicines get them in a timely manner. With customers across the healthcare industry and government, we have a unique view of the healthcare ecosystem. That's why we'll continue to advocate for policy recommendations and technology-driven ideas that we strongly believe can slow the abuse and diversion of opioids, and most important, help to end this national crisis.

As the opioid epidemic persisted, we wanted to help the healthcare system look at holistic ways to combat the problem. That's why in 2015, we created an internal task force of experts, including clinicians, technologists, and public policy experts. In March 2017, McKesson released our policy paper, [Combating the Opioid Abuse Epidemic: A Shared Responsibility that Requires Innovative Solutions](#). It included policy recommendations in six major areas that we believe will help curb the opioid epidemic.

In this paper, we expand upon our 2017 policy recommendations, identify additional opportunities for appropriate intervention and describe approaches for comprehensive, integrated solutions to address the opioid epidemic across the healthcare ecosystem. Our new set of policy recommendations included in this paper continues to reinforce the need for public and private partnerships that:

- Promote patient-centered solutions,
- Foster clinical collaboration across the care continuum, and
- Bolster leadership and accountability.

**For a full listing of McKesson's efforts to combat the opioid crisis, please visit:** [www.mckesson.com/about-mckesson/fighting-opioid-abuse/](http://www.mckesson.com/about-mckesson/fighting-opioid-abuse/)

## Overview of McKesson's New Public Policy Recommendations

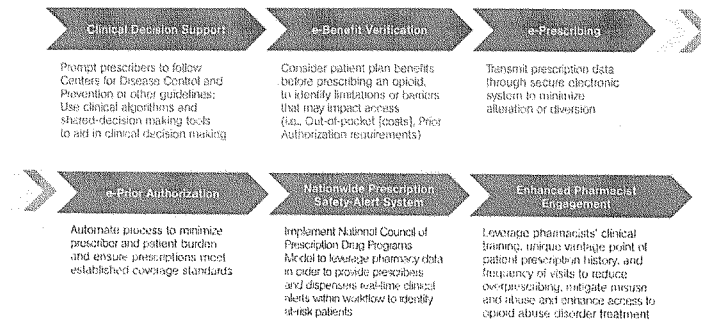
It is critical that we drive a culture of change that embraces a team-based approach to comprehensive pain management. This requires coordination across all stakeholders that impact the supply chain and those on the front lines of care delivery. Data and technology solutions must be thoughtfully deployed to ensure that necessary data flows through the healthcare system, enabling clinicians to meet the diverse needs of patients. However, this cannot be done until stakeholders collectively agree to utilize the tools at our fingertips to modernize the way opioids are prescribed and patients are managed across the care continuum.

The recommendations laid out in the next section, "McKesson's Prioritized Public Policy Recommendations," focus on enhancing clinical knowledge and leveraging data and technology solutions across the care continuum to address overprescribing and dispensing, while enabling real-time technology solutions to reduce supply and identify at-risk patients. We also advocate for additional policy changes that we believe can play a significant role in ending the opioid epidemic.

Details of our full set of 2018 recommendations can be found in Appendix A.

A comprehensive list of our 2017 and 2018 recommendations can be found in Appendix B.

### *Enable Real-Time Solutions to Reduce Supply and Identify Patients at Risk*



## McKesson's Prioritized Public Policy Recommendations

We recognize that modernizing the approach to pain management and opioid prescribing should be driven by enhancing clinical knowledge, understanding prescribing best practices, and using tools and technological solutions to assist in clinical decision making and patient engagement. We believe our policy recommendations can be implemented today and can have an immediate impact in curbing the opioid crisis.

### *Clinical Decision Support*

Independent medical experts have advised that appropriate opioid prescribing is built upon comprehensive pain management knowledge, understanding of opioid prescribing guidelines, and effective patient engagement. However, most opioids are not prescribed by pain specialists. Rather they are prescribed by primary care physicians, internists, dentists, and orthopedic surgeons.<sup>1</sup> While technology embedded within the electronic health record may prompt the clinician with relevant information, we think it is important to ensure clinical behaviors are driven by an expanded knowledge of comprehensive pain management, rather than simply reducing opioid prescriptions. In addition to constraining supply through initiatives such as limiting initial fills, our recommendations seek to increase clinical knowledge and improve patient engagement.

#### Recommendations:

- Implement nationwide prescription safety-alert system that may be used by pharmacists, and ultimately by prescribers, to inform clinical decision making (details on page 5)
- Incentivize implementation of opioid stewardship or similar clinical excellence programs
- Require all prescribers to participate in approved clinical training and continuing medical education as condition of licensure
- Deploy in-person prescriber training programs to reduce overprescribing

### *Electronic (e)-Benefit Verifications*

Use of pharmacy benefit verification tools allows providers to have a more complete picture of a patient's insurance coverage and any limits the payer may have on opioids and alternative treatments, including supply limits and mandatory prior authorizations. These tools also increase cost transparency. They can enable an

open discussion between providers and patients on the impact cost may have on treatment selection. Use of e-benefit verification tools provide prescribers a unique opportunity to discuss the risks and benefits of opioid use, as well as clinically appropriate treatment alternatives. We strongly believe in the value of these solutions. We encourage all prescribers to utilize such tools to increase shared-decision making, and improve adherence and patient knowledge on the risks of opioid addiction.

#### Recommendations:

- Ensure patients receive education on risks and benefits of opioids, and clinically appropriate treatment alternatives, at the time of prescribing and on a consistent basis

### *Electronic Prescribing (eRx)*

Handwritten prescriptions can be forged, altered, or diverted and can enable illegal access to prescription opioids. Moreover, paper prescriptions make it difficult to identify prescribing trends. eRx allows prescriptions to be transmitted to pharmacies securely while minimizing the risk of alteration or diversion. eRx also allows for data analytics and trendspotting regarding opioid prescribing. eRx of controlled substances (EPCS) is currently permitted in all 50 states, yet is only required in a few. Research on EPCS has been scarce, but surveys have shown that prescribers are generally optimistic about its benefits.<sup>2</sup> Because utilization of eRx is still modest despite it being allowed in all states, the use of mandates has become necessary to curb the epidemic.

#### Recommendations:

- Implement mandatory eRx of opioids under Medicare Part D as proposed in pending federal legislation and in some states
- Strongly encourage private payers to adopt similar policies

### *Electronic Prior Authorization (ePA)*

Employers and payers have implemented programs to detect and intervene in inappropriate prescribing of opioids. Prior authorization (PA), a process to verify that medications or procedures are medically necessary, is used by payers before they grant coverage approvals.<sup>3</sup> A study of Medicaid patients



in Pennsylvania found that enrollees within plans that subject opioids to PA policies had lower rates of abuse and overdose after initiating opioid medication treatment.<sup>4</sup> While the use of PA is frequently associated with reductions in use of opioids, traditional PA – most often completed via handwritten faxed forms or phone calls – can frequently place significant burdens on physicians, pharmacists, and patients who legitimately need prescription painkillers to manage their conditions.

#### Recommendations:

- Require use ePA of opioids under Medicare Part D as proposed in pending federal legislation
- Require use of ePA for opioids and other drugs as proposed in several state proposals
- Strongly encourage private payers to adopt similar policies

#### Nationwide Prescription Safety-Alert System

We strongly support the implementation of a nationwide prescription safety-alert system, a model conceived by the National Council for Prescription Drug Programs (NCPDP) and recently cited by the Duke Margolis Center for Health Policy.<sup>5</sup> The prescription safety-alert system would use patient prescription history data and clinical rules to identify patients and prescription patterns that may indicate risks of opioid overuse, abuse, addiction or misuse. Pharmacies would receive real-time alerts in workflow indicating that the pharmacist should gather additional patient information before dispensing. This might include a more in-depth conversation with the patient, a consultation with the prescribing physician(s), and review of the relevant state PDMP data. To maximize success, the prescription safety-alert system must have access to data from all entities dispensing covered controlled substances. e-prescribing would facilitate prescriber access to the prescription safety-alert system.

#### Recommendation:

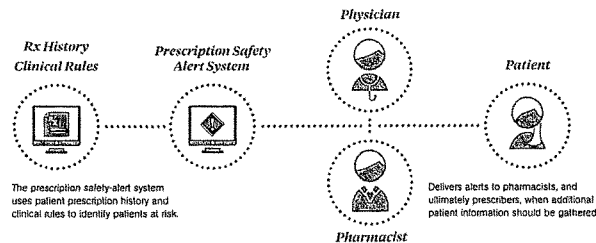
- Health and Human Services/Food and Drug Administration, through its existing Risk Evaluation and Mitigation Strategy authority, should require that manufacturers only provide covered controlled substances to pharmacies and healthcare providers that participate in a prescription safety-alert system

#### Enhanced Pharmacist Engagement

According to the Johns Hopkins Bloomberg School of Public Health, "community pharmacy remains the 'untapped resource' for the national opioid epidemic." Furthermore, the U.S. is also in the early stages of another looming public health crisis – a projected physician shortage of over 100,000 physicians by 2030, due to a growing and aging population.<sup>6</sup> In addition, every year, roughly one out of every four substance-abuse clinicians nationally leaves the profession.<sup>7</sup> Total pharmacist employment, on the other hand, is projected to grow by almost 18,000 jobs by 2026.<sup>8</sup> Given our country's current opioid crisis, impending physician shortage crisis, and the availability of highly skilled, medically-trained pharmacists that can help now, pharmacists must be better equipped to fight against the epidemic.

#### Recommendations:

- Pilot pharmacist-led opioid care management models
- Allow pharmacists to participate in and be reimbursed for Screening, Brief, Intervention and Referral to Treatment (SBIRT) activities
- Expand access to Medication-Assisted Treatment (MAT) by allowing pharmacists to provide and be reimbursed for MAT
- Increase access to opioid overdose antidotes, such as naloxone, by allowing pharmacists to dispense and be reimbursed for such treatments without a prescription
- Permit pharmacists to use greater discretion in partial fills



To watch an explanatory video, visit:  
<http://www.medicines.com/about-us/newsroom/press-releases/2016/06/01/medicines-com-launches-nationwide-prescription-safety-alert-system>

## Appendix A

### Overview of McKesson's Full Set of 2018 Public Policy Recommendations

We recognize some recommendations may require federal or state legislation or regulatory action, and believe such action is warranted. The persistence of this public health crisis calls for more assertive policy interventions. Other recommendations rely on private sector leaders to willingly adopt changes to ensure effective coordination across public and private payers. It is critical we implement solutions that positively affect all patients, regardless of geography or payer coverage, consistently.

Our positions are organized across key stakeholders with the following goals:



**Drug Supply**  
Reduce Supply and Over Prescription



**Prescribers**  
Increase Clinical Knowledge and Patient Engagement



**Dispensers**  
Expand Role of Pharmacists in Care Teams



**Patients**  
Improve Patient Access



**Data & Technology**  
Deploy Solutions to Identify At-Risk Patients

#### Reduce Supply and Over Prescription

- Encourage FDA to require that manufacturers package opioids in limited dose blister packs to reduce potential for unused product
- Establish programs for the return or destruction of unused opioids to ensure that each patient prescribed an opioid can access drug disposal mechanisms



**Drug Supply**

We must implement effective strategies to curb overprescribing across the entire healthcare spectrum now, while protecting access for patients with legitimate medical needs for opioid medications.

**Recommendation:** Encourage FDA to require that manufacturers package opioids in limited dose blister packs to reduce potential for unused product. FDA Commissioner Dr. Scott Gottlieb has effectively convened stakeholders and presented thoughtful ways for the Agency to combat opioid abuse. FDA is contemplating a novel idea to leverage blister packs as a way to give providers better options for tailoring how much should be prescribed, relative to the clinical need.<sup>9</sup> For example, according to Dr. Gottlieb: "Suppose the dental community developed an expert guideline that said that no routine dental procedure should require more than a three or five-day initial fill of an immediate-release opioid, and the FDA

reviewed and determined that blister packs in these quantities were necessary to ensure safe use. If the drugs were then packaged in blister packs that comported with these durations of use, it could help reduce overall dispensing. More doctors might more readily opt to prescribe these blister packs instead of other treatment options."<sup>10</sup> Dr. Gottlieb states FDA could use any conclusive, significant scientific support for these shorter durations of use as the basis for further regulatory action to drive more appropriate prescribing.

*McKesson supports this innovative concept, and recommends that the FDA leverage its current authority to explore optimal packaging approaches. However, we strongly encourage the FDA to work closely with provider specialty societies and guideline developers to ensure that blister packs meet evidence-based guidelines and do not inadvertently encourage overprescribing by limiting prescribers to specific dose ranges.*

**Recommendation:** Establish programs for the return and destruction of unused opioids to ensure that each patient prescribed an opioid can access dispensing drug technology. The Substance Abuse and Mental Health Services Administration (SAMHSA), reports that 50 percent of individuals who misused prescription pain medicines said they obtained them from a friend or relative for free.<sup>11</sup> Patients should not be prescribed excessive amounts of opioids and unused pills should be disposed of promptly and properly. Prescribers must ensure patients understand best practices for storage and disposal to minimize diversion.

*McKesson supports public-private partnerships focused on supplying retail pharmacies with drug deactivation bags to be dispensed with an opioid prescription. This recommendation is supported by the President's Commission on Combating Drug Addiction and the Opioid Crisis.<sup>12</sup>*

- Incentivize implementation of opioid stewardship or similar clinical excellence programs
- Require all prescribers to participate in approved clinical training and CME as a condition of licensure
- Deploy in-person prescriber training programs to inform better prescribing practices
- Ensure patients receive education on risks and benefits of opioids, and clinically appropriate treatment alternatives, at the time of prescribing and on a consistent basis with clinically-appropriate exceptions



Prescribers

Policymakers should ensure that prescribing clinicians have all information necessary to make fully informed decisions about whether to prescribe an opioid drug. The same is true for patients, who should be advised of risks and benefits by fully trained physicians and other qualified healthcare providers — both consistently and across the care spectrum. Supporting team-based approaches to care delivery will enhance opportunities for collaboration and coordination.

**Recommendation: Incentivize implementation of opioid stewardship or similar clinical excellence programs.** Stewardship and clinical excellence programs such as the Center for Disease Control and Prevention's (CDC's) Antibiotic Resistance Solutions Initiative have demonstrated success in driving changes to clinical behaviors, enhanced coordination, and improvement in patient outcomes. While components of these programs will vary, they are likely to include enhancing clinical knowledge of comprehensive pain management, multimodal pain management techniques, opioid prescription best practices, consistent communication with patients regarding the risks and benefits of opioid treatment, importance of appropriate disposal of unused drugs, and use of team-based models to support engagement across providers and settings of care. The National Quality Forum's (NQF's) National Quality Partners (NQP) Opioid Stewardship Playbook developed in partnership with CDC and other healthcare

stakeholders is an example of how these types of programs may be implemented.

*McKesson supports public-private partnerships to incentivize adoption of opioid stewardship and clinical excellence programs. As with any quality improvement effort that seeks to change the way care is delivered, organizational leadership, commitment, and accountability are critical to success. Incentives to implement these programs are critical to drive change across stakeholders — and we specifically encourage communities to reward team-based approaches that bridge the gap between physicians, hospitals, pharmacies and other critical care providers.*

**Recommendation: Require all prescribers to participate in approved clinical training and CME as condition of licensure.** Formal medical education and CME must be improved to better inform clinical practice in pain management. While medical, nursing and pharmacy schools continue to explore avenues to bolster clinical training on comprehensive pain management and opioid use, we recommend that all prescribers participate in approved CME as part of their licensure. It is critical that prescribers have the appropriate clinical knowledge to adhere to best practices in pain management and patient engagement, and not simply focus on reducing opioid use alone. Additionally, a FDA advisory panel has endorsed mandatory training for doctors who prescribe opioids.

*McKesson supports policy initiatives that would require all prescribers of opioids to undergo approved clinical training and CME as a condition of licensure. We also continue to support the use of FDA's REMS authority to require mandatory education for healthcare professionals.<sup>13</sup>*

**Recommendation: Deploy in-person prescriber training programs to reduce overprescribing.** In-person provider training is a promising strategy to help ensure that physicians' medical decisions are based on evidence-based information. This approach, which involves one-on-one educational outreach between a specially trained clinician and a physician, has successfully affected the management of health conditions such as chronic obstructive pulmonary disease (COPD) and atrial fibrillation. Recently, the method has been suggested to target physicians who prescribe opioids. Studies in numerous other settings have shown that the strategy has successfully provided physicians with evidence-based information in a way that improves their prescribing practices. A 2017 study concluded that this method of addressing opioid safety and naloxone prescribing was well-received by primary care providers and associated with an increase

of naloxone prescriptions filled by Medi-Cal patients. The approach is also recommended by the NQF Opioid Stewardship Playbook, and is used by the Veterans Health Administration for treatment of opioid abuse disorder.<sup>17</sup>

*McKesson supports use of in-person training programs by public and private payers. While current programs may target prescribers viewed to be outliers relative to peers, McKesson believes that these types of education programs should be offered to all prescribers desiring to improve their clinical knowledge and seeking to adopt evidence-based opioid prescribing behaviors. We support public-private partnerships that would enable this one-on-one training across specialties, settings of care and communities.*

**Recommendation: Ensure patients receive education on risks and benefits of opioids, and clinically appropriate treatment alternatives, at the time of prescribing and on a consistent basis.** Consistent messaging and use of shared decision-making tools will help patients understand their pain management options, and risks and benefits of opioid use. These discussions also provide an opportunity to educate patients on the safe storage and disposal of unused opioids. Patients should also be informed that under the Comprehensive Addiction and Recovery Act (CARA) rules, they may request partial fills of their prescriptions. Allowing patients to request partial fills helps to reduce the risk of "extra" pills being improperly disposed, lost, stolen, sold or given to others. Patients determined "at risk" by clinical guidelines should undergo consultation, attestation and/or confirmation testing for subsequent fills of prescription opioids.

*McKesson strongly supports policy initiatives to ensure that patients receive this critical education for new and subsequent prescriptions to ensure they are consistently informed of the clinical options and risks of continued opioid use. We support public-private partnerships that ensure this education occurs as part of routine clinician visits, or as part of opioid stewardship programs as recommended by the National Quality Forum's Opioid Stewardship Playbook.<sup>18</sup>*

- Pilot pharmacist-led opioid care management models
- Allow pharmacists to participate in and be reimbursed for SBIRT activities
- Expand access to MAT by allowing pharmacists to provide and be reimbursed for MAT
- Increase access to opioid overdose antidotes, such as naloxone, by allowing pharmacists to dispense and be reimbursed for such treatments without a prescription
- Permit pharmacists to use greater discretion in dispensing partial fills
- Train pharmacists on best practices to evaluate legitimacy of opioid prescriptions



Dispensers

As examples below highlight, states are beginning to recognize and empower pharmacists to do more to combat the opioid crisis. We recommend the following actions to ensure that pharmacists within their scope of licensure are leveraged, trained, and reimbursed for preventing, identifying, and treating opioid abuse disorder (OUD) and other substance use disorders (SUDs).

**Recommendation: Pilot pharmacist-led opioid care management models.** Pharmacists are uniquely positioned to have a comprehensive view of a patient's health status, since they see the prescriptions and diagnoses of multiple physicians and generally have strong relationships with their patients. This vantage point allows pharmacists to detect potential problems of non-adherence, drug interactions with opioids, and potential misuse and/or signs of potential abuse. Additionally, with proper medication adherence increasingly linked to better clinical outcomes and lower healthcare costs, pharmacist-led medication therapy management (MTM) is increasingly being employed by federally qualified health centers (FQHCs) and other care settings.

HHS' Indian Health Service (IHS) offers a noteworthy example of effective employment of pharmacists to provide the clinical expertise and critical leadership support needed to implement a comprehensive approach to opioid safety throughout Indian Country. Clinical pharmacists serving patients at IHS locations in the Southwest, Midwest, and Great Lakes regions have "transcended traditional dispensing roles by augmenting services in the management of primary care patients with pain and opioid use disorders. Novel approaches include patient consultation and education from within the pharmacy, patient management in

chronic non-cancer pain clinics, and care coordination through MAT programs. Pharmacists in some facilities are fully integrated into multidisciplinary chronic pain management programs and deliver care through a patient-centered model. Clinical roles range from individual consultation appointments to full prescriptive authority for controlled substances.”<sup>19</sup>

*We recommend public and private payers, including the Center for Medicare & Medicaid Innovation (CMS Innovation Center), test pharmacist-led care delivery models, with specific focus on opioid care management. Lack of Medicare recognition and inconsistent payer reimbursement often limit the formal roles pharmacists play in alternative payment models. Pharmacists’ clinical training, unique vantage point, and frequency of patient touch points provide a unique opportunity for these experts to engage on the frontlines of the opioid epidemic.*

*We encourage payers and providers to consider a robust team-based approach where the pharmacist is positioned as the pharmacologic leader and coordinator across the care continuum. Services they may provide include: assessing clinically appropriate drug doses, identifying potential drug-drug interactions, educating patients on risks and benefits of treatments, assessing patient risk of misuse and abuse, evaluating pain status and need for ongoing or alternative therapy, and educate on appropriate drug storage and disposal techniques. Pharmacists are also well positioned to assess whether certain high-risk patients would benefit from being co-prescribed opioid reversal agents such as naloxone. It is critical that we leverage all members of the healthcare ecosystem and drive team-based approaches to ending the opioid epidemic.*

**Recommendation: Allow pharmacists to participate in and be reimbursed for SBIRT activities.** Pharmacists should be permitted to provide and be reimbursed for SBIRT activities, which help to identify individuals who may struggle with alcohol and/or substance use. The program includes a screening and, if needed, a brief intervention to educate individuals about their use, alert them to possible consequences, and motivate them to take steps to change their behavior. Virginia is currently the only state that empowers and reimburses pharmacies to provide SBIRT services under Virginia’s Addiction Recovery Treatment Services (“ARTS”) benefit for Medicaid patients.<sup>20</sup>

*McKesson joins the National Community Pharmacists Association (NCPA) in encouraging other states to follow Virginia’s example in permitting pharmacists to provide and be reimbursed for SBIRT services.<sup>21</sup>*

**Recommendation: Expand access to MAT by allowing pharmacists to provide and be reimbursed for MAT.** Addiction experts consider MAT, which combines medications and behavioral therapy, as the gold standard in addiction care. Therefore, as addiction experts contend, policymakers should elevate expanded access to FDA-approved MAT as a critical component of fighting the opioid crisis. We applaud HHS Secretary Alex Azar’s acknowledgement that “the evidence on [MAT] is voluminous and ever-growing.”<sup>22</sup> The President has proposed to “test and expand nationwide [for Medicare] a bundled payment for community-based medication-assisted treatment, including Medicare reimbursement for methadone treatment for the first time.”

*We support this and other proposals to expand community-based MAT, particularly in rural areas. However, we strongly urge that pharmacists be considered eligible to provide and be reimbursed for MAT services in any nationwide pilot and expansion.*

Today, nearly every state permits pharmacists to forge collaborative practice agreements (CPAs) with physicians and other prescribers to provide advanced care to patients, including components of MAT, and some states allow pharmacists to prescribe Schedule II-V controlled substances under a CPA.<sup>23</sup> States that allow such agreements have found that pharmacist involvement in MAT helps to increase access, improve health outcomes, and reduce the risk of relapse.<sup>24</sup> However, pharmacists in states that allow them to prescribe Schedule III controlled substances, such as MAT medications, are still prohibited from doing so. This is because under federal law, pharmacists are ineligible for Drug Addiction Treatment Act (DATA) waivers that are available for other mid-level practitioners, such as physician assistants (PAs) and nurse practitioners (NPs).

*McKesson urges Congress to pass the Expanded Access to Opioid Abuse Treatment Act of 2017 (H.R. 3991), which would enable pharmacists to obtain DATA waivers and expanded access to MAT in states where they are permitted to do so.*

**Recommendation: Increase access to opioid overdose antidotes, such as naloxone, by allowing pharmacists to dispense and be reimbursed for such treatments without a prescription.** Naloxone – also known as Narcan – is deemed by FDA to be a safe and effective antidote to opioid overdoses and is currently available without a written prescription in most states. While such antidotes should not be considered a long-term solution, the reversal agent

can mean the difference between life and death for individuals.

*McKesson believes pharmacists in every state should be permitted to dispense and be reimbursed for opioid overdose antidotes without a prescription. As a matter of good clinical practice and care coordination, the pharmacist would be expected to communicate this care decision to the appropriate prescribing provider(s).*

**Recommendation: Permit pharmacists to use greater discretion in partial fills.** According to a Johns Hopkins Bloomberg School of Public Health study, six out of 10 adults prescribed opioid painkillers have leftover pills,<sup>25</sup> which poses significant risk of misuse and diversion. Pharmacists should be empowered to exercise their clinical judgment to be able to reduce the number of unused opioid pills. CARA permits a prescription for a Schedule II controlled substance to be partially filled if: (1) it is not prohibited by state law; (2) the partial fill is requested by the patient or the prescriber (note: not pharmacist); and (3) the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.<sup>26</sup> To date, only a handful of states allow pharmacists to partially fill a prescription under current CARA rules.

*McKesson supports changes to CARA that would allow pharmacists to exercise their professional judgment in deciding to partially fill prescriptions. We also encourage Drug Enforcement Administration to clarify that pharmacies may dispense less than prescribed amounts of opioids in response to any health plan designs that would limit coverage of opioids.*

**Recommendation: Train pharmacists on best practices to evaluate legitimacy of opioid prescriptions.** Pharmacists receive rigorous clinical training and have strong relationships with their patients. They represent a critical line of defense and should be adequately equipped to help prevent opioid abuse, misuse, and diversion.

*We support pending legislation in Congress that would provide for the development and dissemination of programs and materials for pharmacists and other providers to facilitate detection of fraudulent prescriptions and other behavior linked to abuse and diversion.*

- Require co-prescribing of overdose reversal agents for high-risk patients
- Promote community-based pilot programs focused on veterans
- Pilot recovery coach programs



Patients

Meaningful solutions must have better health for patients as the highest priority. The right solutions will include effective patient safety measures while ensuring access to care for patients in need. McKesson encourages lawmakers to ensure that proper safeguards are in place to make certain that patients with a legitimate medical need do not experience disruptions in their ability to access needed pain medications. It is important that every opioid management program and policy have proper exemptions in place for cancer patients and terminally-ill patients, since it is estimated that pain occurs in up to 70 percent of patients with advanced cancer.<sup>27</sup> In addition, all individuals battling with addiction, regardless of how they got there, should receive the same standard of care that any other patient battling any other disease would receive.

**Recommendation: Require co-prescribing of overdose reversal agents for patients who are considered high-risk and for patients with high-dose prescriptions of opioids.** In 2017, the American Medical Association (AMA) Opioid Task Force issued guidance encouraging physicians to consider co-prescribing naloxone with prescription opioids when clinically appropriate for patients who are at risk for opioid overdose or might be in a position to help someone else at risk.<sup>28</sup> The guidance includes several questions that physicians should consider to determine whether they should co-prescribe naloxone to a patient, a family member, or close friend of the patient. Furthermore, the Johns Hopkins Bloomberg School of Public Health also recommends that patients on a high-dose opioid carry naloxone, just as individuals with peanut allergies carry an EpiPen in case they accidentally ingest a peanut product.<sup>29</sup>

*McKesson supports policies that would require health plans to cover naloxone when prescribed by a physician or other qualified healthcare provider for clinically appropriate patients. Additionally, we believe that pharmacists in all states should be able to dispense naloxone for clinically appropriate patients without a prescription. As a matter of good clinical practice and care coordination, the pharmacist would be expected to communicate this care decision to the appropriate prescribing provider.*

**Recommendation: Promote community-based pilot programs focused on prevention and care for veterans.** The Department of Veterans Affairs (VA) has reported that veterans are twice as likely as non-veterans to die from overdose of addictive pain medicines, reflecting the high levels of chronic pain among the veteran population, particularly those who served in Iraq and Afghanistan.<sup>30</sup> We applaud VA efforts to combat overprescribing, including the Department's recent initiative to publicize information on opioids dispensed from VA pharmacies<sup>31</sup> and its commitment to implement academic detailing programs focused on overdose education, naloxone distribution, and opioid use disorder.<sup>32</sup>

*McKesson encourages the development of community-based pilot programs focused on preventing opioid abuse and misuse among veterans, including those that draw on VA-tested best practices.*

**Recommendation: Pilot recovery coach programs to help patients.** Recovery coach programs are currently being piloted in eleven emergency departments across Massachusetts.<sup>33</sup> Governor Charlie Baker recently filed legislation to create a commission to review and make recommendations regarding the credentialing and registration standards that should govern recovery coaches.<sup>34</sup> Under a pharmacist-led care management model, pharmacists could also be trained to provide counseling and recovery coaching services whenever patients have difficulty in accessing substance-abuse clinicians due to the increasing number leaving the profession.

*We are encouraged by these programs and support policies that would drive the development of national recovery coach models. We encourage public and private payers to cover these services today when provided by qualified healthcare providers, such as pharmacists.*

- Implement a national prescription safety-alert system for both dispensers and ultimately prescribers
- Require use of electronic prior authorization (ePA)
- Ensure PDMP interoperability by 2020 and compatible safety alert systems that will increase utilization and provision of real time and actionable data for clinical decision making at the point of prescribing and dispensing
- Require DEA to provide more data to registrants who report to the Automation of Reports and Consolidated Orders System (ARCOS) database
- Encourage wholesale distributors to provide states with the same ARCOS and suspicious order monitoring (SOM) data submitted to DEA
- Harmonize controlled substances sales reporting system



**Data & Technology**

The U.S. is the global leader in technological innovation. But when it comes to harnessing technology to address the worst public health crisis in modern history, our country has failed to mobilize its full potential. This is unacceptable for patients and for the healthcare professionals who are on the front lines caring for patients. Physicians, pharmacists, and clinicians agree that the realities of delivering care today – patient demands and tightening reimbursement – require 21st century technology that is interoperable, real time and easily accessible, in workflow. We recommend the following policy recommendations and private sector-led solutions to protect against abuse and to equip doctors, pharmacists, public health officials, and others with the tools necessary to help end the opioid crisis.

**Recommendation: Implement a nationwide prescription safety-alert system that would provide pharmacists, and ultimately prescribers with real-time alerts to identify patients who are at risk for opioid overuse, abuse, addiction or misuse.** We strongly support the implementation of a nationwide prescription safety-alert system, a model conceived by the National Council for Prescription Drug Programs (NCPDP) and recently cited by the Duke Margolis Center for Health Policy.<sup>35</sup> The prescription safety-alert system would use patient prescription history data and clinical rules to identify patients and prescription patterns that may indicate risks of opioid overuse, abuse, addiction or misuse. Pharmacies would receive real-time in workflow alerts indicating

that the pharmacist should gather additional patient information before dispensing. This might include a more in-depth conversation with the patient, a consultation with the prescribing physician(s), and review of the relevant state PDMP data. To maximize success, the prescription safety-alert system must have access to data from all entities dispensing covered controlled substances.

*McKesson urges HHS/FDA, through its existing REMS authority to require that manufacturers only provide covered controlled substances to pharmacies and healthcare providers that participate in a prescription safety-alert system.*

**Recommendation: Harness ePA to prevent misuse and accelerate access for patients with legitimate need.** Employers and payers have implemented programs to detect and intervene in inappropriate prescribing of opioids. PA, a process to verify that medications or procedures are medically necessary, is used by payers before they grant coverage approvals.<sup>36</sup> A study of Medicaid patients in Pennsylvania found that enrollees within plans that subject opioids to PA policies had lower rates of abuse and overdose after initiating opioid medication treatments.<sup>37</sup> While the use of PA is frequently associated with reductions in use of opioids, traditional PA – most often completed via handwritten faxed forms or phone calls – can frequently place significant burdens on physicians, pharmacists, and patients who legitimately need prescription painkillers to manage their conditions.

A 2016 AMA survey reported that 75 percent of respondents said handling PA requests were a “high” or “extremely high” burden and that an average of 16.4 hours of physician and staff time each week was spent on completing PA requirements to get patients the medicines and procedures they needed.<sup>38</sup> Pharmacists also reported similar challenges. According to the ePA National Adoption Scorecard, 66 percent of prescriptions rejected at the pharmacy require PA and 36 percent of those prescriptions are abandoned.<sup>39</sup> Clinicians, including pain experts, report that patients with legitimate need for pain medications are increasingly, involuntarily losing access to the medicines they need due partially to rigid and needlessly cumbersome efforts to prevent overprescribing. Prior authorization and other interventions meant to combat overprescribing must be improved by harnessing technology. ePA is a proven and promising solution that helps physicians and pharmacists securely and electronically transmit PA requests within their clinical workflows up to three times faster than paper-based PA and with fewer mistakes.

*McKesson supports policy initiatives that would enhance the use of ePA across all payers. We support current federal legislation that would mandate use of ePA in Medicare Part D and strongly urge commercial payers to adopt similar policies. Additionally, we support state legislative efforts to standardize the PA process for drugs and services. It is critical we reduce access hurdles for patients and minimize administrative burden on our already strained healthcare ecosystem.*

**Recommendation: Require eRx of all controlled substances.** Handwritten prescriptions can be forged, altered, or diverted and can enable illegal access to prescription opioids.<sup>40</sup> eRx allows prescriptions to be transmitted to pharmacies securely without risk of alteration or diversion. E-prescribing of controlled substances (EPCS) is currently permitted in all 50 states, yet is only required in a handful of states. Research on EPCS has been scarce, but surveys have shown that prescribers are generally optimistic about the benefits of EPCS.<sup>41</sup>

*We join the National Association of Chain Drug Stores (NACDS) and others in support of efforts by Congress to require e-prescribing of opioids in Medicare Part D, and encourage other payers to adopt similar policies. We strongly believe that all opioids in this country should be prescribed electronically.*

**Recommendation: Require DEA to provide more data to registrants who report to the ARCOS database.** The Controlled Substances Act requires wholesale distributors and other DEA registrants to report certain transaction data to DEA, which is housed in a database known as ARCOS. This data shows how many pills were sold, where in the U.S. they were sent, and what pharmacies bought them.

*McKesson supports pending legislation that would require DEA to provide registrants who report to the ARCOS database with information regarding (1) total number of specific distributors serving a specific pharmacy for reportable drugs (aggregated by the name and address of each pharmacy) and (2) the total number and type of opioids distributed to each pharmacy in order to help distributors further assess product orders or provide other supportive information.*

**Recommendation: Encourage wholesale distributors to provide states with the same ARCOS and SOM data submitted to DEA.** States may not have access to the ARCOS data, as well as reports of suspicious orders – requests from customers that are unusual in size, deviate substantially from normal patterns, and unusually frequent.



*McKesson is committed to voluntarily providing ARCOS and SOM data to any state that requests the information.*

**Recommendation: Harmonize controlled substances sales reporting systems.** McKesson is committed to working with governors, attorneys general, the National Association of Boards of Pharmacy (NABP), and DEA to harmonize controlled substances sales reporting systems. Such a policy would be in a form and frequency conducive to rigorous and timely analysis, would facilitate data sharing between state and federal governments, and would ultimately help to better identify and prevent non-medical use of prescription drugs.

*McKesson supports state efforts to adopt a uniform system for suspicious order reporting, so that states can receive standardized reports of suspicious orders in a timely and consistent manner.*

## Conclusion

Our country has made some progress in prioritizing and combating the opioid epidemic, but more must be done. Until we implement innovative solutions, like the ones we've recommended, we fear that the opioid crisis will persist. Meaningful solutions require doctors, pharmacists, distributors, manufacturers, payers, policymakers, and regulators, to come together. McKesson is committed to partnering with the Administration, Congress, the states, and all stakeholders who share our dedication to working together, with urgency, to help to end this national crisis. As never before, we must look to private sector innovation to inform and power public and regulatory policies that will break through the barriers that have stymied meaningful and sustainable barriers to addressing the public health crisis of our day. If you'd like partner with us on these solutions or would like more information, contact McKesson Public Affairs at [PublicAffairs@McKesson.com](mailto:PublicAffairs@McKesson.com).

## Appendix B

## Summary of McKesson 2017 – 2018 Public Policy Recommendations



Drug Supply

We continue to support our 2017 recommendations and new emergent public and regulatory policies that encourage policymakers to look "upstream" in the supply chain to prevent abuse, misuse and diversion: (1) Enact nationwide opioid prescription limits (7-day supply limit for acute pain), (2) Permit partial fills, and (3) Require DEA to revisit annual production quotas.

Additionally, we call for expanded reforms to better manage supply of drugs in our communities and facilitate the proper disposal of unused opioids.

- Encourage FDA to consider limited dose blister packs
- Establish programs for the return and destruction of unused opioids



Prescribers

We continue to support our 2017 recommendation that the FDA harness the power of its REMS programs, particularly as it relates to prescriber education and training.

Appropriate opioid prescribing is built upon comprehensive pain management knowledge, understanding of opioid prescribing guidelines, and effective patient engagement. As such, we recommend immediate reforms to ensure prescribers adopt evidence-based strategies today.

- Incentivize implementation of opioid stewardship or similar clinical excellence programs
- Require all prescribers to participate in approved clinical training and CME as a condition of licensure
- Deploy in-person provider training programs by independent medical experts
- Ensure all patients receive education on risks and benefits of opioids and clinically appropriate treatment alternatives consistently



Dispensers

We continue to support our 2017 recommendation requiring opioid management programs for all payers and providers.

However, this year we are also focused on ensuring that pharmacists practicing within the scope of their licensure are leveraged, trained, and reimbursed for preventing, identifying and treating opioid abuse disorder and other substance abuse disorders.

- Pilot pharmacist-led opioid care management models
- Recognize and reimburse pharmacists for Screening, Brief, Intervention and Referral to Treatment (SBIRT) and MAT, and opioid overdose antidotes
- Permit pharmacists to use greater discretion in partial fills
- Train pharmacists on best practices to evaluate legitimacy of opioid prescriptions



### *Patients*

While our policy recommendations for prescribers and dispensers also seek to improve patient engagement and expand access to treatments such as SBIRT and MAT, we also recommend:

- **Require co-prescribing of overdose reversal agents for high-risk patients**
- **Promote community-based pilot programs focused on veterans**
- **Pilot recovery coach programs**



### *Data & Technology*

We continue to support our 2017 recommendations that leverage data and technology to improve the flow of prescription data and ensure clinicians and pharmacies have the necessary clinical data prior to prescribing and dispensing opioids: (1) **Integrate a national prescription safety system into the pharmacy dispensing process**, (2) **Require eRx for all controlled substances nationally**, and (3) **Promote utilization of and improve information sharing among PDMP and data integration into a patient's electronic health record**.

This year we build upon these recommendations and seek to increase data sharing across stakeholders.

- **Implement the NCPDP national prescription safety-alert system concept for dispensers, and ultimately prescribers**
- **Require use of electronic prior authorization (ePA)**
- **Require DEA to provide more data to registrants who report to the ARCOS database**
- **Encourage wholesale distributors to provide states with the same ARCOS and SOM data submitted to DEA**
- **Harmonize controlled substances sales reporting systems**

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GREG WALDEN, OREGON  
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY  
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May 31, 2018

Mr. George S. Barrett  
Executive Chairman of the Board  
Cardinal Health, Inc.  
7000 Cardinal Place  
Dublin, OH 43017

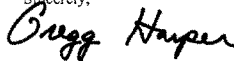
Dear Mr. Barrett:

Thank you for appearing before the Subcommittee on Oversight and Investigations on May 8, 2018, to testify at the hearing entitled "Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Thursday, June 14, 2018. Your responses should be mailed to Ali Fulling, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to [Ali.Fulling@mail.house.gov](mailto:Ali.Fulling@mail.house.gov).

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



Gregg Harper  
Chairman  
Subcommittee on Oversight and Investigations

cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachment

Responses of Cardinal Health, Inc. to Letter from Chairman Harper, dated May 31, 2018

**The Honorable Gregg Harper**

*1. Does your company request dispensing data from both prospective and existing pharmacy customers as part of its due diligence efforts to mitigate controlled substance diversion? If so, at what frequency does your company request this information and how is the dispensing data utilized? If no, why not?*

As part of its comprehensive anti-diversion program, Cardinal Health periodically requests and receives aggregate dispensing data and total number of prescriptions filled for both controlled and non-controlled substances from prospective and existing pharmacy customers. Cardinal Health requests total number of prescriptions filled for certain controlled substances from prospective customers as part of its initial Know Your Customer account set up process. In addition, outside of the account set up process, requests for aggregate dispensing data or total number of prescriptions filled may be made by Cardinal Health professionals working in Cardinal Health's anti-diversion program when they determine such a request is appropriate pursuant to the monitoring, inspection, and escalation protocols of the company's anti-diversion policies and procedures. That aggregate dispensing data and total number of prescriptions filled, along with Cardinal Health's complete data about its own distributions to each customer, is utilized to set and evaluate customer thresholds for controlled substance distributions.

Also, Cardinal Health reports all distributions of controlled substances to the DEA, which receives similar reports from every distributor through its ARCOS data reporting system. These reports, taken together, provide DEA with contemporaneous data reflecting all opiates purchased by every pharmacy in the United States.

*2. In its contracts with pharmacy customers, is your company able to require that a pharmacy produce dispensing data upon request? If so, does your company include such a requirement in the contracts it enters into with its pharmacy customers? If your company doesn't include such a requirement in its contracts, why not?*

Cardinal Health will not distribute opioids to a pharmacy customer without receiving sufficient information about its dispensing to allow the company to evaluate the pharmacy customer and its orders under Cardinal Health's anti-diversion program, nor will Cardinal Health distribute opioids to pharmacy customers who refuse to provide such information upon request.

*3. As part of your company's due diligence efforts related to prospective and existing customers, does your company review and maintain a list of the number of pharmacies that are located in the prospective/existing customer's service region? If so, how long has that been your company's practice and how does your company determine what a pharmacy's potential service region is?*

Among the many factors Cardinal Health considers when evaluating customers are the pharmacy's size, business model, location, historical volume of controlled substance purchasing, and its ratio of controlled substance purchasing to non-controlled substance purchasing. This multifaceted analysis is performed because appropriate thresholds for a pharmacy are not necessarily reflective of the size of the community where the pharmacy is located or how many pharmacies are located in a particular geographic area. Other relevant factors include the volume

Responses of Cardinal Health, Inc. to Letter from Chairman Harper, dated May 31, 2018

of patients served as reflected by the volume of non-controlled substances dispensed, and the pharmacy's proximity to or affiliation with hospitals, clinics, surgery centers, hospice facilities, and long-term care facilities.

*4. Does your company request dispensing data from both prospective and existing pharmacy customers as part of its due diligence efforts to mitigate controlled substance diversion? If so, at what frequency does your company request this information and how is the dispensing data utilized? If no, why not?*

Cardinal Health refers the Committee to the response to Question 1 above.

*5. In its contracts with pharmacy customers, is your company able to require that a pharmacy produce dispensing data upon request? If so, does your company include such a requirement in the contracts it enters into with its pharmacy customers? If your company doesn't include such a requirement in its contracts, why not?*

Cardinal Health refers the Committee to the response to Question 2 above.

*6. As part of your company's due diligence efforts related to prospective and existing customers, does your company review and maintain a list of the number of pharmacies that are located in the prospective/existing customer's service region? If so, how long has that been your company's practice and how does your company determine what a pharmacy's potential service region is?*

Cardinal Health refers the Committee to the response to Question 3 above.

**The Honorable Michael C. Burgess**

*1. While your companies seem to have put forth effort to improve your system of flagging possible drug diversion, there remains work to be done. In February, the Drug Enforcement Administration announced that it would begin sharing select data it collects on controlled substance prescriptions with drug distributors. Have your companies been able to access that data, and if so, has it been useful?*

On February 14, 2018, DEA announced that it added a feature to the ARCOS Online Reporting System that would allow distributors and manufacturers the opportunity to "view the number of competitors who have sold a particular controlled substance to a prospective customer in the last six months." Cardinal Health has been able to access this data, but its usefulness is limited because it does not reflect specific products within drug families and because it reflects only the number of distributors who shipped to the customer within the prior six months, but not the volume of controlled substances shipped. Many if not most pharmacies purchase controlled and non-controlled substances from multiple distributors for a variety of business reasons, including price and product availability. The fact that a particular pharmacy purchased controlled substances from more than one distributor is not necessarily indicative of a risk of diversion.

Responses of Cardinal Health, Inc. to Letter from Chairman Harper, dated May 31, 2018

*2. What is the largest hurdle you face as your companies scale up your diversion prevention activities? Is data-sharing, or lack thereof, the primary challenge?*

As an intermediary in the pharmaceutical supply chain, Cardinal Health does not ultimately control either the supply of or the demand for opioids. The demand for legal opioids is generated by licensed physicians prescribing medications for individual patients, and the supply of legal opioids is controlled by the annual DEA procurement and manufacturing quotas. The company's role as a distributor is to provide a secure channel to deliver medications of all kinds, from the hundreds of manufacturers who make them, to the thousands of hospitals and pharmacies authorized by the DEA to dispense them. Cardinal Health has a dual responsibility—to ensure that prescription medications are available for prescribers and their patients when needed, while working to limit the potential for those prescription medications to fall into the wrong hands. Cardinal Health shares the judgment of policymakers at the Department of Health and Human Services, the Food and Drug Administration, the Surgeon General, the Centers for Disease Control and Prevention, and others that there have been too many prescriptions for too many pills across the country. However, other participants in the healthcare delivery system have greater access to information than distributors. For example, many individual states have taken enormous strides in improving data sharing amongst licensed healthcare providers and pharmacies through prescription drug monitoring programs (“PDMPs”). DEA also has access to comprehensive data through ARCOS.

*3. Throughout each of your written testimonies, you mentioned your efforts to report suspicious orders to the DEA, and in cases that exceed the volume threshold, you stop the orders entirely. Where is the line drawn between drug manufacturers and the DEA in responding to suspicious orders? Does the DEA take enforcement action after you report the suspicious order?*

Cardinal Health generally does not have knowledge of what actions DEA may take in response to suspicious order reporting, nor can it speak to the role of drug manufacturers. As a distributor, Cardinal Health has reported to DEA hundreds of thousands of opioid orders that exceeded the company's conservative thresholds and that we have refused to ship. The company also has terminated or refused to distribute controlled substances to over a thousand pharmacies.

*4. Distributors and other pieces of the drug supply chain have a responsibility to help prevent diversion. What can Congress do legislatively to strengthen oversight of that supply chain?*

Cardinal Health supports appropriate prescribing limits on opioid pain medications, the creation of a national prescription drug monitoring program through collaboration with industry participants, and state and federal regulations and legislation that would require prescriptions to be issued electronically. Cardinal Health also supports legislation aimed at illegal street narcotics interdiction that target the supply of heroin and illicit fentanyl within communities. Finally, Cardinal Health shares the Committee's view that all parties in the health care community have a responsibility to help prevent opioid abuse and diversion, and the company is committed to doing its part to help ensure opioids are not diverted from the distribution channels within which Cardinal Health operates. In this regard, Cardinal Health supports legislative solutions that would harness the power of modern data analytics to strengthen oversight of the entire supply chain by encouraging greater data sharing and visibility among industry



Responses of Cardinal Health, Inc. to Letter from Chairman Harper, dated May 31, 2018

participants and with regulators. Cardinal Health also supports and encourages increased communication between distributors and the federal and state regulators responsible for licensure of prescribers and dispensers.

**The Honorable David B. McKinley**

*1. As a Wholesale Distributor of prescription opiates, do you agree that you owe a duty under federal law to monitor, detect, investigate, refuse and report suspicious orders? 21 U.S.C. § 823, 21 CFR 1301.74.*

As a licensed pharmaceutical distributor, Cardinal Health is subject to regulatory oversight by the Drug Enforcement Administration, including pursuant to the laws cited above. Cardinal Health has a dual responsibility—to ensure that prescription medications are available for prescribers and their patients when needed, while working to limit the potential for those prescription medications to fall into the wrong hands. Cardinal Health takes its regulatory obligations to the DEA seriously, and has worked continuously to improve its anti-diversion program to address the ever-changing diversion landscape and to account for changing regulatory expectations.

*2. Do you agree that the foreseeable harm of a breach of this duty is the diversion of prescription opiates for nonmedical purposes?*

Cardinal Health's dual responsibility is to ensure that prescription medications are available for prescribers and their patients when needed, while working to limit the potential for those prescription medications to fall into the wrong hands. Licensed pharmacies order medications from Cardinal Health. As a distributor, Cardinal Health is not licensed to engage in the practice of medicine, never sees or examines the patient, and cannot second guess the professional judgments of licensed prescribers, pharmacists and pharmacies, FDA, DEA, or state Boards of Pharmacy. The medications Cardinal Health supplies should never be dispensed by a pharmacy unless the pharmacy receives a lawful prescription from a licensed prescriber.

*3. In other words, if you ship a suspicious order, it is likely that prescription opiates will be diverted into the illicit market. Agree?*

Licensed pharmacies order medications from Cardinal Health. As a distributor, Cardinal Health does not write prescriptions to patients (doctors do that), and does not transact directly with customers of a pharmacy seeking to fill those prescriptions (pharmacists do that). The medications Cardinal Health supplies never reach a patient unless a doctor prescribes them and the pharmacy dispenses them. The fact that a particular pharmacy places large orders to fill prescriptions by licensed doctors can be reflective of the practice of medicine and pharmacy and not necessarily reflective of diversion. Cardinal Health maintains and continuously improves robust anti-diversion controls to prevent the shipment of opioids to customers that it believes present a substantial risk of diversion, and does not ship orders it determines are suspicious.

*4. Do you concur that filling suspicious orders is a direct and proximate cause of prescription opiate abuse, addiction, morbidity and mortality?*

Responses of Cardinal Health, Inc. to Letter from Chairman Harper, dated May 31, 2018

Cardinal Health refers the Committee to the response to Question 3 above.

*5. Do you agree the United States is in the midst of a prescription opiate epidemic?*

There is a public health crisis involving drug abuse including both legal and illegal opioid drugs. Cardinal Health is committed to doing its part to fight opioid abuse and misuse. For over a decade, Cardinal Health has funded education and prevention programs in communities across the country through Generation Rx, which the Cardinal Health Foundation developed in partnership with the Ohio State University School of Pharmacy. Generation Rx is a national prescription drug misuse prevention program that has been used in every state, at more than 100 colleges of pharmacy, and has provided more than a million people with tools and educational resources to prevent and address the issues that drive opioid abuse. More recently, Cardinal Health launched its Opioid Action Program (OAP), which has four elements, each of which has been cited by leading experts as essential to the fight to reduce opioid abuse and casualties. The OAP includes: 1) partnership with a leading school of medicine to refine and share medical school curricula that address opioid abuse and treatment through a collaboration with over 20 medical schools nationwide; 2) increased support of drug take back efforts to ensure excess medications are not available for abuse; 3) grants for community organizations engaged in youth prevention education, prescriber opioid awareness and reduction efforts, and community responses to the epidemic; and 4) the distribution of overdose reversal drug Narcan free-of-charge to first responders and law enforcement. Cardinal Health piloted OAP in four of the nation's hardest-hit states across Appalachia—Ohio, Kentucky, Tennessee, and West Virginia—to help alleviate the opioid epidemic.

*6. Do you concur that filling suspicious orders is a direct and proximate cause of the prescription opiate epidemic plaguing our country?*

Cardinal Health refers the Committee to the response to Question 3 above.

*7. Do you believe the prescription opiate epidemic is an immediate hazard to public health and safety?*

Cardinal Health refers the Committee to the response to Question 5 above.

*8. Do you believe the prescription opiate epidemic is a public nuisance?*

Cardinal Health refers the Committee to the response to Question 5 above.

*9. Are you aware of your company's efforts to detect, address, and report suspiciously large orders in West Virginia?*

Cardinal Health has invested significant resources to develop and operate a rigorous anti-diversion system. Through its anti-diversion program, Cardinal Health employs technology and analytics to evaluate its customers and scrutinize orders to identify potentially suspicious orders.

Responses of Cardinal Health, Inc. to Letter from Chairman Harper, dated May 31, 2018

Cardinal Health reports potentially suspicious orders to federal and state authorities, including the West Virginia Board of Pharmacy.

*10. Are you aware that for years your company never followed West Virginia's law by reporting all suspicious orders to the West Virginia Board of Pharmacy?*

Cardinal Health produced documents to the Committee identifying over 1,900 potentially suspicious orders that were reported to West Virginia regulatory authorities. See CAH\_HOUSE-000024 and CAH\_HOUSE-002299.

*11. Did your company have a policy that orders had to be less than 50% controlled substances to be filled?*

Cardinal Health processes orders on a line item basis, meaning each order is for a single pharmaceutical product. As part of its anti-diversion program, Cardinal Health evaluates the controlled substance purchasing and non-controlled substance purchasing across a pharmacy's total orders, not within a particular order or subset of orders. Every Cardinal Health customer has an individualized threshold limit for all drug families of controlled substances Cardinal Health distributes. The thresholds are based on various factors specific to the customer as well as analysis of third-party data detailing dispensing volumes of pharmacies nationwide.

**The Honorable Frank Pallone, Jr.**

*1. Cardinal's responses to the Committee do not appear to include any suspicious orders submitted by Cardinal to DEA prior to 2012. But the opioid crisis was exploding during the mid-2000s, and West Virginia has the highest death rate in the country from opioids. In retrospect, what could Cardinal have done to more proactively monitor its orders and help spot diversion?*

Cardinal Health has had a suspicious order monitoring process in place going back decades. From at least the late 1980's through approximately 2007, Cardinal Health used the DEA's mandated algorithm to identify excessive purchases that were reported to DEA. See Drug Enforcement Administration, Office of Diversion Control Suspicious Order Task Force, Report to the U.S. Attorney General, October 1998, Ex. II. Cardinal Health's system has been continually enhanced and improved as the diversion landscape has changed over time, and as DEA provided letters to industry and undertook enforcement actions. Cardinal Health takes its regulatory obligations seriously; on Cardinal Health's own initiative and in response to regulators, Cardinal Health has increased the size of its anti-diversion team, including bringing in personnel with additional regulatory, pharmaceutical, and law enforcement experience to further enhance the anti-diversion program. The company developed an analytical model to evaluate customers, assigned threshold ordering volumes, created a centralized database to store and track data on customers and orders, and designed new policies and procedures for anti-diversion personnel. No program can be perfect, which is why Cardinal Health is so focused on continuous improvement.

**The Honorable Jan Schakowsky**

Responses of Cardinal Health, Inc. to Letter from Chairman Harper, dated May 31, 2018

*1. According to the DEA records, Cardinal Health paid \$34 million in civil penalties to the DEA regarding allegations that you failed to report suspicious orders, as required by the Controlled Substances Act. Do you accept and admit to this Committee that your company repeatedly shipped and failed to report suspicious orders?*

As was stated in Mr. Barrett's written testimony, despite the development of a quality anti-diversion system, Cardinal Health has not always gotten every decision right, and in the past has entered into settlements with regulators to address aspects of its anti-diversion program. The company has learned and improved from each of them. While no program can ever be perfect, the company's goal is always to get it right, and Cardinal Health has stopped suspicious orders for the shipment of hundreds of millions of dosage units of controlled substances over the last decade. Cardinal Health does not ship opioids to customers that it believes present a substantial risk of diversion, and does not ship orders it determines are suspicious.

*2. Does your company buy the drugs from the manufacturers, take title and move pallets to and from your warehouse? Or are you like brokers, working on consignment, arranging sales to pharmacies and then taking a percentage of the sale price?*

In the vast majority of cases, Cardinal Health buys medications from manufacturers, taking title to the product. Cardinal Health generally does not sell medications on a consignment arrangement.

*3. In setting prices to pharmacies, is your markup more like a flat rate (for example, selling \$5 more than the price at which you bought), or is your markup more like a percentage (for example, selling for 5% higher than the price at which you bought)?*

Cardinal Health negotiates a variety of different pricing arrangements with its pharmacy customers depending on their needs and preferences.

*4. Is it possible that even if your company pays a higher price to get those drugs in stock, you end up making more money on those sales where your acquisition prices are higher? And would the same be true for your consignment/broker sales?*

Cardinal Health refers the Committee to the response to Question 3 above.

GREG WALDEN, OREGON  
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY  
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**  
COMMITTEE ON ENERGY AND COMMERCE  
2125 RAYBURN HOUSE OFFICE BUILDING  
WASHINGTON, DC 20515-6115  
Majority (202) 225-2927  
Minority (202) 225-3641

May 31, 2018

Mr. Steven H. Collis  
Chairman, President, and CEO  
AmerisourceBergen Corporation  
1300 Morris Drive  
Chesterbrook, PA 19087

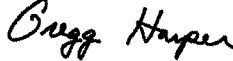
Dear Mr. Collis:

Thank you for appearing before the Subcommittee on Oversight and Investigations on May 8, 2018, to testify at the hearing entitled "Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Thursday, June 14, 2018. Your responses should be mailed to Ali Fulling, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to [Ali.Fulling@mail.house.gov](mailto:Ali.Fulling@mail.house.gov).

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



Gregg Harper  
Chairman  
Subcommittee on Oversight and Investigations

cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachment

House Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations

Additional Questions for the Record  
Responses Submitted by Mr. Steven Collis  
on Behalf of AmerisourceBergen Drug Corporation

The Honorable Gregg Harper

1. Does AmerisourceBergen request dispensing data from both prospective and existing pharmacy customers as part of its due diligence efforts to mitigate controlled substance diversion? If so, at what frequency does your company request this information and how is the dispensing data utilized? If no, why not?

Answer: ABDC does, at times, request dispensing data from both current and prospective customers. There is no specific frequency at which dispensing data is requested from customers. When received, the dispensing data is reviewed to identify data patterns and trends that could be indicative of possible diversion, such as unusually high dispensing of formulations or strengths of controlled substances that are more likely to be abused.

2. Does H. D. Smith request dispensing data from both prospective and existing pharmacy customers as part of its due diligence efforts to mitigate controlled substance diversion? If so, at what frequency does your company request this information and how is the dispensing data utilized? If no, why not?

Answer: H. D. Smith's customers are in the process of being integrated into the ABDC diversion control program and currently are treated in accordance with the response to Question 1 above.

Historically, H. D. Smith did periodically request dispensing data from current or prospective customers, which was analyzed to identify patterns or trends indicative of possible diversion.

3. In its contracts with pharmacy customers, is AmerisourceBergen able to require that a pharmacy produce dispensing data upon request? If so, does your company include such a requirement in the contracts it enters into with its pharmacy customers? If your company doesn't include such a requirement in its contracts, why not?

Answer: ABDC's contracts with its pharmacy customers do not typically include a provision that would require its customers to provide dispensing data, although such contracts do provide that ABDC can reject customers' orders or place restrictions on the ordering of controlled substances at the discretion of ABDC's Diversion Control Team. Such restrictions can include declining to ship controlled substances to a customer who refuses to provide dispensing data when asked. Nevertheless, ABDC is always evaluating additional measures it can take to enhance its Diversion Control Program and will consider potential contractual amendments as part of that ongoing evaluation.

4. In its contracts with pharmacy customers, is H. D. Smith able to require that a pharmacy produce dispensing data upon request? If so, does your company include such a requirement in the contracts it enters into with its pharmacy customers? If your company doesn't include such a requirement in its contracts, why not?

Answer: H. D. Smith will use ABDC contracts moving forward.

**House Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations**

**Additional Questions for the Record  
Responses Submitted by Mr. Steven Collis  
on Behalf of AmerisourceBergen Drug Corporation**

H. D. Smith's historic contracts with its pharmacy customers do not include a provision that would require its customers to provide dispensing data. H. D. Smith did, however, periodically request such data of its customers and a customer's refusal to comply with that request may have resulted in the termination of the ability to purchase controlled substances and potentially the termination of the account, if the customer never complied.

5. **As part of AmerisourceBergen's due diligence efforts related to prospective and existing customers, does your company review and maintain a list of the number of pharmacies that are located in the prospective/existing customer's service region? If so, how long has that been your company's practice and how does your company determine what a pharmacy's potential service region is?**

Answer: ABDC does not use the term "service region." ABDC's diversion control program believes factors besides the size of a service community are more relevant to analyzing the customer's purchasing patterns, including the pharmacy's purchases of both controlled and non-controlled substances, and the type of patients being served by the pharmacy. Moreover, ABDC recognizes that a pharmacy in a small town may serve a population much larger than the town itself. ABDC does not have access to the geographic dispersal of patients served by a pharmacy because of patient privacy protections.

Notwithstanding the above, as part of its diversion control program, ABDC does compare purchasing patterns of customers served by the same distribution center, and ABDC does currently consider various factors involving the customer's geographic location in making decisions about suspicious orders. These factors include population, opioid overdose death rates and Medicare part D prescribing rates for opioids.

6. **As part of H. D. Smith's due diligence efforts related to prospective and existing customers, does your company review and maintain a list of the number of pharmacies that are located in the prospective/existing customer's service region? If so, how long has that been your company's practice and how does your company determine what a pharmacy's potential service region is?**

Answer: H. D. Smith's customers are in the process of being integrated into the AmerisourceBergen diversion control program and currently are treated in accordance with the response to Question 5 above.

Historically, H. D. Smith did occasionally consider the population of the town in which a pharmacy was located when evaluating that pharmacy, but did not have access to information regarding the patient population being served by a pharmacy because of patient privacy protections. The size of the town being served was not always considered and was only one of the factors H. D. Smith used in evaluating pharmacies because the population of the town in which the pharmacy is located may be smaller or larger than the patient population being served. Other factors considered by H. D. Smith included the proximity of hospitals, long term care facilities and hospice centers when evaluating customer orders.

7. **Does AmerisourceBergen request dispensing data from both prospective and existing pharmacy customers as part of its due diligence efforts to mitigate controlled substance**

House Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations

Additional Questions for the Record  
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**diversion? If so, at what frequency does your company request this information and how is the dispensing data utilized? If no, why not?**

Answer: ABDC does, at times, request dispensing data from both current and prospective customers. There is no specific frequency at which dispensing data is requested from customers. When received, the dispensing data is reviewed to identify data patterns and trends that could be indicative of possible diversion, such as unusually high dispensing of formulations or strengths of controlled substances that are more likely to be abused.

**8. Does H. D. Smith request dispensing data from both prospective and existing pharmacy customers as part of its due diligence efforts to mitigate controlled substance diversion? If so, at what frequency does your company request this information and how is the dispensing data utilized? If no, why not?**

Answer: H. D. Smith's customers are in the process of being integrated into the AmerisourceBergen diversion control program and currently are treated in accordance with the response to Question 1 above.

Historically, H. D. Smith did periodically request dispensing data from current or prospective customers, which was analyzed to identify patterns or trends indicative of possible diversion.

**9. In its contracts with pharmacy customers, is AmerisourceBergen able to require that a pharmacy produce dispensing data upon request? If so, does your company include such a requirement in the contracts it enters into with its pharmacy customers? If your company doesn't include such a requirement in its contracts, why not?**

Answer: ABDC's contracts with its pharmacy customers do not typically include a provision that would require its customers to provide dispensing data, although such contracts do provide that ABDC can reject customers' orders or place restrictions on the ordering of controlled substances at the discretion of ABDC's Diversion Control Team. ABDC can also decline to ship controlled substances to a customer who refuses to provide dispensing data when asked, so a separate contractual provision regarding dispensing data is not needed to achieve the goals of ABDC's Diversion Control Program.

**10. In its contracts with pharmacy customers, is H. D. Smith able to require that a pharmacy produce dispensing data upon request? If so, does your company include such a requirement in the contracts it enters into with its pharmacy customers? If your company doesn't include such a requirement in its contracts, why not?**

Answer: H. D. Smith will use ABDC contracts moving forward.

H. D. Smith's historic contracts with its pharmacy customers do not include a provision that would require its customers to provide dispensing data. H. D. Smith did, however, periodically request such data of its customers and a customer's refusal to comply with that request may have resulted in the termination of the ability to purchase controlled substances and potentially the termination of the account, if the customer never complied.



House Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations

Additional Questions for the Record  
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11. **As part of AmerisourceBergen's due diligence efforts related to prospective and existing customers, does your company review and maintain a list of the number of pharmacies that are located in the prospective/existing customer's service region? If so, how long has that been your company's practice and how does your company determine what a pharmacy's potential service region is?**

Answer: ABDC does not use the term "service region." ABDC's diversion control program believes factors besides the size of a service community are more relevant to analyzing the customer's purchasing patterns, including the pharmacy's purchases of both controlled and non-controlled substances, and the type of patients being served by the pharmacy. Moreover, ABDC recognizes that a pharmacy in a small town may serve a population much larger than the town itself. ABDC does not have access to the geographic dispersal of patients served by a pharmacy because of patient privacy protections.

Notwithstanding the above, as part of its diversion control program, ABDC does compare purchasing patterns of customers served by the same distribution center, and ABDC does currently consider various factors involving the customer's geographic location in making decisions about suspicious orders. These factors include population, opioid overdose death rates and Medicare part D prescribing rates for opioids.

ABDC does not maintain a list of pharmacies by potential geographic reach as doing so would have with little meaningful impact on ABDC's ability to evaluate its customers' orders. The retail pharmacy community is constantly shifting, with the opening of new pharmacies and the closure of existing pharmacies a regular occurrence. Even assuming the ability to track this activity, simply knowing the number of pharmacies servicing a particular geographic region would have limited value to the wholesale distributor without knowing the patient community that each pharmacy is servicing, how many and what controlled substances distributors are supplying to those pharmacies and what precisely those pharmacies are dispensing to their patient customers.

12. **As part of H. D. Smith's due diligence efforts related to prospective and existing customers, does your company review and maintain a list of the number of pharmacies that are located in the prospective/existing customer's service region? If so, how long has that been your company's practice and how does your company determine what a pharmacy's potential service region is?**

Answer: H. D. Smith's customers are in the process of being integrated into the AmerisourceBergen diversion control program and currently are treated in accordance with the response to Question 5 above.

H. D. Smith did not use the term "service region." Historically, H. D. Smith did occasionally consider the population of the town in which a pharmacy was located when evaluating that pharmacy, but did not have access to information regarding the patient population being serviced by a pharmacy, which may be smaller or larger than the population of the town in which the pharmacy was located, because of patient privacy protections. The size of the town being serviced was not always considered and was only one of the factors H. D. Smith used in evaluating pharmacies. Other factors considered by H. D. Smith included the

**House Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations**

**Additional Questions for the Record  
Responses Submitted by Mr. Steven Collis  
on Behalf of AmerisourceBergen Drug Corporation**

proximity of hospitals, long term care facilities and hospice centers when evaluating customer orders.

**13. Why did AmerisourceBergen begin doing business with Beckley Pharmacy in 2016 after cutting the pharmacy off as a customer in 2015?**

Answer: In 2016, Beckley Pharmacy sought reconsideration of the decision to terminate sales of controlled substances to the pharmacy. At that time, ABDC requested de-identified dispensing data from the pharmacy, which the pharmacy provided. A detailed review of that dispensing data revealed that several of the concerns that had resulted in the pharmacy's termination of ability to purchase controlled substances had been alleviated. As a result of that review, ABDC concluded that there was a reduced risk of diversion at the pharmacy which made allowing the pharmacy to purchase controlled substances appropriate. Beckley Pharmacy's purchases continue to be processed through ABDC's Diversion Control Program, which will allow ABDC to continue to monitor for signs of possible diversion from the pharmacy and take appropriate action again, if necessary.

House Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations

Additional Questions for the Record  
Responses Submitted by Mr. Steven Collis  
on Behalf of AmerisourceBergen Drug Corporation

The Honorable Michael C. Burgess

1. **While your companies seem to have put forth effort to improve your system of flagging possible drug diversion, there remains work to be done. In February, the Drug Enforcement Administration announced that it would begin sharing select data it collects on controlled substance prescriptions with drug distributors. Have your companies been able to access that data, and if so, has it been useful?**

Answer: ABDC has accessed the information on purchasing by other distributors referenced in the DEA's February 14, 2018 press release and has found it useful, but with certain limitations. While knowing that a customer has purchased opioids from other suppliers can help to inform decisions, not knowing the quantities of such products purchased limits the utility of that information.

2. **What is the largest hurdle you face as your companies scale up your diversion prevention activities? Is data-sharing, or lack thereof, the primary challenge?**

Answer: ABDC has had in place since the 1980s a robust diversion control program. ABDC has continually enhanced and upgraded this comprehensive program over time and continues to do so to this day. We believe the lack of data sharing and transparency is certainly a challenge to our diversion control efforts. It is, however, only one of the challenges ABDC faces in its diversion control program. For example, ABDC's limited role in the supply chain also presents challenges when evaluating pharmacy orders; as a result of its limited role, ABDC has no access to patient-specific data, no access to prescriptions, no access to medical records, and no way to evaluate the legitimacy of patient need.

3. **Throughout each of your written testimonies, you mentioned your efforts to report suspicious orders to the DEA, and in cases that exceed the volume threshold, you stop the orders entirely. Where is the line drawn between drug manufacturers and the DEA in responding to suspicious orders? Does the DEA take enforcement action after you report the suspicious order?**

Answer: As a preliminary matter, orders placed by ABDC's customers that exceed that customer's threshold are held and evaluated to determine whether that order is suspicious. If the determination was made that the order is suspicious, it is cancelled and reported to DEA. If, however, after evaluation of the order, ABDC determines that the order is not suspicious, it is released and shipped to the customer.

ABDC does not know whether DEA shares suspicious order reports with drug manufacturers, or even with DEA's own local field offices. ABDC does not provide its suspicious order reports to any drug manufacturers.

ABDC does not have visibility into DEA's internal processes and does not know how DEA processes, analyzes and uses the suspicious order data it provides. ABDC does know that pharmacies remain DEA-licensed even after suspicious orders are reported.

**House Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations**

**Additional Questions for the Record  
Responses Submitted by Mr. Steven Collis  
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4. **Distributors and other pieces of the drug supply chain have a responsibility to help prevent diversion. What can Congress do legislatively to strengthen oversight of that supply chain?**

Answer: ABDC would welcome the following measures:

- greater supply chain data transparency (including ARCOS data sharing and/or data sharing among distributors);
- additional resources for patient and prescriber education and medication safe storage and disposal;
- additional support for e-prescribing;
- mandating the use of electronic ordering for controlled substances;
- notice to distributors when one of its customers has ordered controlled substances from another distributor – including the amount of the order – before the order is processed;
- additional funding for DEA IT enhancement and future enforcement;
- creation of new DEA registration classifications, such as Pain Specialty Pharmacy, that would require more in-depth investigation by DEA and Boards of Pharmacy and allow greater scrutiny by distributors; and
- enhancing state prescription drug monitoring programs.

**House Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations**

**Additional Questions for the Record  
Responses Submitted by Mr. Steven Collis  
on Behalf of AmerisourceBergen Drug Corporation**

**The Honorable David B. McKinley**

- 1. As a Wholesale Distributor of prescription opiates, do you agree that you owe a duty under federal law to monitor, detect, investigate, refuse and report suspicious orders? 21 U.S.C. § 823, 21 CFR 1301.74**

Answer: ABDC acknowledges the provisions of 21 U.S.C. § 823 and 21 CFR 1301.74. ABDC administers a robust anti-diversion program in order to meet, and in fact exceed, the requirements imposed on it as a distributor. ABDC's Order Monitoring Program ("OMP") is the means by which the Company monitors for and reports suspicious orders of controlled substances and listed chemicals. The OMP is a multi-faceted approach to awareness, monitoring, investigation, and reporting overseen by ABDC Corporate Security and Regulatory Affairs ("CSRA").

- 2. Do you agree that the foreseeable harm of a breach of this duty is the diversion of prescription opiates for nonmedical purposes?**

Answer: ABDC has operated a system to monitor, detect and report suspicious orders to the DEA for many decades. ABDC invests significantly in its effort to deter diversion, but there are unavoidable limits to ABDC's ability to monitor and prevent diversion given its limited role in the supply chain. ABDC has no access to patient-specific data, no access to prescriptions, no access to medical records, and no way to evaluate the legitimacy of patient need. ABDC has no control over, nor input into, the amount of controlled substances that are produced in a given year. Instead, production quotas are set by the DEA with input from manufacturers. Nor is ABDC involved in the licensing and regulation of the medical and pharmaceutical professionals who actually prescribe or dispense controlled substances. That responsibility belongs to federal and state governmental agencies, including the DEA. Finally, ABDC does not promote the prescribing or use of opioids to physicians, healthcare providers or patients.

- 3. In other words, if you ship a suspicious order, it is likely that prescription opiates will be diverted into the illicit market. Agree?**

Answer: ABDC does not ship the orders it reports as suspicious. In an effort to comply with all regulatory requirements, ensure a safe delivery system, and help address this crisis, ABDC has implemented rigorous anti-diversion policies and procedures and is actively engaged in various industry and policy group initiatives that support the fight against opioid abuse.

- 4. Do you concur that filling suspicious orders is a direct and proximate cause of prescription opiate abuse, addiction, morbidity and mortality?**

Answer: ABDC identifies and reports suspicious orders. ABDC does not fill any suspicious orders.

Prescription opioid abuse is a multi-faceted problem with many causes. As a distributor, ABDC plays a limited role in the distribution chain for prescription opioids. ABDC (1) is not involved in obtaining FDA approval for opioids, labeling or warning about opioids, setting guidelines for prescribing opioids, or promoting the prescribing or use of opioids to

**House Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations**

**Additional Questions for the Record  
Responses Submitted by Mr. Steven Collis  
on Behalf of AmerisourceBergen Drug Corporation**

pharmacies, physicians, or patients; (2) has no control over the amount of controlled substances that are produced in a given year (instead, production quotas are set by the DEA with input from manufacturers); (3) is not involved in the licensing and regulation of the medical and pharmaceutical professionals who actually prescribe or dispense controlled substances (that responsibility belongs to federal and state governmental agencies, including the DEA); and (4) does not receive or have access to any prescription-level information or other patient-specific data.

**5. Do you agree the United States is in the midst of a prescription opiate epidemic?**

Answer: ABDC shares the Committee's concern about the tragic epidemic of opioid abuse. ABDC desires to be part of much-needed, and unquestionably multi-faceted, solutions to address this public health crisis.

To that end, AmerisourceBergen funded a grant to the Health Care Improvement Fund to support prescriber education for post-surgical procedures. AmerisourceBergen has also partnered with Walgreens to support the safe disposal of unused controlled substances and has provided drug disposal bags to multiple communities to assist with the disposal of unused controlled substances.

AmerisourceBergen also supports mandatory e-prescribing, which would generate real-time information on opioid use and reduce the number of opioids obtained through fraudulent prescriptions or doctor shopping. We support policies to make state PDMPs interoperable, which would allow physicians and regulators to determine if patients are obtaining prescriptions from physicians in more than one state. We are also the only distributor member of the Collaborative for Effective Prescription Opioid Policies ("CEPOP"), which supports policies to reduce prescription opioid abuse and promote treatment options.

AmerisourceBergen is also eager to collaborate with policymakers and stakeholders throughout the pharmaceutical supply chain to improve distributors' ability to assess and act on possibly suspicious orders of prescription opioids. As part of the National Association of Drug Diversion Investigators, AmerisourceBergen has presented on effectively combatting drug diversion at the distribution level and collaborating with law enforcement. AmerisourceBergen also supports increased fees for DEA registration to help support such enhanced data capabilities.

**6. Do you concur that filling suspicious orders is a direct and proximate cause of the prescription opiate epidemic plaguing our country?**

Answer: ABDC identifies and reports suspicious orders. ABDC does not fill any suspicious orders.

The prescription opioid epidemic is a multi-faceted problem with many causes. As a distributor, ABDC plays a limited role in the distribution chain for prescription opioids. ABDC (1) is not involved in obtaining FDA approval for opioids, labeling or warning about opioids, setting guidelines for prescribing opioids, or promoting the prescribing or use of opioids to pharmacies, physicians, or patients; (2) has no control over the amount of

**House Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations**

**Additional Questions for the Record  
Responses Submitted by Mr. Steven Collis  
on Behalf of AmerisourceBergen Drug Corporation**

controlled substances that are produced in a given year (instead, production quotas are set by the DEA with input from manufacturers); (3) is not involved in the licensing and regulation of the medical and pharmaceutical professionals who actually prescribe or dispense controlled substances (that responsibility belongs to federal and state governmental agencies, including the DEA); and (4) does not receive or have access to any prescription-level information or other patient-specific data.

**7. Do you believe the prescription opiate epidemic is an immediate hazard to public health and safety?**

Answer: The prescription opioid epidemic is a complex problem that affects many aspects of our society. As a distributor, ABDC plays a limited role in the distribution chain for prescription opioids. ABDC (1) is not involved in obtaining FDA approval for opioids, labeling or warning about opioids, setting guidelines for prescribing opioids, or promoting the prescribing or use of opioids to pharmacies, physicians, or patients; (2) has no control over the amount of controlled substances that are produced in a given year (instead, production quotas are set by the DEA with input from manufacturers); (3) is not involved in the licensing and regulation of the medical and pharmaceutical professionals who actually prescribe or dispense controlled substances (that responsibility belongs to federal and state governmental agencies, including the DEA); and (4) does not receive or have access to any prescription-level information or other patient-specific data.

**8. Do you believe the prescription opiate epidemic is a public nuisance?**

Answer: The prescription opioid epidemic is a complex problem that affects many aspects of our society. As a distributor, ABDC plays a limited role in the distribution chain for prescription opioids. ABDC (1) is not involved in obtaining FDA approval for opioids, labeling or warning about opioids, setting guidelines for prescribing opioids, or promoting the prescribing or use of opioids to pharmacies, physicians, or patients; (2) has no control over the amount of controlled substances that are produced in a given year (instead, production quotas are set by the DEA with input from manufacturers); (3) is not involved in the licensing and regulation of the medical and pharmaceutical professionals who actually prescribe or dispense controlled substances (that responsibility belongs to federal and state governmental agencies, including the DEA); and (4) does not receive or have access to any prescription-level information or other patient-specific data.

**9. Are you aware of your company's efforts to detect, address, and report suspiciously large orders in West Virginia?**

Answer: Since at least the 1980s, AmerisourceBergen Drug Corporation has had in place a system to monitor the orders it receives, the OMP. We worked with the DEA to enhance the system in 1998, and again in 2007, and have continually reviewed and improved it, including a comprehensive 2015 revision to build on current data, respond to trends in prescription drug abuse, and adopt improved technological capabilities, including data-driven analytical tools. ABDC's Order Monitoring Program has been consistent with DEA's guidance, including the September 2006, February 2007, and December 2007 letters sent by DEA to the distributors.

**House Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations**

**Additional Questions for the Record  
Responses Submitted by Mr. Steven Collis  
on Behalf of AmerisourceBergen Drug Corporation**

**10. Are you aware that for years your company never followed West Virginia's law by reporting all suspicious orders to the West Virginia Board of Pharmacy?**

Answer: ABDC reached out to the West Virginia Board of Pharmacy multiple times, including in 2012 after the litigation filed against ABDC on behalf of the Attorney General and certain West Virginia agencies was filed. During the course of those conversations, ABDC was instructed that it was not required to report suspicious orders to the West Virginia Board of Pharmacy as long as those orders were reported to DEA. Since that time, the head of the West Virginia Board of Pharmacy has repeatedly stated publicly, and testified in the litigation, that the West Virginia Board of Pharmacy received very few suspicious order reports prior to 2012 and, when it started to receive suspicious orders, took no action in response to those orders. ABDC began providing suspicious order reports to the West Virginia Board of Pharmacy in early 2017, once it received instruction to do so.

**11. Did your company have a policy that orders had to be less than 50% controlled substances to be filled?**

Answer: While ABDC does not have such a policy, the percentages of controlled substances purchased by its customers is one of the factors monitored by ABDC as part of its diversion control program.

Within West Virginia, controlled substances were only 3.9% of all ABDC prescription drug sales by dosage unit and 2.1% of all ABDC prescription drug sales by dollar value.



House Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations

Additional Questions for the Record  
Responses Submitted by Mr. Steven Collis  
on Behalf of AmerisourceBergen Drug Corporation

The Honorable Frank Pallone, Jr.

1. In AmerisourceBergen's response to the Committee, you provided the number of pills the company distributed to West Virginia. In 2016, AmerisourceBergen shipped about 6 million hydrocodone pills. But back in 2008 and 2009, AmerisourceBergen shipped 16.2 million and 17.5 million pills annually. What explains why in 2009 AmerisourceBergen shipped nearly 3 times the amount the company would later ship in 2016? Did additional due diligence or recognition of the unfolding opioid crisis lead AmerisourceBergen to ship far fewer pills in the later years than in 2008 and 2009? Were there other factors?

Answer: The primary driver of ABDC's sales is and always has been the orders placed by its customers, licensed and regulated pharmacies, to fill prescriptions written by licensed and regulated practitioners. ABDC monitors orders placed by its customers and reports suspicious orders to the DEA, and did so in both 2008/2009 and in 2016. In addition to its suspicious order monitoring, ABDC conducted due diligence on prospective customers and monitored its current customers. As a result of that additional due diligence, ABDC refused to sell controlled substances to a number of pharmacies that were licensed to be able to purchase those products.

There are many factors that could have resulted in the reduction in orders placed by customers in West Virginia, including changes in physician prescribing practices that may have resulted in reduced ordering by pharmacies.

House Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations

Additional Questions for the Record  
Responses Submitted by Mr. Steven Collis  
on Behalf of AmerisourceBergen Drug Corporation

The Honorable Jan Schakowsky

1. **Does your company buy the drugs from the manufacturers, take title and move pallets to and from your warehouse? Or are you like brokers, working on consignment, arranging sales to pharmacies and then taking a percentage of the sale price?**

Answer: ABDC purchases prescription medications, including controlled substances, from the manufacturers. ABDC typically takes title to the product it sells but does, in limited circumstances, facilitate shipments directly from a manufacturer to a pharmacy.

2. **In setting prices to pharmacies, is your markup more like a flat rate (for example, selling \$5 more than the price at which you bought), or is your markup more like a percentage (for example, selling for 5% higher than the price at which you bought)?**

Answer: ABDC sells some products at a mark-up (profit) and some products at a mark-down (loss). The price structure varies depending on product and contract. As a general matter, however, ABDC makes approximately 1% net profit on its entire suite of products.

3. **Is it possible that even if your company pays a higher price to get those drugs in stock, you end up making more money on those sales where your acquisition prices are higher? And would the same be true for your consignment/broker sales?**

Answer: ABDC sells some products at a mark-up (profit) and some products at a mark-down (loss). The price structure varies depending on product and contract. As a general matter, however, ABDC makes approximately 1% net profit on its entire suite of products.

GREG WALDEN, OREGON  
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY  
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**  
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May 31, 2018

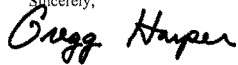
Mr. J. Christopher Smith  
Former President and CEO  
H.D. Smith  
C/o AmerisourceBergen Corporation  
1300 Morris Drive  
Chesterbrook, PA 19087

Dear Mr. Smith:

Thank you for appearing before the Subcommittee on Oversight and Investigations on May 8, 2018, to testify at the hearing entitled "Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Thursday, June 14, 2018. Your responses should be mailed to Ali Fulling, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to [Ali.Fulling@mail.house.gov](mailto:Ali.Fulling@mail.house.gov).

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,  
  
Gregg Harper  
Chairman  
Subcommittee on Oversight and Investigations

cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations  
Attachment

House Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations

Additional Questions for the Record  
Responses Submitted by Mr. James Christopher Smith  
on Behalf of H.D. Smith, LLC

**The Honorable Michael C. Burgess**

1. **While your companies seem to have put forth effort to improve your system of flagging possible drug diversion, there remains work to be done. In February, the Drug Enforcement Administration announced that it would begin sharing select data it collects on controlled substance prescriptions with drug distributors. Have your companies been able to access that data, and if so, has it been useful?**

Answer: AmerisourceBergen began its acquisition of H. D. Smith in late 2017, which was consummated on January 2, 2018, before this data was made available, and thus H. D. Smith has had no experience with it. It is true that the DEA added a new feature to its ARCOS Online Reporting System which allows DEA-registered manufacturers and distributors to view the number of competitor companies who have sold a particular controlled substance to a prospective customer in the last six months.

2. **What is the largest hurdle you face as your companies scale up your diversion prevention activities? Is data-sharing, or lack thereof, the primary challenge?**

Answer: H. D. Smith had in place a robust diversion control program, continually enhanced and upgraded its program over time, and was in frequent contact with the DEA while developing and then continuously components of the program.

For H. D. Smith, a lack of data sharing and transparency was the primary challenge to our diversion control efforts. We did not have access to information that would allow us to verify whether a particular pharmacy was purchasing from other suppliers, and until very recently did not have access to any prescriber information unless a particular pharmacy voluntarily supplied it.

3. **Throughout each of your written testimonies, you mentioned your efforts to report suspicious orders to the DEA, and in cases that exceed the volume threshold, you stop the orders entirely. Where is the line drawn between drug manufacturers and the DEA in responding to suspicious orders? Does the DEA take enforcement action after you report the suspicious order?**

Answer: Beginning in 2008 when our automated Controlled Substance Monitoring Program (“CSOMP”) system was put in place, orders placed by H. D. Smith’s customers that “triggered” the system were held from shipment and evaluated to determine whether the order was suspicious. For a period of time, orders were reported to the DEA as suspicious as soon as they were held and flagged for evaluation. However, in response to feedback from DEA, we subsequently reported orders to the DEA as suspicious only when a determination was made that an order was suspicious, and was cancelled.

At no time did the DEA ever share any suspicious order reports made by others with respect to orders placed by any West Virginia pharmacy. H. D. Smith does not know whether the DEA shared suspicious order reports made by wholesale drug distributors with drug manufacturers. H. D. Smith did not provide its suspicious order reports to any drug manufacturers.

**House Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations**

**Additional Questions for the Record  
Responses Submitted by Mr. James Christopher Smith  
on Behalf of H.D. Smith, LLC**

H. D. Smith did not have visibility into DEA's internal processes and did not know how the DEA processes, analyzes or uses the suspicious order data the company provided to the agency.

4. **Distributors and other pieces of the drug supply chain have a responsibility to help prevent diversion. What can Congress do legislatively to strengthen oversight of that supply chain?**

Answer: Congress should focus on issues such as: enhanced supply chain data transparency (including ARCOS data sharing and/or data sharing among distributors), additional resources for education and medication safe storage and disposal, and additional support for e-prescribing and enhancing interoperable prescription drug monitoring programs.

**House Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations**

**Additional Questions for the Record  
Responses Submitted by Mr. James Christopher Smith  
on Behalf of H.D. Smith, LLC**

**The Honorable David B. McKinley**

1. **As a Wholesale Distributor of prescription opiates, do you agree that you owe a duty under federal law to monitor, detect, investigate, refuse and report suspicious orders? 21 U.S.C. § 823, 21 CFR 1301.74**

Answer: H. D. Smith has always acknowledged its duties pursuant to the applicable laws. We administered a robust anti-diversion program in order to meet, and in fact exceed, the requirements imposed on it as a distributor. H. D. Smith's CSOMP system allowed us to monitor for suspicious orders of controlled substances, and we also maintained complementary programs such as our robust "Know Your Customer" policies and procedures in connection with its regular education and training of personnel in anti-diversion efforts.

2. **Do you agree that the foreseeable harm of a breach of this duty is the diversion of prescription opiates for nonmedical purposes?**

Answer: H. D. Smith operated a system to monitor, detect, block, and report suspicious orders to the DEA. H. D. Smith invested significantly in our efforts to deter diversion, but there were unavoidable limits to our ability to monitor and prevent diversion given our limited role in the supply chain. For example, distributors such as H. D. Smith have no control over, nor input into, the amount of controlled substances that are produced in a given year. Instead, production quotas are set by the DEA with input from manufacturers. Nor are distributors involved in the licensing and regulation of the medical and pharmaceutical professionals who actually prescribe or dispense controlled substances. That responsibility belongs to federal and state governmental agencies, including the DEA. Finally, distributors do not promote opioids to physicians, healthcare providers or patients.

3. **In other words, if you ship a suspicious order, it is likely that prescription opiates will be diverted into the illicit market. Agree?**

Answer: Beginning in 2008, H. D. Smith automatically blocked any pharmacy order that triggered our CSOMP program by appearing "of interest." H. D. Smith maintained that block unless and until our due diligence demonstrated that the particular order was in fact not a suspicious one.

4. **Do you concur that filling suspicious orders is a direct and proximate cause of prescription opiate abuse, addiction, morbidity and mortality?**

Answer: Beginning in 2008, H. D. Smith automatically blocked any pharmacy order that triggered our CSOMP program by appearing "of interest." H. D. Smith maintained that block unless and until our due diligence demonstrated that the particular order was in fact not a suspicious one. H. D. Smith identified and reported suspicious orders, and did not ship any suspicious orders.

Prescription opiate abuse is a multi-faceted problem with many causes. Distributors play a limited role in the distribution chain for prescription opioids. They (1) are not involved in

**House Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations**

**Additional Questions for the Record  
Responses Submitted by Mr. James Christopher Smith  
on Behalf of H.D. Smith, LLC**

obtaining FDA approval for opioids, labeling or warning about opioids, setting guidelines for prescribing opioids, or marketing opioids to pharmacies, physicians, or patients; (2) have no control over the amount of controlled substances that are produced in a given year (instead, production quotas are set by the DEA with input from manufacturers); (3) are not involved in the licensing and regulation of the medical and pharmaceutical professionals who actually prescribe or dispense controlled substances (that responsibility belongs to federal and state governmental agencies, including the DEA); (4) do not receive or have access to any prescription-level information, unless a pharmacy voluntarily supplies that information; and (5) do not have access to any state prescription drug monitoring program information.

**5. Do you agree the United States is in the midst of a prescription opiate epidemic?**

Answer: H. D. Smith has shared the Committee's concern about the tragic epidemic of opioid abuse. H. D. Smith has always desired and tried to be part of much-needed, and unquestionably multi-faceted, solutions to address this public health crisis. For example, our efforts are evidenced in part by the implementation of our robust CSOMP and training programs, particularly with respect to the reporting not just of suspicious orders but also of potentially problematic individual prescribers.

**6. Do you concur that filling suspicious orders is a direct and proximate cause of the prescription opiate epidemic plaguing our country?**

Answer: Beginning in 2008, H. D. Smith automatically blocked any pharmacy order that triggered its CSOMP program by appearing "of interest." H. D. Smith maintained that block unless and until our due diligence demonstrated that the particular order was in fact not a suspicious one.

Prescription opiate abuse is a multi-faceted problem with many causes. Distributors play a limited role in the distribution chain for prescription opioids. Distributors (1) are not involved in obtaining FDA approval for opioids, labeling or warning about opioids, setting guidelines for prescribing opioids, or marketing opioids to pharmacies, physicians, or patients; (2) have no control over the amount of controlled substances that are produced in a given year (instead, production quotas are set by the DEA with input from manufacturers); (3) are not involved in the licensing and regulation of the medical and pharmaceutical professionals who actually prescribe or dispense controlled substances (that responsibility belongs to federal and state governmental agencies, including the DEA); (4) do not receive or have access to any prescription-level information, unless a pharmacy voluntarily supplies that information; and (5) do not have access to any state prescription drug monitoring program information.

**7. Do you believe the prescription opiate epidemic is an immediate hazard to public health and safety?**

Answer: Prescription opiate abuse is a complex problem that affects many aspects of our society. Distributors play a limited role in the distribution chain for prescription opioids. Distributors (1) are not involved in obtaining FDA approval for opioids, labeling or warning about opioids, setting guidelines for prescribing opioids, or marketing opioids to pharmacies, physicians, or patients; (2) have no control over the amount of controlled substances that are produced in a

**House Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations**

**Additional Questions for the Record  
Responses Submitted by Mr. James Christopher Smith  
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given year (instead, production quotas are set by the DEA with input from manufacturers); (3) are not involved in the licensing and regulation of the medical and pharmaceutical professionals who actually prescribe or dispense controlled substances (that responsibility belongs to federal and state governmental agencies, including the DEA); (4) do not receive or have access to any prescription-level information unless a pharmacy voluntarily supplies that information; and (5) do not have access to any state prescription drug monitoring program information.

**8. Do you believe the prescription opiate epidemic is a public nuisance?**

Answer: Prescription opiate abuse is a complex problem that affects many aspects of our society. Distributors play a limited role in the distribution chain for prescription opioids. Distributors (1) are not involved in obtaining FDA approval for opioids, labeling or warning about opioids, setting guidelines for prescribing opioids, or marketing opioids to pharmacies, physicians, or patients; (2) have no control over the amount of controlled substances that are produced in a given year (instead, production quotas are set by the DEA with input from manufacturers); (3) are not involved in the licensing and regulation of the medical and pharmaceutical professionals who actually prescribe or dispense controlled substances (that responsibility belongs to federal and state governmental agencies, including the DEA); (4) do not receive or have access to any prescription-level information unless a pharmacy voluntarily supplies that information; and (5) do not have access to any state prescription drug program monitoring information.

**9. Are you aware of your company's efforts to detect, address, and report suspiciously large orders in West Virginia?**

Answer: H. D. Smith's CSOMP system was specifically designed to identify potential suspicious orders before the orders are shipped. The CSOMP system was used across all areas of the country that we served, including for customers in West Virginia. The development of H. D. Smith's CSOMP was consistent with DEA's guidance, including the September 2006, February 2007, and December 2007 letters sent by DEA to the distributors.

H. D. Smith reported to the DEA all suspicious orders, including those in West Virginia. Between 2008 and 2009, we reported many suspicious orders to the DEA from West Virginia customers.

Although gathering dispensing and prescribing data from customers was often difficult, if H. D. Smith could obtain it, we were able to analyze such information to great effect along with the data collected by way of CSOMP. For example, in February 2008, we requested, obtained, and evaluated data from West Virginia customers Hurley Drug Company, Tug Valley Pharmacy, and Sav-Rite No. 1/Strosnider Pharmacy. We concluded that two physicians were frequently writing prescriptions for hydrocodone, and that their patterns were cause for concern. H. D. Smith reported our analysis and concerns to the DEA on April 25, 2008, and cooperated with additional follow-up requests from the DEA.

**10. Are you aware that for years your company never followed West Virginia's law by reporting all suspicious orders to the West Virginia Board of Pharmacy?**

Answer: No, H. D. Smith did not always report suspicious orders to the West Virginia Board of Pharmacy because we believed it was not required to do so. At the time, H. D. Smith was



**House Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations**

**Additional Questions for the Record  
Responses Submitted by Mr. James Christopher Smith  
on Behalf of H.D. Smith, LLC**

classified as an out-of-state permit holder (as opposed to an in-state licensee), and one of our employees was told by the West Virginia Board of Pharmacy that we were required to comply with the West Virginia Controlled Substances Act, but that the Board of Pharmacy regulations (which include suspicious order reporting to the Board) did not apply to us as a permittee. Additionally, the head of the West Virginia Board of Pharmacy has repeatedly stated publicly, and testified in litigation, that the West Virginia Board of Pharmacy received very few suspicious order reports prior to 2012 and, when it started to receive suspicious orders, took no action in response to those orders. Since then, to the extent H. D. Smith reported a suspicious order to the DEA, it also reported that order to the West Virginia Board of Pharmacy.

It is also worth noting that West Virginia was an “early adopter,” in 1995, of a Prescription Drug Monitoring Program. The program is extremely detailed and comprehensive, and requires every prescriber and every dispenser in the state to report every controlled substance pill prescribed and dispensed at least daily. The DEA, the State Police, all medical licensing boards, etc., have unlimited access to this database. The Legislature charges the Board with several duties, including the duty to capture and report on “abnormal or unusual practices of patients and prescribers.”

**11. Did your company have a policy that orders had to be less than 50% controlled substances to be filled?**

Answer: H. D. Smith did not have such a policy. However, all prospective customers were asked when filling out new customer forms what percentage of their orders they expected would be controlled substances. Additionally, H. D. Smith’s CSOMP system took into account the ratios between purchases of controlled substances and purchases of other prescription and over-the-counter products by its customers. That ratio was closely monitored to identify any issues of concern regarding potential diversion activity.

House Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations

Additional Questions for the Record  
Responses Submitted by Mr. James Christopher Smith  
on Behalf of H.D. Smith, LLC

**The Honorable Frank Pallone, Jr.**

1. In one of the documents H.D. Smith provided to the Committee, you list the total hydrocodone and oxycodone pills sold by H.D. Smith to purchasers in West Virginia from 2006 through 2017. According to that information, H.D. Smith sent over 17 million hydrocodone and oxycodone pills to West Virginia between 2007 and 2011. That includes 6 million pills sent to the state in 2008 alone. But H.D. Smith's shipments to West Virginia plummeted in later years. For example, H.D. Smith provided 583,400 hydrocodone pills to West Virginia in 2017. Back in 2008, H.D. Smith had shipped almost 10 times that amount, or about 5.4 million hydrocodone pills, according to the company's data. The next year, 2009, H.D. Smith also shipped a very high amount, which was about 2.8 million pills. I understand that prescribing went down in recent years, but did additional due-diligence or recognition of the unfolding opioid crisis lead to far fewer pills in these later years than in the earlier years?

Answer: The primary driver of H. D. Smith's sales is and always has been the orders placed by its customers. There are many factors that could be driving the reduction in orders placed by customers in West Virginia. For example, changes in the number of customers being served could drive changes in shipments. It is possible that the implementation of the automated CSOMP system contributed to the decline in controlled substances being shipped. H.D. Smith used data collected through its CSOMP system to identify, investigate and terminate certain West Virginia customers for suspicious order patterns or other reasons related to diversion control. CSOMP data contributed to H. D. Smith's decision to close West Virginia pharmacy Sav-Rite No. 1's account in April 2009. As a result of CSOMP data and an on-site visit, H. D. Smith terminated another West Virginia pharmacy Tug Valley's account in August 2009. H. D. Smith closed another West Virginia Pharmacy, Westside Pharmacy's account in January 2011. Additionally, H. D. Smith blocked two West Virginia pharmacies, Family Discount and Hurley Drug, from purchasing certain controlled substances in February and March of 2011, respectively.

Moreover, changes in physician prescribing practices could have resulted in reduced ordering by pharmacies.

2. Did H. D. Smith attempt to look at these trends both rising and falling to determine if something problematic was happening regarding the company's distribution in West Virginia?

Answer: It is also worth noting that during the time it was designing and implementing its CSOMP system, H. D. Smith understood that the DEA was very concerned about internet pharmacies and diversion in Florida in particular. But the DEA did not communicate that there were any diversion issues then existing in West Virginia or Appalachia generally. Indeed, Internet pharmacies were the specific topic of a DEA distributor briefing Kyle Wright made to H. D. Smith's head of compliance on January 4, 2007. On October 10, 2007, H. D. Smith met with Wright again for another distributor briefing and agreed to develop what became CSOMP. But before conducting that distributor briefing on October 10, 2007, Wright performed his own detailed analysis of H. D. Smith's national ARCOS data to identify H. D. Smith customers whom

**House Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations**

**Additional Questions for the Record  
Responses Submitted by Mr. James Christopher Smith  
on Behalf of H.D. Smith, LLC**

he believed needed additional scrutiny based on unusual or suspicious ordering patterns. Wright, through his analysis, found that no West Virginia pharmacy warranted additional scrutiny.

House Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations

Additional Questions for the Record  
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on Behalf of H.D. Smith, LLC

The Honorable Jan Schakowsky

1. Does your company buy the drugs from the manufacturers, take title and move pallets to and from your warehouse? Or are you like brokers, working on consignment, arranging sales to pharmacies and then taking a percentage of the sale price?

Answer: H. D. Smith is now part of ABC as a result of the ABC acquisition and thus defers to ABC on these questions.

2. In setting prices to pharmacies, is your markup more like a flat rate (for example, selling \$5 more than the price at which you bought), or is your markup more like a percentage (for example, selling for 5% higher than the price at which you bought)?

Answer: H. D. Smith is now part of ABC as a result of the ABC acquisition and thus defers to ABC on these questions.

3. Is it possible that even if your company pays a higher price to get those drugs in stock, you end up making more money on those sales where your acquisition prices are higher? And would the same be true for your consignment/broker sales?

Answer: H. D. Smith is now part of ABC as a result of the ABC acquisition and thus defers to ABC on these questions.