

MODERNIZING FDA'S REGULATION OF OVER-THE-COUNTER DRUGS

HEARING BEFORE THE SUBCOMMITTEE ON HEALTH OF THE COMMITTEE ON ENERGY AND COMMERCE HOUSE OF REPRESENTATIVES ONE HUNDRED FIFTEENTH CONGRESS FIRST SESSION

SEPTEMBER 13, 2017

Serial No. 115-55



Printed for the use of the Committee on Energy and Commerce
energycommerce.house.gov

U.S. GOVERNMENT PUBLISHING OFFICE

27-228 PDF

WASHINGTON : 2018

COMMITTEE ON ENERGY AND COMMERCE

GREG WALDEN, Oregon

Chairman

JOE BARTON, Texas	FRANK PALLONE, Jr., New Jersey
<i>Vice Chairman</i>	<i>Ranking Member</i>
FRED UPTON, Michigan	BOBBY L. RUSH, Illinois
JOHN SHIMKUS, Illinois	ANNA G. ESHOO, California
TIM MURPHY, Pennsylvania	ELIOT L. ENGEL, New York
MICHAEL C. BURGESS, Texas	GENE GREEN, Texas
MARSHA BLACKBURN, Tennessee	DIANA DEGETTE, Colorado
STEVE SCALISE, Louisiana	MICHAEL F. DOYLE, Pennsylvania
ROBERT E. LATTA, Ohio	JANICE D. SCHAKOWSKY, Illinois
CATHY McMORRIS RODGERS, Washington	G.K. BUTTERFIELD, North Carolina
GREGG HARPER, Mississippi	DORIS O. MATSUI, California
LEONARD LANCE, New Jersey	KATHY CASTOR, Florida
BRETT GUTHRIE, Kentucky	JOHN P. SARBANES, Maryland
PETE OLSON, Texas	JERRY McNERNEY, California
DAVID B. McKINLEY, West Virginia	PETER WELCH, Vermont
ADAM KINZINGER, Illinois	BEN RAY LUJAN, New Mexico
H. MORGAN GRIFFITH, Virginia	PAUL TONKO, New York
GUS M. BILIRAKIS, Florida	YVETTE D. CLARKE, New York
BILL JOHNSON, Ohio	DAVID LOEBSACK, Iowa
BILLY LONG, Missouri	KURT SCHRADER, Oregon
LARRY BUCSHON, Indiana	JOSEPH P. KENNEDY, III, Massachusetts
BILL FLORES, Texas	TONY CARDENAS, California
SUSAN W. BROOKS, Indiana	RAUL RUIZ, California
MARKWAYNE MULLIN, Oklahoma	SCOTT H. PETERS, California
RICHARD HUDSON, North Carolina	DEBBIE DINGELL, Michigan
CHRIS COLLINS, New York	
KEVIN CRAMER, North Dakota	
TIM WALBERG, Michigan	
MIMI WALTERS, California	
RYAN A. COSTELLO, Pennsylvania	
EARL L. "BUDDY" CARTER, Georgia	

SUBCOMMITTEE ON HEALTH

MICHAEL C. BURGESS, Texas

Chairman

BRETT GUTHRIE, Kentucky	GENE GREEN, Texas
<i>Vice Chairman</i>	<i>Ranking Member</i>
JOE BARTON, Texas	ELIOT L. ENGEL, New York
FRED UPTON, Michigan	JANICE D. SCHAKOWSKY, Illinois
JOHN SHIMKUS, Illinois	G.K. BUTTERFIELD, North Carolina
TIM MURPHY, Pennsylvania	DORIS O. MATSUI, California
MARSHA BLACKBURN, Tennessee	KATHY CASTOR, Florida
CATHY McMORRIS RODGERS, Washington	JOHN P. SARBANES, Maryland
LEONARD LANCE, New Jersey	BEN RAY LUJAN, New Mexico
H. MORGAN GRIFFITH, Virginia	KURT SCHRADER, Oregon
GUS M. BILIRAKIS, Florida	JOSEPH P. KENNEDY, III, Massachusetts
BILLY LONG, Missouri	TONY CARDENAS, California
LARRY BUCSHON, Indiana	ANNA G. ESHOO, California
SUSAN W. BROOKS, Indiana	DIANA DEGETTE, Colorado
MARKWAYNE MULLIN, Oklahoma	FRANK PALLONE, Jr., New Jersey (<i>ex officio</i>)
RICHARD HUDSON, North Carolina	
CHRIS COLLINS, New York	
EARL L. "BUDDY" CARTER, Georgia	
GREG WALDEN, Oregon (<i>ex officio</i>)	

C O N T E N T S

	Page
Hon. Michael C. Burgess, a Representative in Congress from the State of Texas, opening statement	1
Prepared statement	2
Hon. Gene Green, a Representative in Congress from the State of Texas, opening statement	3
Hon. Greg Walden, a Representative in Congress from the State of Oregon, opening statement	5
Prepared statement	6
Hon. Frank Pallone, a Representative in Congress from the State of New Jersey, opening statement	7
Prepared statement	8

WITNESSES

Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, Food and Drug Administration, Department of Health and Human Services	10
Prepared statement	12
Answers to submitted questions ¹	140
Scott Melville, President and Chief Executive Officer, Consumer Healthcare Products Association	95
Prepared statement	97
Answers to submitted questions	143
Kirsten Moore, Project Director, Healthcare Products, The Pew Charitable Trusts	100
Prepared statement	102
Answers to submitted questions	146
Michael Werner, Partner, Holland & Knight, on behalf of the Public Access to SunScreens (PASS) Coalition	107
Prepared statement	109
Answers to submitted questions	150
Bridgette L. Jones, M.D., Chair, Committee on Drugs, American Academy of Pediatrics	118
Prepared statement	120
Gil Y. Roth, President, Pharma and Biopharma Outsourcing Association	125
Prepared statement	127

SUBMITTED MATERIAL

Discussion Draft, H.R. _____, the Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2017 ²	
Letter of September 13, 2017, from Colin MacKenzie, Region Head, Americas, GSK Consumer Healthcare, to Mr. Burgess and Mr. Green, submitted by Mr. Lance	139

¹ Dr. Woodcock did not answer submitted questions for the record by the time of printing.

² The information has been retained in committee files and also is available at <http://docs.house.gov/meetings/IF/IF14/20170913/106396/BILLS-115pjh-OTCMonograph.pdf>.

MODERNIZING FDA'S REGULATION OF OVER-THE-COUNTER DRUGS

WEDNESDAY, SEPTEMBER 13, 2017

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:15 a.m., in Room 2322, Rayburn House Office Building, Hon. Michael C. Burgess (chairman of the subcommittee) presiding.

Members present: Representatives Burgess, Guthrie, Barton, Upton, Murphy, Lance, Griffith, Bilirakis, Long, Bucshon, Brooks, Mullin, Hudson, Collins, Carter, Walden (ex officio), Green, Engel, Schakowsky, Butterfield, Sarbanes, Schrader, Kennedy, Eshoo, DeGette, and Pallone (ex officio).

Also present: Representatives Latta, Costello, and Dingell.

Staff present: Mike Bloomquist, Deputy Staff Director; Kelly Collins, Staff Assistant; Zack Dareshori, Staff Assistant; Paul Edattel, Chief Counsel, Health; Jay Gulshen, Legislative Clerk, Health; Elena Hernandez, Press Secretary; Edward Kim, Senior Policy Advisor, Health; Alex Miller, Video Production Aide and Press Assistant; Jennifer Sherman, Press Secretary; Jeff Carroll, Minority Staff Director; Samantha Satchell, Minority Policy Analyst; Andrew Souvall, Minority Director of Communications, Member Services, and Outreach; C.J. Young, Minority Press Secretary.

Mr. BURGESS. The Subcommittee on Health will now come to order. I will recognize myself 5 minutes for an opening statement.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Today's hearing marks the Health Subcommittee's first public discussion on modernizing the current system at the United States Food and Drug Administration to review, approve, and update over-the-counter drugs. This hearing provides us and the American public with an opportunity to better understand the Food and Drug Administration's regulatory framework to regulate over-the-counter drugs and to consider a proposal to reform the monograph system.¹

Today we will convene two panels of witnesses. First, I want to welcome Dr. Woodcock back to our subcommittee this morning. Later, we will hear from representatives of other key stakeholders

¹The proposed legislation has been retained in committee files and also is available at <http://docs.house.gov/meetings/IF/IF14/20170913/106396/BILLS-115pth-OTCMonograph.pdf>.

and I would to commend all for their efforts throughout the negotiation process and for offering their insights to the committee.

Both the Energy and Commerce Health Subcommittee and the full committee have a strong record of bipartisanship on important public health issues such as 21st Century Cures, the FDA reauthorization Act, and I hope to add to that record of success with today's hearing.

Over-the-counter drug products treat a wide variety of ailments. Time and again, consumers seek antacids, pain relievers, eye drops, cough products as a first line treatment option before going to see their doctor and getting a prescription. These products also include anti-bacterial soaps, hand sanitizers, sunscreens and the sunscreens commonly used by many families in the United States.

Currently, there are more than 300,000 over-the-counter products on the market according to the Food and Drug Administration. These products go through one of two approval processes to reach the store shelf. Manufacturers can one, submit a new drug application similar to new prescription drugs; or, they may conform to an OTC monograph which is a set of specific standards created by the Food and Drug Administration that ensures the product's active ingredients are generally recognized as safe and effective.

The vast majority of over-the-counter products rely on the over-the-counter drug monograph system. Unfortunately, the current system has not had a significant update since the Food and Drug Administration first established this in 1972. So that is well over 40 years. In addition, this system requires a burdensome multistep rulemaking process that can take years to resolve. All of this has led to a lack of innovation and an inability for timely updates to address safety issues and much work unfinished at the Food and Drug Administration. Most of us on the committee feel that is unacceptable.

The good news is, is that there is broad support from the Food and Drug Administration, from industry stakeholders, from patient groups for significant reform to regulate over-the-counter products. The Health Subcommittee will examine Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2017. The discussion draft was recently released by Representatives Latta, DeGette, Guthrie, Dingell, Green and myself. This bipartisan proposal establishes the over-the-counter monograph user fee program that makes a number of meaningful modifications to the monograph process. The goal is to create a system that is more flexible and more efficient, that reflects scientific innovations so that patients and consumers have greater access to better and safer over-the-counter drug products.

Again, I want to welcome and thank all of our witnesses for being here this morning. We certainly look forward to your testimony.

PREPARED STATEMENT OF HON. MICHAEL C. BURGESS

The subcommittee will come to order.

The Chair will recognize himself for an opening statement.

Today's hearing marks the Health Subcommittee's first public discussion on modernizing the current system at the U.S. Food and Drug Administration (FDA) to review, approve, and update over-the-counter (OTC) drugs. This hearing provides us and the American public with an opportunity to better understand FDA's regulatory

framework to regulate OTC drugs and to consider a proposal to reform the OTC monograph system.

Today we will convene two panels of witnesses. First, I want to welcome Dr. Woodcock back to this subcommittee this morning. Later, we will hear from representatives of other key stakeholders. I would like to commend all of their efforts throughout the negotiation process, and for offering their insights to Congress. Both the Energy and Commerce Health Subcommittee and the full committee have a strong record of bipartisanship on important public health issues, such as the 21st Century Cures Act and the FDA Reauthorization Act. I hope to add to that record with today's hearing.

OTC drug products treat a wide variety of ailments. Time and again, consumers seek antacids, pain relievers, eye drops, and cough products as first-line treatment options before going to see their doctor and getting a prescription. These products also include antibacterial soaps, hand sanitizers, and sunscreens commonly used by many families in the U.S. Currently, there are more than 300,000 OTC products on the market according to FDA. These products go through one of two approval processes to reach store shelves. Manufacturers can (1) submit a new drug application similar to new prescription drugs, or (2) conform to an OTC drug monograph, which is a set of specific standards created by FDA, that ensures the products' active ingredients are generally recognized as safe and effective.

The vast majority of OTC products rely on the OTC drug monograph system. Unfortunately, the current system has not had a significant update since FDA first established it in 1972—that's over 40 years. In addition, this system requires a burdensome, multi-step rule-making process that can take years to resolve. All of this has led to a lack of medical innovation, an inability for timely updates to address safety issues, and much work left unfinished at FDA. That is unacceptable. The good news is there is broad support from FDA, industry stakeholders, and patient groups for significant reform to regulate OTC products.

The Health Subcommittee will examine the Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2017 discussion draft recently released by Representatives Latta, DeGette, Guthrie, Dingell, Green, and myself. This bipartisan proposal establishes the OTC Monograph User Fee Program and makes a number of meaningful modifications to the monograph process. The goal is to create a system that is more flexible and more efficient, and reflects the scientific innovations so that patients and consumers have greater access to better and safer OTC drug products.

I again want to welcome all of our witnesses and thank you for being here. I look forward to your testimony.

Mr. BURGESS. Before I yield to the ranking member, one housekeeping detail. Although this is the premier committee for technology in the United States Congress, some of our systems are not working this morning. So, I understand Dr. Woodcock had a series of slides, so those will be made available to you in paper form. We require our doctors to go paperless, but here on the committee, we can still deal with paper. And the clock is working, but only I can see it, Dr. Woodcock. So the red, green, and yellow lights are not working. I will give a brief two clicks when we are getting down into the yellow zone so that you will know that the time is to wrap up, and we will do that obviously for everyone on the committee, just as a gentle reminder we are coming to the end.

So with that, I yield back and recognize the ranking member of the subcommittee, Mr. Green of Texas.

**OPENING STATEMENT OF HON. GENE GREEN, A
REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS**

Mr. GREEN. Thank you, Mr. Chairman. Thank you, Dr. Woodcock, and all of our witnesses here this morning.

The over-the-counter OTC drugs are routinely used to treat a wide variety of ailments. We can go our local Walgreen's, CVS, or other retailer and don't even think about that bottle of Ibuprofen or sunscreen like we do with a prescription drug. OTC drugs provide a low cost, convenient way to take care of everyday healthcare

needs. We have a growing number of choices in our local drug-stores.

According to the FDA and the Consumer Healthcare Products Association, the OTC market now includes more than 300,000 products with annual sales of \$32 billion. The items available over-the-counter are diverse, ranging from cough and cold medications, and pain relievers to sunscreens, and soon, hearing aids. The FDA regulates most of these drugs on store shelves under the OTC monograph system. The active ingredients in these nonprescription products are considered safe and effective when the consumers follow their instructions on the label without direction from a healthcare provider. While that is largely true in theory, many contain ingredients that the FDA that is not yet evaluated or known to be misused for labels, have not been modified to warn consumers of potential harms.

The current system also poses challenges for consumer access to potentially better, safer, innovative products. The regulatory framework for FDA oversight of most over-the-counter products are put into place in 1972 and has not been updated, despite an increasingly diverse and large market. The need for reform was brought into sharper focus when this committee worked on the Sunscreen Innovation Act in the 113th Congress. Under the current system, an OTC drugs monograph is established through a three-step public ruling process, with each step requiring publication in the Federal Register in the public comment period. This antiquated system is overly burdensome and time consuming, and, frankly, doesn't work very well. It is unable to respond quickly to safety concerns and keep pace with scientific discovery, which places consumers at risk and slows development of new drugs.

Today, the FDA has an estimated 88 rulemakings in 26 therapeutic categories that cover over 100 OTC products. It is one of the largest and most complex regulatory schemes and also dramatically underresourced. The agency has 30 full-time employees for the entire monograph program, and a budget of roughly \$8 million. For context, 18 full-time employees are devoted to the review of one novel drug application. And again, the OTC market now includes more than 300,000 products with annual sales of \$32 billion.

Recognizing the resource and process, challenges the OTC monograph program stakeholders and FDA begin to think about how it could work better and value the establishing of the user fee program. Congressman Latta and I, along with Representative Dingell, DeGette, Guthrie and Burgess have been working on a bipartisan fashion to put together a bill that would establish and OTC user fee program and reform the monograph system.

Today, we have a discussion draft that reflects the work of the stakeholders, the FDA, and Congress. And I am happy to see the committee moving forward. I want to note that we should be considering doing the same with cosmetics. There are many parallels between cosmetics and OTC products and the way consumers use and think about cosmetics and OTC products. And also, the challenges the FDA faces in overseeing the category of everyday items that impact our health. OTC monograph reform will help foster growth in the availability of these medicines. Policy reforms can make the system even more flexible, responsive and accommo-

dating to innovation and knowledge about potential harms for misuse, ultimately modernizing the OTC monograph system will ensure that the FDA industry can update products with safe, effective ingredients, broad and consumer choice, and ensure the FDA has the resources to approve safety, labeling changes innovation in the OTC market. I look forward to hearing from our witnesses about this. And I would like to yield the remainder of my time to Congresswoman DeGette.

Ms. DEGETTE. I would like to thank you for working on this important bill with us. As the chairman said, it has been 40 years that we have had this monograph system, but we haven't really made any updates to it and as a result, the system does not respond to emerging safety issues which creates serious problems for consumers. In 2006, for example, the FDA learned common cough medication tragically caused several toddlers to die. For 10 years, the FDA has been trying to revise the cough and cold monograph to warn parents of the risks to young children. Their efforts have been unsuccessful due to the extremely burdensome process the FDA must use to update and change monographs. What this would do is give the FDA new tools protect consumers streamline how FDA would use over-the-counter medicines.

Dr. Woodcock, I am extremely glad you are here with us today to give us the same kind of guidance you give us in 21st Century Cures and other issues. We really have a great opportunity to upgrade the regulatory process in a way that benefits everybody, the American public, and the Federal Government, and the regulated industry alike. I look forward to continuing to work with my colleagues to support this bill and I thank you very much, Mr. Chairman, for holding this hearing.

I yield back.

Mr. BURGESS. The gentleman from Texas yields back. The Chair recognizes the gentleman from Oregon, the chairman of the full committee, Mr. Walden, 5 minutes.

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

Mr. WALDEN. Thank you, Mr. Chairman. I appreciate your holding the hearing on these important issues and the long overdue reforms needed at the FDA to improve efficiency and update their framework for regulating over-the-counter drug products.

Following the successful 5-year reauthorization of several of FDA's critical medical device user fee programs, there is no better time to continue our work than now and in this space. I am pleased with the bipartisan effort that has already begun. From cough and cold medicines to antiperspirants and antacids, the pharmacy aisles and medicine cabinets are filled with over-the-counter, or OTC drugs that American consumers rely upon daily.

Unfortunately, the regulatory process as we have heard has been the same since the 1970s, and while bell bottom pants I see are coming back, we need to—it is remarkable, isn't it? We need to innovate in this sector, and safety-related changes often take years to implement is simply unacceptable.

Fortunately, FDA, regulated industry patients, consumer groups, all agree that significant reform is something we all need to join

hands on. For several years now, they have engaged in productive conversations about how to substantially improve upon the status quo. Informed by this ongoing dialogue, we now have bipartisan resolution before us today that will ensure Americans have more timely access to innovative, safe and effective OTC medicines.

Consumers will no longer have to wait years for an inflexible rulemaking process to wind its way through the bureaucracy before benefiting from product improvements. So I really want to thank our colleagues Mr. Latta, Ms. DeGette, Mr. Guthrie, Mrs. Dingell, as well as Chairman Burgess, Ranking Member Green, my colleague, Mr. Pallone, and others who have put their shoulder to the wheel on this one. We have proven time and again in the committee, we know how to legislate in a bipartisan way to get good things done for the American consumers, and we are going to do it again here.

[The prepared statement of Mr. Walden follows:]

PREPARED STATEMENT OF HON. GREG WALDEN

Thank you, Chairman Burgess, for holding this important hearing to consider long overdue reforms to FDA's inefficient and outdated framework for regulating over-the-counter (OTC) drug products.

Following the successful 5-year reauthorization of several of FDA's critical medical device user fee programs, there is no better time to continue our work in this space.

From cough and cold medicines to antiperspirants and antacids, pharmacy aisles and medicine cabinets are filled with over-the-counter, or OTC, drugs that American consumers rely on daily. Unfortunately, the regulatory process in place at FDA has not been updated since the 1970s. As a result, there has been little to no innovation in this sector, and safety-related changes often take years to implement. This is simply unacceptable.

Fortunately, FDA, regulated industry, and patient and consumer groups all agree that significant reform is necessary. For several years now, they have engaged in productive conversations about how to substantially improve upon the status quo. Informed by this ongoing dialogue, we have a bipartisan solution before us today that will ensure Americans have more timely access to innovative, safe and effective OTC medicines. Consumers will no longer have to wait years for an inflexible rulemaking process to wind its way through the bureaucracy before benefiting from product improvements.

I would like to thank my colleagues Bob Latta (R-OH), Diana DeGette (D-CO), Brett Guthrie (R-KY), Debbie Dingell (D-MI), as well as Chairman Burgess and Ranking Member Green for their hard work on getting us to this point. I look forward to hearing from our witnesses today about ways we can improve the draft legislation being considered, and I yield the balance of my time to Rep. _____.

Mr. WALDEN. With that, I am going to yield to the gentleman from Ohio, Mr. Latta, the remainder of my time.

Mr. LATTA. Well, I thank the chairman for yielding. And I also thank Chairman Burgess for holding today's hearing on this very important issue. I also want to thank our witnesses for being with us today to provide the insight on this topic and on the legislation. It has already been said, over-the-counter medicines are in nearly every household in our Nation. Yet despite widespread utilization, the system in place to regulate these drugs has been outdated for decades. It is time to move forward to a more flexible framework that will spur innovation, expand consumer choice, and better address potential safety concerns.

I believe the discussion draft before us today will achieve these goals and provide predictability to the drug approval process. The OTC Monograph Safety, Innovation Reform Act is the product of

the bipartisan collaboration between myself, the chairman of the subcommittee, Mr. Burgess, Ranking Member Green, Ms. DeGette, Vice Chairman Guthrie, and Mrs. Dingell, as well as significant contributions from the FDA and the industry.

I would like to thank all those involved who worked tirelessly on this effort in order to increase consumer choice and safety. I appreciate the chairman for allowing the opportunity to discuss the monograph reform and improve upon the proposed and presented in the discussion draft today. I look forward to hearing today's testimony receiving input from my colleagues on the subcommittee. I thank the chairman for holding today's hearing, and for our witnesses and I yield back. I am sorry, and I yield to Mr. Guthrie.

Mr. GUTHRIE. Thank you for yielding the chairman's time. I appreciate it. Mr. Chairman, I want to thank you for holding this important hearing today and examine the review process of over-the-counter drugs.

This important bill would enable greater innovations and foster FDA efficiencies within the approval process of over-the-counter drugs, something that has not been done since the 1970s. And I want to specifically thank the Congressman Latta for his leadership on this issue. I am proud to be a lead cosponsor with Congressman Latta and several of my colleagues on this important bipartisan bill which industry FDA and the committee staff have worked so hard to move forward. I strongly believe this legislation help every American as these products are the first in the line of defense against common ailments.

And Dr. Woodcock, I always appreciate you being here, and I thank our other witnesses who will follow for being here as well today. If there is no one else who is yielding Chairman Walden's time, I will yield back.

Mr. BURGESS. The gentleman from Oregon yields back. The Chair thanks the gentleman. The Chair now recognizes the gentleman from New Jersey, Mr. Pallone, for 5 minutes for an opening statement, please.

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

Mr. PALLONE. Thank you, Mr. Chairman. I want to thank you also for holding today's hearing on the over-the-counter drug monograph reform and establishment of over-the-counter monograph user fee program. I also want to commend our Ranking Member Green, Representatives DeGette, Latta, Guthrie, and Dingell, as well as the chairman of the full committee for your work in crafting a proposal that will accomplish these goals.

The safety and effectiveness of over-the-counter drugs is established today through conformance with a monograph, this so-called rule book outlines the conditions of use for particular drug ingredient that outlines the dosage form, patient population, labeling and warnings and other requirements. This rule book is established through a three-phase rulemaking process, but is oftentimes inflexible and time-consuming, making it difficult for FDA to quickly revise or update monographs in response to safety or other issues. We have also heard from FDA and industry that the mono-

graph process does not lend itself well to evolving science and technology, and may have the unintended effect of discouraging the development of new formulation. Not only is it clear that regulatory reform is needed, but the current program is drastically under-resourced.

So today, the OTC monograph program oversees more than 100,000 products with a staff of 30 people, and a budget of just over \$8 million. It is my hope that through regulatory reform and increased predictable resources, we can streamline the over-the-counter process to allow for swift finalization of current monographs, timely updates, and encourage innovation where possible.

And while we are beginning the process of making significant improvements to the review of over-the-counter products, I had hoped that we would begin taking action today on cosmetics. Millions of Americans use cosmetic products every day, but FDA's regulatory authority over cosmetics is woefully inadequate. In just the last year, millions of women and children have been exposed to shampoos that can cause extraordinary hair loss, lip balm that can cause blistering and rashes, and eye shimmer tainted by asbestos.

Unfortunately, FDA does not have the authority today to hold these manufacturers responsible, and has very little ability to assure that these cosmetics are safe. And this simply can't continue. And as we move forward with this process, we should provide adequate resourcing and authority for cosmetics as well. And I look forward to continuing to work with my colleagues, the FDA industry and other stakeholders to accomplish both of these goals and ensure that continued availability and safety of the means of drug products and personal care products people use every day.

[The prepared statement of Mr. Pallone follows:]

PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

Thank you, Mr. Chairman. Today we will markup bipartisan bills aimed at improving care in the Medicare program. Medicare plays a critical role in the lives of our Nation's seniors and Americans with disabilities. The committee's efforts to continuously improve this program will ensure the highest quality care to these beneficiaries.

First, I'm pleased we're marking up H.R. 1148, the FAST Act, introduced by Representatives Joyce and Griffith. Stroke telemedicine, also known as telestroke, breaks down barriers to care and is a valuable tool for combatting our Nation's fifth leading cause of death. The FAST Act would expand coverage of telestroke services so that beneficiaries can get the right treatment at the right time, no matter where they live. When it comes to stroke—every second counts.

I am also pleased to markup H.R. 3263, to extend the Independence at Home Demonstration, which allows seniors with complex and expensive chronic conditions to receive team-based, primary care in their own home. This model reduces costs and barriers to access for vulnerable seniors while also ensuring that beneficiaries receive care where they feel most comfortable. Improving both the quality and comfort of care for seniors suffering from complex conditions is critical to the sustainability of Medicare.

I also look forward to more discussion today on H.R. 3271, introduced by Representatives DeGette and Brooks. Medicare beneficiaries with diabetes should have a choice in their testing supplies. They should be able to access testing strips compatible with the blood glucose monitor of their choice. They should also be protected by law from coercive practices from suppliers. H.R. 3271 would require stronger CMS assurances that suppliers carry a greater variety of testing supplies and make it easier for beneficiaries to switch testing supplies when they want to. This bill will improve the quality of service available through the national mail-order program to the growing number Medicare beneficiaries living with diabetes.

We are also marking up four other bills that aim to make meaningful changes to the Medicare program by protecting beneficiaries, reducing provider burden, and improving program integrity. I look forward to working on a bipartisan basis today to advance these important bills to the full committee.

Thank you, I yield back.

Mr. PALLONE. So I would like to yield the time that I have left to Mrs. Dingell.

Mrs. DINGELL. I thank my colleague for yielding.

Americans deserve piece of mind in knowing that all drugs they take are safe and effective, whether it is a prescription drug or an over-the-counter drug. There are 300,000 over-the-counter products on the market today, which American's use in everyday life. Yet, FDA's regulatory system for OTCs is completely broken. The agency has a meager budget of \$8 million, which all of us keep saying over and over in a cumbersome process that hinders the agency's ability to both address safety risks and let new and innovative products come to market.

The draft legislation creates a new user fee system for the OTC products to give FDA the resources it needs to do its job of ensuring patient safety. It also allows the agency to move quickly to update and revise the monograph system through administrative orders, rather than noticing comment rulemaking, which are similar to the reforms made under the Sunscreen Innovation Act.

We have seen the benefits that user fees have brought to the regulation of prescription drugs and medical devices, and it is time to bring the system to the OTC space as well. And while I am very pleased that we are holding this hearing and moving forward with the OTC legislation, I want to commend Mr. Pallone for the same comments made about the cosmetic industry, which also would desperately benefit from singular reforms, and hope the committee soon move forward with legislation establishing a user fee program for these products.

I want to thank my colleagues, Congressman Latta, Green, Burgess, Guthrie, and DeGette, for working with me on this draft legislation. I look forward to continuing our work together to reach consensus on this important issue, and as always, our chairman and ranking minority member are supportive.

I yield back the balance of my time.

Mr. PALLONE. And I yield back, Mr. Chairman.

Mr. BURGESS. The gentleman from New Jersey yields back. This concludes Member opening statements. And the Chair would remind Members that, pursuant to committee rules, all Members' opening statements will be made part of the record. We do want to thank our witnesses for being here with us this morning, for taking the time to testify before the subcommittee.

Each witness will have the opportunity to give an opening statement, followed by questions from Members. Today we will start with our first panel and hear from Dr. Janet Woodcock, the Director of FDA's Center for Drug Evaluation and Research. We appreciate you being here this morning, Dr. Woodcock. You are recognized for 5 minutes for your opening statement, please.

STATEMENT OF JANET WOODCOCK, M.D., DIRECTOR, CENTER FOR DRUG EVALUATION AND RESEARCH, FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. WOODCOCK. Thank you. We are here to talk about modernizing the monograph system for OTC drugs. Probably everyone in this room has used an OTC drug at one time or another, an OTC monograph drug, in fact. I know I have. These medicines allow us to manage minor health problems without going consulting a health professional, to manage them on our own. And millions of Americans use these products every day. They are widespread, and I believe there is more exposure of Americans to these OTC monograph drugs than there are to prescription drugs in this country. The monograph system allows manufacturers to come on the market without the burdensome per product application process that we use for generics or for new drugs. So this is a much-simplified system.

So why the push for reform? Well, as the Members have already said, the monograph process was put in place a long time ago to deal with the hundreds of thousands of products on the market after Congress passed the 62 amendments to the Food and Drug Administration Act requiring drugs on the market to show that they were effective. And so FDA had to deal with that in some way.

And since many of the OTC products were a different version of the same basic ingredients, FDA decided to deal with them in groups. If it was found that X ingredient at Y dose in dosage form was effective for Z condition, OK? These facts would be put in a regulation and any manufacturer could come on the market as long as they conformed to those conditions. Of course, these manufacturers were also subject to inspection and GMP's for their manufacturing and that is still the case.

But their problems emerged, as Members have already said. The rulemaking process that was put in place has become lengthy, burdensome and there are huge delays. There are 88 monographs that are not finalized. It also means that we can't respond rapidly to safety issues. There was perhaps a naive thought at the time that science wouldn't evolve, our understanding wouldn't evolve, and that new safety issues wouldn't come up for the products that have already been marketed. But that is by no means the case. We have really been hampered in responding rapidly to safety problems. Sometimes this leaves consumers unprotected, it may leave manufacturers open to liability. And then this process is frozen in 1972 and before.

So it doesn't apply to anything later than that. So this is only still trying to deal with those products that were on the market at that time. So there is really nothing for innovation in this entire process.

So the reform that we are proposing keeps the features in the monograph system that work well, which is products that follow the conditions could still be marketed without prior FDA approval if they conformed to the conditions for marketing. And it is a public process. So the public has input and it is an open and transparent process. But it streamlines this process by replacing rulemaking with administrative orders. So using an order system is very simi-

lar to what we do it for new drugs or generic drugs, and it is quite appropriate for scientific decisionmaking. We would issue a proposed order under the discussion draft, allow public comment, and then issue a final order, and it provides due process, a healing—an appeal and hearing process to permit challenges to FDA decisions. So that process is in place.

But there are fewer requirements that have to do with rule-making so that this can be accomplished in a much speedier manner. It also would encourage innovation by expanding eligibility for the monograph and no longer limiting it to pre 1972 type of products.

So industry can request that we amend a monograph, or they could even submit to these kinds of products. And what we envision allows for confidential meetings early in the process between industry and the FDA before we move into the public process, to allow for that innovation to be explored. It also would allow, very importantly, FDA to quickly respond to urgent safety issues. So we could issue interim final rule, and definitively get that safety information out. Now that rule then would be subject to further public comment and discussion and so forth, but it would be in place during that time so that people could be protected quickly. And that is something we are really missing right now. And it would reduce the backlog of unfinished monographs by transferring these pending regulations and so forth by statute. And this would allow us to deal in an orderly and effective manner with the pending work that has not been finalized up to this point.

The public health, I think, also would be served if there were provision to clarify our authority to require certain types of packaging, such as unit dose packaging. This can protect people from taking too many pills. And we know that for our elderly and for children, especially they may mistake medicines for candy, they overdose, and so that kind of protective packaging is very important. And this clarification would complement the authority of the Consumer Product Safety Commission, which can require child resistant closures on different packages, and we do conform to their standards for that.

So all in all, this modernization proposal, along with the user fees that would provide the staff to enable to do it, I think would really benefit both the public, most importantly, public safety and it would benefit the industry, and the FDA has been talking to many stakeholders about this over the last 3 or 4 years, and we feel the proposals that are on the table would really serve the public well.

Thank you very much.

[The prepared statement of Dr. Woodcock follows:]



TESTIMONY
OF
JANET WOODCOCK, M.D.
DIRECTOR, CENTER FOR DRUG EVALUATION AND RESEARCH

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

“MODERNIZING FDA’S REGULATION OF OVER-THE-COUNTER DRUGS.”

SEPTEMBER 13, 2017

RELEASE ONLY UPON DELIVERY

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

INTRODUCTION

Good morning Chairman Walden, Ranking Member Pallone, and members of the Subcommittee. I am Janet Woodcock, Director of the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). Thank you for the opportunity to be here today to discuss potential reforms to the over-the-counter (OTC) monograph system and a new OTC monograph user fee program.

OTC drugs have long provided an efficient, low-cost way for Americans to take care of everyday health needs, without the need to visit a doctor and obtain a prescription. OTC regulation is considered appropriate for most drugs that can be safely administered without the supervision of a health care practitioner. FDA regulates most of the drugs on drug store shelves under the “OTC monograph system,” though manufacturers do have the option to file a new drug application (NDA) in lieu of using the OTC monograph system for OTC products. FDA publishes monographs that provide a rulebook for marketing safe and effective products containing particular active ingredients for specific OTC conditions. Products that conform to the monograph rules and other relevant requirements are not required to be reviewed by FDA before marketing. This contrasts with the NDA system, where sponsors of drugs must submit an application to FDA and obtain approval prior to marketing. The OTC Monograph system provides lower regulatory burden for industry and helps to keep OTC drug costs low through the extensive array of potential products that final monographs can cover.

When it was first created over 40 years ago, the monograph system was relatively efficient, permitting timely monograph development to address safety and effectiveness issues. As product innovation unfolded, however, the monograph system has not kept up, leaving a system that does not well-serve consumers or industry. FDA still has not been able to complete many monographs begun decades ago. Nor has it been able to make timely monograph modifications to account for evolving science and emerging safety issues, or to accommodate product innovation or marketing changes. Approximately one third of the monographs are not yet final, and several hundred individual ingredients (monographs can include multiple ingredients) do not have a final determination of safety and effectiveness. In addition, a number of planned safety labeling changes for monograph ingredients have not yet taken place while similar changes have already been made to prescription drugs containing the same ingredient. Finally, restrictions in the monograph system may discourage manufacturers from innovating.

Reforms to modernize and support FDA's OTC monograph activities are needed to better serve patients, consumers, and industry. Stakeholders from across patient groups, healthcare providers, public health groups, and industry support reforms to streamline and improve the timeliness of review activities, spur innovation on behalf of consumers, and enable the Agency to better respond to urgent safety issues. FDA agrees that these changes will better protect the public health.

In addition to structural reforms, the oversight of the OTC marketplace must have more resources if FDA is to fully realize the goals of reform and ensure the safety and effectiveness of OTC drugs, as well as support innovation by industry. Together with industry, FDA has developed a proposed OTC monograph user fee program, modeled on the successful Prescription Drug User Fee Act (PDUFA) program which, over the past 25 years, has ensured a more

predictable, consistent, and streamlined premarket program for industry and helped speed access to new safe and effective prescription drugs for patients. Following the success of PDUFA, Congress enacted additional user fee agreements (UFAs), such as those that cover medical devices, generic drugs, and biosimilar drug products, as well as animal drug products and generic animal drug products. Under a user fee program, industry agrees to pay fees to help fund a portion of FDA's drug review activities while FDA agrees to overall performance goals, such as reviewing a certain percentage of applications within a particular time frame. As a result of the continued investment of UFA resources, FDA has dramatically reduced the review time for drug products without compromising the Agency's high standards for demonstration of safety, efficacy, and quality of such products. New legislation is needed to allow FDA to establish a similar program for OTC monograph drug products that will help ensure a better resourced and more streamlined, efficient process.

BACKGROUND

OTC Review is one of the Agency's largest and most complex regulatory programs.

The OTC Drug Review program was created by FDA in 1972 to facilitate the efficient review of hundreds of thousands of OTC medicines. Rather than approve each product, as typically is done for prescription drugs and certain OTC drugs, the OTC Drug Review develops monographs for various therapeutic categories (e.g. internal analgesics, cough/cold products). The monographs establish conditions, such as active ingredients, indications, dosage form and labeled directions, under which an OTC drug is generally recognized as safe and effective (GRASE) for use. There are three categories for OTC products: Category I includes products that are GRASE. Category II includes products that are not GRASE. Category III include products for which more data is needed to determine whether they are GRASE. An OTC medication that meets the specific conditions contained in the monograph is not required to be approved by FDA before marketing.

The OTC Drug Review Program has proven to be one of the largest and most complex regulatory programs ever undertaken at FDA. It now consists of approximately 88 simultaneous rulemakings in 26 broad therapeutic categories that encompass hundreds of thousands of OTC drug products marketed in the United States. Collectively, these monographs cover some 800 active ingredients for over 1,400 different uses, ranging from antacids to diaper rash creams, and from analgesics to cough/cold products.

The current OTC Review system is slow and antiquated.

OTC medications play an increasingly vital role in our health care system. Although the current system has provided consumers with access to a wide variety of OTC medicines for decades, OTC products have become scientifically more challenging to regulate and the regulatory framework for OTC monograph products has become increasingly difficult to administer.

Challenges in the current system include:

- Burdensome, lengthy, multi-step processes to gather and evaluate data that take many years to complete;
- Limitations on what new products can be marketed under the OTC Review; and
- Limited resources to carry out the Agency's responsibilities.

Together, these challenges are responsible for several widely-recognized shortcomings of the OTC Review, including:

- Inefficient and time consuming process for completing safety and effectiveness reviews of OTC monographs;
- Limited speed and flexibility in responding to urgent safety issues;
- Challenges in keeping pace with evolving science; and
- Challenges in accommodating innovation.

Monograph rulemaking takes much too long.

Rulemaking can be a particularly inefficient process for scientific decisions, where new information frequently emerges over time, often requiring FDA to start the rulemaking process over to account for evolving science.

The OTC Drug Review was intended to be a three-step, public notice and comment rulemaking process. As originally implemented, the process began with publication in the Federal Register of reports from an outside panel of experts. These reports were published in Advance Notices of Proposed Rulemakings, or ANPRs. Public comments on these reports were submitted by the drug industry, by medical professionals, and by consumers – anyone with an interest in the topic of the report could submit comments. FDA considered the reports, comments, any new data and information, revised the ANPR accordingly, and published the revisions as a proposed rule. The proposed rule is also known as the tentative final monograph, or TFM.

In response to the TFM, a second round of comments was received and evaluated. Following submission of comments to the TFM, the last step of the process was for FDA to analyze the comments and data that were submitted in response to the TFM, and to revise the monograph and publish it as a final rule. Once published, the final monograph would contain the regulations that establish the conditions under which a category of OTC drugs is considered GRASE. The final monographs would then be published in the Code of Federal Regulations in Title 21, Food and Drugs.

Although some monographs in the OTC drug review were finalized using this three-step public notice and comment rulemaking process, for many other monographs, the reality has deviated

from this plan to account for distinctions between products contained in the same monograph. Figure 1 (below) shows the journey that the external analgesic drug product monograph has taken. This lengthy and circuitous path is not unusual.

Burdensome, Multi-Step Rulemakings



Published	Federal Reg. Citation	Topic
12-4-79	44FR69768	ANPR for External Analgesic Drug Products
2-5-80	45FR7820	Correction
9-28-80	45FR63878	Reopening of administrative record
9-7-82	47FR30412	Reopening of administrative record
12-7-82	47FR54981	Correction
12-28-82	47FR57738	Extension of comment and reply periods
2-6-83	48FR5852	TFM (Tentative Final Monograph = Proposed Rule)
3-11-83	48FR10373	Correction
10-2-85	50FR40280	Amend TFM to add male genital desensitizer indication
7-30-86	51FR27360	Amend TFM to add seborrheic dermatitis and psoriasis indication
8-25-88	53FR32582	Amend TFM warnings and directions for external anal itching
4-3-89	54FR13490	Amend TFM to remove astringent drug products
10-3-89	54FR40818	Amend TFM to add poison ivy, poison oak, poison sumac, and insect bite indications
1-31-90	55FR33370	Amend TFM to address fever blister and cold sore indications
2-27-90	55FR6932	Amend TFM to make hydrocortisone 1% OTC
3-27-90	55FR11291	Correction
6-20-90	55FR25234	Amend TFM to address treatment and prevention of diaper rash
8-30-91	56FR43025	Hydrocortisone; Notice of Enforcement Policy
6-19-92	57FR27654	FR (Final Rule) Male genital desensitizer
12-18-92	57FR60426	FR (Final Rule) Diaper rash labeling
8-29-97	62FR45787	Amend TFM to add warning about diphenhydramine
11-19-97	62FR61710	Reopening of administrative records to consider new data

Figure 1

Some of these entries show that the administrative record was reopened to accept new data; the comment period was extended; and the TFM was amended to add new indications or uses, to remove some ingredients that were moved to other monographs, and to incorporate changes prompted by new scientific data, including new safety warnings. You will notice that some indications became final even though the entire monograph has not become final. This example illustrates the complexity that FDA now faces with trying to keep monographs updated to address the safety and effectiveness of OTC drugs.

There is a lack of speed and flexibility in responding to urgent safety issues. Using the current monograph process to address safety labeling changes and other public health priorities limits FDA's ability to address safety issues for OTC drugs in a timely manner.

Under the current monograph system, FDA is limited in its ability to require safety issues to be definitively addressed, unless it goes through rulemaking. While not a substitute for final rulemaking, wherever possible FDA has acted to address these public health issues through other methods such as consumer education efforts and guidance to industry. A few recent examples include:

- **Safety of pediatric cough and cold products**

FDA has published a number of consumer updates (available on FDA's website) to inform consumers on the safe and effective use of OTC products due to reports of harm, and even death in young children. Examples include:

- a checklist for choosing OTC medicines for children
<https://www.fda.gov/downloads/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandingover-the-countermedicines/ucm094879.pdf>;
- guidance on how to choose medicine for children
<https://www.fda.gov/Drugs/ResourcesForYou/ucm133419.htm>;
- use of OTC cough and cold products in children
<https://www.fda.gov/drugs/resourcesforyou/specialfeatures/ucm263948.htm>; and
- advice on caring for infants and young children with a cold
<https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm422465.htm>.

- **Adverse events related to use of codeine for the treatment of cough**

FDA held advisory committee (AC) meetings on December 10, 2015, and September 11, 2017, to review pediatric codeine use. Codeine carries serious risks, including slowed or difficult breathing or death, which appear to be a greater risk in children younger than 12 years (*<https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm315497.htm>*). These

meetings followed a number of communications issued by FDA to inform both consumers and health care providers about the safe use of codeine in children.

- **Serious skin reactions with acetaminophen**

In 2013, FDA published a drug safety communication alerting the public to serious skin reactions with acetaminophen. For prescription drugs marketed under the NDA process, FDA was able to take action quickly to have a warning added to the label. For OTC monograph drugs, which comprise the majority of the market, the Agency could not have generally required the necessary safety changes without undertaking a lengthy rulemaking. In order to more quickly encourage appropriate labeling changes, the Agency opted to issue a guidance instead, requesting that manufacturers add a warning to their labels.

Although these non-rulemaking approaches have been helpful as alternative ways to effect safety labeling changes and to notify consumers of safety concerns, these approaches are far from optimal because they do not result in changing the relevant monograph to reflect the new safety labeling.

To address these challenges with the existing OTC monograph system, FDA, industry, and other stakeholders have discussed a series of potential reforms with Members of Congress. These reforms would:

- Streamline the process for adopting OTC monographs and for amending existing monographs;
- Provide a special mechanism for rapidly responding to urgent safety issues;
- Eliminate certain barriers to innovation and provide a more nimble process for their review by FDA; and

- Reduce the backlog of unfinished monographs, for example by finalizing those FDA rulemakings that reached the stage of a Tentative Final Monograph.

Monograph reform can streamline processes, but will not address resource challenges.

As noted previously, the OTC monograph program is one of the largest and most complex regulatory programs ever undertaken at FDA. But FDA has very limited resources to carry out the Agency's responsibilities in the OTC monograph program. With current resource levels, FDA struggles to meet the requirements of Congressional mandates, keep pace with science, and meet public health needs for monograph products in a timely fashion. The OTC monograph review does not currently receive user fee funding, and funds from other user fee programs cannot be used to support monograph work.

For a perspective on the resource challenges faced by the monograph program, the Agency currently spends approximately 40 times as much budget authority (BA) on the process of reviewing PDUFA products as it does on OTC monograph products. In FY2016, the Agency spent \$320.9M in BA reviewing PDUFA products and \$7.9M in reviewing OTC monograph products. Because a user fee program is intended to supplement BA spending and not to supplant it, in that year, the Agency had access to additional funds from PDUFA user fees in the amount of \$836.9M. The total Agency spending on the PDUFA program was therefore \$1.16 billion, despite the fact that there are far more OTC monograph drug products than there are branded prescription drug products (see Figure 2 below).

OTC Monograph Resourcing Fiscal Year 2014 - 2016

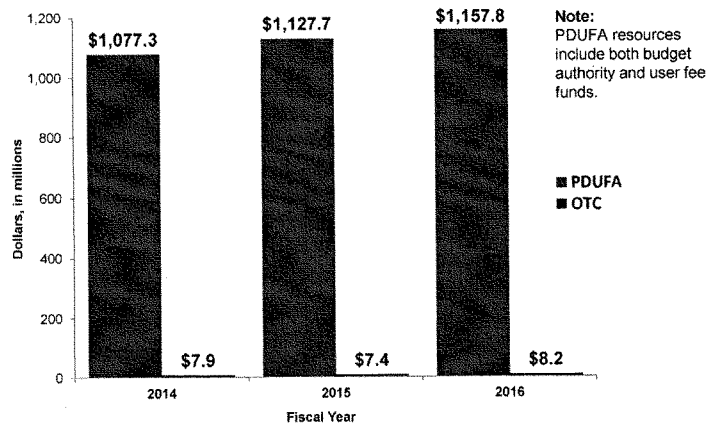


Figure 2

OTC Monograph Reforms and User Fee Program would address these challenges.

The proposed OTC Monograph Reforms and User Fee Program are designed to address the regulatory challenges mentioned above, as well as to provide benefits to the public health and to regulated industry. Potential benefits of OTC Monograph reform with supporting user fees include:

- Timely determination on the conditions for GRASE general recognition of safety and effectiveness that would cover thousands of marketed monograph drug products;
- Ability to address safety issues in a more timely and efficient manner;
- Ability to consider certain OTC product innovations proposed by industry;
- Streamlined ability to update monographs to provide for modern testing methods that can improve the effectiveness of products available to consumers;

- Development of information technology infrastructure for submission, review and archiving of monograph information;
- Development of a modern, useful, transparent Web interface; and
- Increased ability to respond to monograph-related concerns from the public and industry.

OVERVIEW

We have worked with numerous stakeholders, including consumer, patient, academic research, and health provider groups, and various representatives of industry to get their input on the proposed OTC Monograph Reform and User Fee Program.

At the request of Chairman Lamar Alexander of the Senate Committee on Health, Education, Labor, and Pensions in 2015, FDA began discussions with industry to discuss ways to reform the OTC Monograph review program. As part of this process, FDA solicited input from and worked with various stakeholders, including representatives from consumer, patient, academic research, and health provider groups, and engaged in discussions with the nonprescription drug industry to help Congress develop authorization language, with user fees, that would launch a reformed OTC Monograph drug review program. In addition, FDA held a public stakeholder meeting and two public webinars to obtain additional feedback and share progress of discussions regarding user fees and goals. The final proposed agreement and the goals to which FDA and industry agreed to were transmitted to Congress on June 7, 2017. *(Please see Appendix for “Goals Letter” that details our goals, implementation plan, and timelines.)*

The goals of the OTC Monograph User Fee program are to:

- Build a basic infrastructure (hiring, training, and IT) to meet the goals of monograph reform;
- Enable industry-initiated innovation (including innovation order requests, development meetings, timelines, and performance goals);

- Enhance communication and transparency;
- Enable streamlining of industry and FDA safety efforts;
- Enable efficient completion of final GRASE determinations for Category III drugs requested by industry or initiated by FDA; and
- Develop and incorporate measures to track successes and Agency accountability.

FDA estimates that the fees collected under the OTC Monograph User Fee program would start at \$22 million in Year 1 and gradually increase to a steady state of \$34 million by Year 4. For the sake of comparison, in FY18, the prescription drug user fee program is projected to be over \$800 million per year and the generic drug user fee program is projected to be just under \$500 million per year; the biosimilar drug user fee program, which is projected to be at around \$40 million, is much closer in size to the proposed OTC monograph program.

OTC manufacturers would pay an annual facility fee under the proposal, and there would be an additional fee each time a sponsor submitted what is known as an OMOR – Over-the-counter Monograph Order Request (this is analogous to the NDA under PDUFA). The fee amounts would be set before the beginning of each fiscal year, and would be set at an amount to generate the required level of revenue each year. The per-facility fee will be a function of the number of facilities when the program goes live.

Performance and Procedural Goals

The performance and procedural goals and other commitments specified in the Goals Letter apply to aspects of the OTC monograph drug review program that are important for implementing the aforementioned policy reforms and for facilitating timely access to safe and effective medicines regulated under the OTC drug monograph. FDA is committed to meeting

the performance goals specified in the goals document under the baseline assumptions described and to continuous improvement of its performance. FDA and industry would periodically assess the progress of the OTC monograph review program. This would allow FDA and industry to develop strategies to address emerging challenges to ensure the efficiency and effectiveness of the OTC monograph drug review program.

Infrastructure Development: Hiring, Training, and Growth of Effective Review Capacity

The goals document outlines hiring targets for each of the first five years of the proposed monograph user fee program. FDA would work toward these hiring goals. An important concept is that of the growth of effective review capacity. A newly hired scientist does not come to FDA with all the specialized skills and knowledge required to be an effective scientific reviewer. FDA scientific review work is highly technical and specialized. It requires knowledge and skills that are acquired through training at FDA, and typically takes approximately two years for a new staff person to become fully effective in monograph review work. This training process occurs simultaneously with assigned review work, with increasing review workload as a new reviewer gains experience and training. As these new employees come on board and are trained, total FDA effective review capacity for the monograph will increase in a measured fashion.

During FY15, FY16, and FY17, essentially all of FDA's monograph review capacity has been dominated by the following three activities:

- Statutory requirements of the Sunscreen Innovation Act;
- Court-mandated requirements of the consent decree pertaining to antiseptic drug products; and
- Urgent safety activities.

During FY18 and FY19, FDA will continue to have court-mandated obligations under the antiseptic consent decree. Congressionally-mandated obligations will also continue under the Sunscreen Innovation Act during those years (and perhaps subsequent years as well), unless Congress chooses to amend that law as part of the OTC monograph reform process because sunscreens are OTC products. Safety activities, for both pressing issues and routine pharmacovigilance, are continuous at FDA.

There will also be numerous implementation activities for monograph reform that would absorb additional review capacity in the first three years of a monograph user fee program. Therefore, FDA expects to have built sufficient effective review capacity to begin to have timelines and performance goals for review activities anticipated to be part of the steady state of a monograph review program beginning in years four and five of the program (and to a limited extent in year three).

Development and Implementation of an Information Technology Platform

The OTC Monograph User Fee program would involve the development of a new IT platform. FDA would leverage an existing FDA IT platform to develop an IT system for the OTC Monograph User Fee program. FDA would work with industry to develop specifications for a public-facing IT dashboard, and would establish a fully functioning IT platform for OTC drug monograph review within five years of the program.

In order to maximize the efficiency of the monograph review process, all monograph submissions would be electronic. FDA would modify existing guidance regarding the content and format of submissions to provide clarity to industry on how to structure its submissions.

Enabling Industry-Initiated Innovation

Innovation under the current monograph framework has been difficult. Under monograph reform, sponsors would be able to submit data packages (OMORs) to FDA, with requests that FDA issue an administrative order for a change to a monograph. There would be two types of Innovation OMORs, referred to as Tier One Innovation OMORs and Tier Two Innovation OMORs. The Goals Letter provides examples of each type of Innovation OMOR, but basically, most Innovation OMORs will be Tier One OMORs, and a few specific types of less resource-intensive OMORs would be Tier Two.

Innovation OMORs for new active ingredients would require an eligibility determination, to show that there is a sufficient marketing history of the drug being safely used in an OTC setting under comparable conditions of use, e.g., in other countries. Industry could submit a request for an ingredient's eligibility determination well in advance of submission of the OMOR. Minimum advance submission periods for eligibility determination requests are specified in the Goals Letter. Other types of innovations would not require an eligibility determination.

In-Review Meeting

For filed Innovation OMORs and for filed industry-requested GRASE Finalization OMORs, FDA would schedule an in-review meeting to be held between the requestor of the OMOR and FDA. The Goals Letter details submission requirements and timelines.

Guidance Development for Innovation

Under the proposed policy reforms for the monograph, most innovations would occur through submission of an OMOR by an industry requestor. However, it is possible that a few types of changes could be accomplished through a process that would not require an OMOR for each

change. One area where such changes might occur is for minor dosage form changes. In order to clarify which types of minor changes to solid oral dosage forms might be possible without an OMOR (when the monograph does not already specifically provide for these types of changes), FDA would issue an administrative order outlining key requirements and guidance providing details of what sponsors should do in order to comply with the administrative order. This order and guidance are referred to together as an “order/guidance pair”. Sponsors would need to have data on file, available at FDA request, to support the safety and efficacy of drugs with the minor change.

Timelines

Currently, it takes many years to make a change to a monograph, and the goal under monograph reform is to shorten that timeframe substantially, while still maintaining a public comment process between proposed and final orders, and maintaining FDA’s standards for safety and efficacy. For example, it took approximately seven years to amend a monograph to require new warnings for liver injury for acetaminophen and GI bleeding for nonsteroidal anti-inflammatory drugs. The Advisory Committee meeting was held September 19 and 20, 2002. The proposed rule was published December 26, 2006, and the final rule was published April 29, 2009. These warnings were very high priorities for the Agency to address urgent safety issues, yet it took that long. These substantially shortened timeframes are reflected in the tables in the Goals Letter, and would reduce what is currently a years-long process to between 17.5 and 23.5 months, with support from user fees (see Figure 3 below).

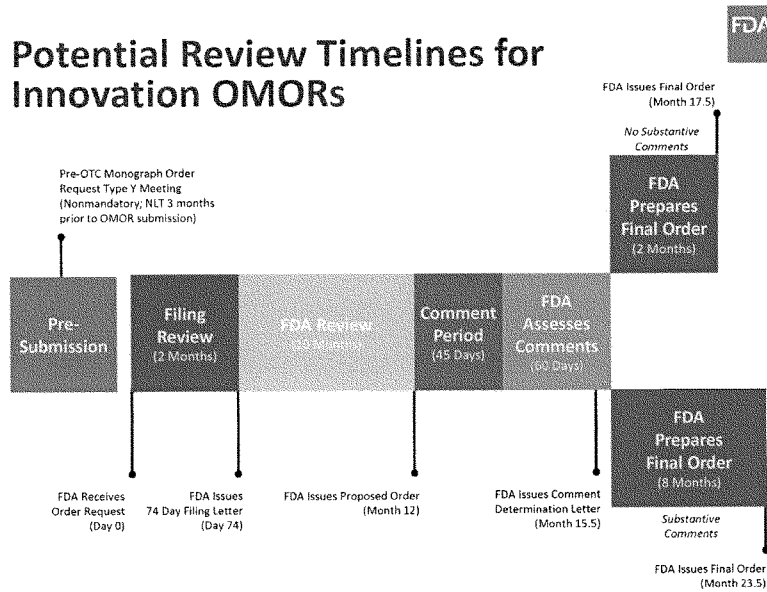


Figure 3

Communication and Transparency

FDA is committed to enhancing communication and transparency for the public and regulated industry. The Goals Letter details meeting management goals, which include timely responses to meeting requests, meeting scheduling, meeting background packages, preliminary responses to requestor questions, requestor notifications, anticipated agendas, meeting minutes, number of meetings per year, performance goals, and meetings guidance development, and a forecast of planned monograph activities.

Conclusion

FDA is committed to enhancing its core mission, which includes efforts to ensure and improve the safety and effectiveness of OTC Monograph drugs. Americans use OTC drugs every day, and

these products will become increasingly important as patients take greater control of their own health. And yet the existing monograph system no longer functions well. We face significant challenges in completing monographs, addressing safety issues, and supporting innovation in the OTC marketplace. Reforms of the existing system are needed to promote innovation and choice for patients and consumers while also improving FDA's ability to address urgent safety issues in a timely fashion and ensure the safety and effectiveness of OTC products. A wide range of stakeholders has come together to support these reforms and we hope to continue to work with Congress on legislation to make them a reality.

APPENDIX

**Over-the-Counter Monograph User Fee Program Performance Goals and
Procedures - Fiscal Years 2018-2022**

1	Table of Contents
2	
3	I. Introduction and Background
4	II. Goals for the First Cycle of an Over-the-Counter Monograph User Fee Program
5	A. Building the Basic Infrastructure to Enable the Goals of Monograph Reform to be Met
6	1. Hiring
7	2. Training and Growth of Effective Review Capacity
8	3. Development and Implementation of an Information Technology Platform
9	a. Development of the Information Technology Platform
10	b. Electronic Submissions
11	c. Content and Format of Monograph Submissions
12	d. Cataloging of Pre-OMUFA Paper Documents
13	B. Enabling Industry-Initiated Innovation
14	1. Over-the-Counter Monograph Requests (OMORs) for Innovations
15	a. Tier One and Tier Two Innovation OMORs
16	b. Innovations May Only be Made to Ingredients that have had a Final Determination of
17	“Generally Recognized as Safe and Effective” (GRASE)
18	c. OMOR Packages Expected to be Complete at Time of Submission
19	d. Timelines
20	e. Comment Review Extension
21	f. Performance Goals
22	g. Assumptions Regarding Expected Numbers of Innovation OMORs in the First Five
23	Years of OMUFA
24	h. Major Amendments
25	i. In-Review Meeting
26	j. Resubmitted Original OMORs
27	2. Guidance Development for Innovation
28	C. Enhancing Communication and Transparency for the Public and Regulated Industry
29	1. Meeting Management Goals
30	a. Responses to Meeting Requests
31	b. Meeting Scheduling
32	c. Meeting Background Packages
33	d. Preliminary Responses to Requestor Questions
34	e. Requestor Notification to FDA Regarding Whether Meeting is Still Needed, and
35	Anticipated Agenda
36	f. Meeting Minutes
37	g. Assumptions Regarding Number of Meetings Industry Expects to Request per Year
38	h. Performance Goals
39	i. Conditions for Performance Goals for Meetings
40	j. Meetings Guidance Development
41	2. FDA Forecasting of Planned Monograph Activities
42	D. Enhancing Industry’s and FDA’s Core Mission Efforts to Ensure and Improve the Safety of OTC
43	Monograph Drugs
44	1. Timelines for Industry-Initiated OMORs for Specified Safety Changes to Drug Facts Labeling

**Over-the-Counter Monograph User Fee Program Performance Goals and
Procedures - Fiscal Years 2018-2022**

45	2. Assumptions Regarding the Number of Specified Safety Change OMORs Industry Expects to
46	Submit in the First Five Years of OMUFA
47	3. Performance Goals
48	4. Timelines for FDA-Requested Safety Changes
49	5. Major Amendments
50	6. Comment Review Extension
51	7. Resubmitted Original OMORs
52	E. Enhancing Efficiency in Continuing FDA's Core Mission Work of Completion of Final GRASE
53	Determinations of Monograph Ingredients
54	F. Enabling Efficient Completion of Final GRASE Determinations Requested by Industry
55	1. Timelines
56	2. Assumptions Regarding the Number of GRASE Finalization OMORs Industry Expects to Submit
57	in the First Five Years of OMUFA
58	3. Performance Goal
59	4. Major Amendments
60	5. In-Review Meeting
61	6. Comment Review Extension
62	7. Resubmitted Original OMORs
63	G. Implementing a New Dispute Resolution System Agreed Upon as Part of Monograph Policy
64	Reform
65	H. Carrying Out Other Aspects of Monograph Reforms
66	1. Consolidated Proceedings Guidance
67	2. Administrative Activities for Finalization of Category I Ingredients and other Monograph
68	Conditions of Use from Tentative Final Monographs
69	3. Conditions that Apply to Over-the-Counter Monograph Order Requests Filed Over Protest
70	I. Routine Inspections
71	J. Creating a System to Measure the Success of Goals Laid Out in the User Fee Agreement
72	1. Summary of Performance Goals for OMUFA
73	2. Summary of Timelines for Industry-Initiated Over-the-Counter Monograph Order Requests
74	3. Summary of Dates of Specified Activities under OMUFA
75	4. Annual Performance Reporting
76	III. Definitions and Explanations of Terms
77	
78	
79	
80	
81	
82	
83	
84	
85	
86	
87	
88	
89	

**Over-the-Counter Monograph User Fee Program Performance Goals and
Procedures - Fiscal Years 2018-2022**

90 I. Introduction and Background

91
92 This draft document contains the performance goals and procedures for the Over-the-Counter
93 Monograph Drug User Fee Act initial program. If the program is enacted by Congress, the
94 program will likely subsequently be abbreviated OMuFA. For simplicity, the program will
95 generally be abbreviated as OMuFA in the remainder of this document. The over-the-counter
96 drug monograph will generally be referred to simply as the monograph. The document assumes
97 that the effective date of the OMuFA program will be October 1, 2017, and that it will cover
98 fiscal years (FYs) 2018-2022. If the program has a different effective date, goal dates in this
99 document will need to be adjusted accordingly.

100
101 For user fee programs, this type of document is commonly referred to as the "goals letter" or
102 "commitment letter." This goals document represents the product of FDA's discussions with
103 the regulated Industry, and consideration of input by public stakeholders.

104
105 OMuFA discussions ensued from prior discussions of the need for extensive policy reforms in
106 order to preserve and modernize the over-the-counter drug monograph regulatory system.
107 These reforms, if enacted by Congress, will result in numerous positive benefits to the public
108 health, and to regulated Industry. The United States Food and Drug Administration (hereafter
109 generally referred to as FDA) and regulated Industry have also come to agreement on the
110 principles of a system of monograph user fees through which regulated Industry will provide
111 resources to enable the range of review activities necessary to meet the goals of the
112 monograph reform.

113
114 The performance and procedural goals and other commitments specified in this letter apply to
115 aspects of the over-the-counter monograph drug review program that are important for
116 facilitating timely access to safe and effective medicines regulated under the over-the-counter
117 drug monograph, and to implementing the aforementioned policy reforms. While much of
118 FDA's work is associated with formal tracked performance goals, FDA and Industry mutually
119 agree that it is appropriate to manage some areas of the human drug review program with
120 internally tracked timeframes. This provides FDA the flexibility needed to respond to a highly
121 diverse workload, including unanticipated public health needs. FDA is committed to meeting
122 the performance goals specified in this goals document and to continuous improvement of its
123 performance. FDA and the regulated Industry will periodically assess the progress of the over-
124 the-counter drug monograph review program. This will allow FDA and the regulated Industry to
125 identify emerging challenges and develop strategies to address these challenges to ensure the
126 efficiency and effectiveness of the over-the-counter monograph drug review program.

127
128 Many aspects of this goals document will be addressed in statutory language. If differences are
129 noted between the OMuFA goals document and statutory language, statutory language will
130 supersede this goals document.

**Over-the-Counter Monograph User Fee Program Performance Goals and
Procedures - Fiscal Years 2018-2022**

131
132 II. Goals for the First Cycle of an Over-the-Counter Monograph User Fee Program
133
134 It should be noted that, when there are very few instances of a given activity, adherence to
135 performance goals should be interpreted accordingly. For example, if there are so few
136 occurrences of an activity that missing only one or two goal dates would make it appear that
137 the performance goal was not met, a qualitative description of performance may provide more
138 useful data to be used in improving future performance.
139
140 A. Building the Basic Infrastructure to Enable the Goals of Monograph Reform
141 to be Met
142
143 1. Hiring
144
145 The FDA will target onboarding of the following numbers of new fulltime employee equivalents
146 (FTEs) in each of the fiscal years (FYs) specified below.
147
148 Hiring Onboarding Targets:
149
150 FY 2018: 30
151 FY 2019: 24
152 FY 2020: 23
153 FY 2021: 19
154 FY 2022: 9
155
156 2. Training and Growth of Effective Review Capacity
157
158 FDA will work toward the above hiring goals, but it is important to note that, although new
159 scientific reviewers begin review work immediately, new reviewers will not be fully effective
160 immediately as scientific reviewers, and that effective review capacity will grow slowly at first.
161 FDA scientific review work is highly technical and specialized, requiring knowledge and skills
162 that must be taught after onboarding. Typically, two years are required for a scientific reviewer
163 to take all the necessary training, and acquire all the knowledge and experience needed to be
164 fully effective. This training process occurs simultaneously with assigned review work, with
165 increasing review workload as a new reviewer gains experience and training.
166
167 Immediately prior to OMuFA, FDA expects to have approximately 35 FTE working on
168 monograph issues, only 18 of whom work fulltime in the relevant review division. A total of 29
169 of these 35 FTE are expected to be fully trained at the time OMuFA becomes effective, and 6 are
170 expected to be recent hires who are still training. Given this fact, and the time required for

**Over-the-Counter Monograph User Fee Program Performance Goals and
Procedures - Fiscal Years 2018-2022**

171 training of additional hires under OMUFA, and the above hiring numbers, effective review
172 capacity is expected to grow as follows:

173
174 Mean Effective Monograph Review Capacity, FYs 2018-22:
175

176 FY 2018: 31 FTE
177 FY 2019: 42 FTE
178 FY 2020: 64 FTE
179 FY 2021: 88 FTE
180 FY 2022: 110 FTE
181

182 This concept is important, because it illustrates that during the early years of OMUFA, although
183 FDA will be striving to meet onboarding targets, FDA will actually not begin to see significant
184 growth in effective review capacity until FY 2020. Also of note is the fact that although hiring is
185 to be complete by the end of FY 2022, growth in review capacity will continue beyond the end
186 of FY 2022 as employees hired in FYs 2021 and 2022 continue and complete their training in the
187 ensuing years.
188

189 During FYs 2015, 2016, and 2017 (which began October 1, 2016), essentially all of FDA's current
190 monograph review capacity has been consumed by the following three activities:

- 191 • Statutory requirements of the Sunscreen Innovation Act
- 192 • Court-mandated requirements of the antiseptic consent decree
- 193 • Pressing safety activities

194
195 During FYs 2018 and 2019, FDA will continue to have mandated obligations under the antiseptic
196 consent decree. As of the writing of this goals document, mandated obligations also continue
197 under the Sunscreen Innovation Act during those years (and perhaps subsequent years as well),
198 unless Congress chooses to change that law. Safety activities, for both pressing issues and
199 routine pharmacovigilance, are continuous at FDA.
200

201 In addition, during the first three years of OMUFA, numerous activities will need to occur to put
202 the necessary infrastructure into place, and to begin to implement the various aspects of the
203 proposed monograph reforms. Examples of these activities include:

- 204 • Leadership development (particularly important when beginning from such a small
205 initial staff knowledgeable in the monograph)
- 206 • Information technology (IT) platform development and implementation (no IT platform
207 exists for the monograph prior to OMUFA)
- 208 • Development and posting of a nonbinding list of forecasted monograph activities (see
209 Section II.C.2)
- 210 • Activities to reflect finalization of Category I ingredients from Tentative Final
211 Monograph (TFM) status to Generally Recognized as Safe and Effective (GRASE)

**Over-the-Counter Monograph User Fee Program Performance Goals and
Procedures - Fiscal Years 2018-2022**

- For TFM Category II ingredients, which will be deemed not GRASE (not Generally Recognized as Safe and Effective) at time of enactment, Industry requestors may elect to submit requests to submit data packages supporting the safety and/or efficacy of these ingredients. FDA resources will be required to consider these requests.
- User fee collection system implementation and collection activities

Resource estimates indicate that, in order to implement all these activities and continue externally mandated activities, FDA will be substantially “net-negative” in terms of effective review capacity for the first 3 years of OMUFA. There will be performance goals for implementation activities such as development of guidances and hiring in the first three years. By Year 3, review resources will grow to the point where limited performance goals can begin for meetings. In Years 4 and 5, FDA expects to be able to implement timelines and limited performance goals for OMOR submissions, and will continue progressive performance goals for meeting management, guidance development, and other activities, although FDA’s effective monograph review capacity will still not be expected to be at the steady state required to handle the eventual anticipated full workload of OMUFA activities. Training will continue, with expected continued growth of review capacity beyond the first five years of OMUFA as all hirees finish their training and reach full review capability.

After establishment of the necessary infrastructure, and based on estimates of review activity expected numbers provided by Industry, FDA expects that the FTE need for monograph activities at steady state will be the equivalent of approximately 140 FTE. The steady state estimate includes those activities that are expected to be part of a continuing program over time, and does not include activities that are only part of start-up and implementation. Some examples of activities expected to occur at steady state include:

- Industry-requested Over-the-Counter Monograph Order Requests (OMORs) for innovations and other changes to the monograph
- Industry-requested guidances for innovations (and administrative orders that will accompany these guidances)
- Industry-requested meetings with FDA
- Industry-requested dispute resolution, up to the Center for Drug Evaluation and Research (CDER) level, and above CDER under a new administrative hearing procedure
- Industry-requested finalizations of GRASE determinations for nonfinal monograph ingredients and other monograph conditions of use
- Industry-requested safety changes to monograph drug labeling
- Industry resubmissions of OMORs for which a previous final order did not result in the requested change to the monograph
- FDA-requested safety changes to monograph drug labeling
- FDA-requested packages for GRASE determinations
- Other monograph review activities

**Over-the-Counter Monograph User Fee Program Performance Goals and
Procedures - Fiscal Years 2018-2022**

- Other guidance and policy development
- Information technology support
- Reporting
- User fee management
- Other activities specified in the OMUFA statute

In summary, during the first three years of OMUFA, essentially all effective review capacity is expected to be consumed by current external mandates, safety activities, and OMUFA implementation and infrastructure development activities. Beginning in Years 4 and 5 (and to a limited extent in Year 3), FDA expects to have built sufficient effective review capacity to begin to have timelines and performance goals for review activities expected to be part of the steady state of a monograph review program.

3. Development and Implementation of an Information Technology Platform

Prior to OMUFA, no IT platform exists for the monograph, a lack which greatly hampers review efficiency.

a. Development of the Information Technology Platform

FDA will develop specifications for a public-facing IT dashboard and award a contract by October 1, 2018.

FDA will implement the above public-facing IT dashboard by October 1, 2019.

FDA will issue a Request for Proposals for an information technology (IT) platform for receiving electronic submissions, archiving review work, and generating reports, for over-the-counter (OTC) drug monograph review, by February 1, 2019.

FDA will award the initial contracts for the above IT platform by April 1, 2019.

FDA will establish business requirements for the above IT platform by April 1, 2020.

FDA will establish a fully functioning IT platform for OTC drug monograph review by April 1, 2022.

b. Electronic Submissions

**Over-the-Counter Monograph User Fee Program Performance Goals and
Procedures - Fiscal Years 2018-2022**

293
294 In order to maximize the efficiency of the monograph review process, all monograph
295 submissions from industry are to be electronic rather than paper. Industry may submit
296 monograph electronic submissions to FDA starting on October 1, 2017.
297
298 FDA will provide additional information regarding electronic submissions for the monograph in
299 draft guidance to be issued by October 1, 2019. FDA will issue final guidance for electronic
300 submissions for the monograph by April 1, 2021.
301
302 c. Content and Format of Monograph Submissions
303
304 Initially (beginning October 1, 2017), Over-the-Counter Monograph Order Requests (OMORs)
305 are to be submitted using content and format recommendations described in the guidance for
306 *Industry Nonprescription Sunscreen Drug Products – Content and Format of Data Submissions*.
307 The format recommendations of this guidance, although developed for sunscreen drug
308 products, are generally applicable to all monograph submissions.
309
310 FDA will modify the above content and format guidance to clarify its applicability across
311 monograph drug products. FDA will issue updated draft guidance by April 1, 2019. FDA will
312 issue final guidance by October 1, 2020.
313
314 OMORs are expected to be complete at the time of submission, and are expected to include all
315 information, both positive and negative, relevant to the determination of general recognition of
316 safety and effectiveness for the ingredient or other condition(s) of use under consideration.
317 OMOR requestors are required to submit a certification that the requestor has submitted all
318 evidence created, obtained, or received by that requestor that is relevant to whether the
319 ingredient or other condition of use is generally recognized as safe and effective (GRASE).
320
321 d. Cataloging of Pre-OMUFA Paper Documents
322
323 Some paper documents that reside with FDA contain information of importance relating to
324 monograph ingredients and their review. Prior to OMUFA, FDA has not had the resources to
325 catalog and archive these documents. Many of these documents are old and fragile. It is
326 important to catalog the content of these documents, and FDA must retain paper documents as
327 required by established records retention policies. Because of the large volume of these
328 documents, and the fragility of many of them, the process of sorting, scanning, and archiving
329 them would be costly and time-consuming. Industry does not support provision of user fee
330 funds to permit electronic archiving of these documents during the first five years of OMUFA,
331 but agrees that cataloging them could have value to Industry, because some of the documents
332 may contain data that Industry requestors could use to support order requests or other
333 activities of interest to Industry. FDA and Industry have agreed that, among IT-related goals, the

**Over-the-Counter Monograph User Fee Program Performance Goals and
Procedures - Fiscal Years 2018-2022**

334 priority of creating the IT platform is higher than that of cataloging these paper documents, and
335 therefore IT platform development would be pursued first. Cataloging will have a limited goal of
336 identifying the monograph ingredient(s) discussed in each document, and creation of a
337 searchable electronic catalog. Cataloged paper documents will be stored per records retention
338 policies, but the paper documents themselves will not be scanned and electronically archived.
339 By February 3, 2020, FDA will award a contract for the cataloging project. By Feb 3, 2022, the
340 cataloging project will be complete. FDA will be able to initiate GRASE determinations prior to
341 completion of the cataloging project.

342
343 **B. Enabling Industry-Initiated Innovation**

344
345 **1. Over-the-Counter Monograph Order Requests (OMORs) for Innovations**

346
347 Prior to the proposed monograph reforms, innovation under the monograph has been difficult.
348 Under monograph reform, sponsors (hereafter referred to as requestors when referencing
349 submission of OMORs) will be able to submit data packages (Over-the-Counter Monograph
350 Order Requests, or OMORs) to FDA, with requests that FDA issue an administrative order for a
351 change to a monograph. Hereafter, these packages requesting changes to monographs will be
352 referred to as "Innovation OMORs."

353
354 **a. Tier One and Tier Two Innovation OMORs**

355
356 There will be two types of Innovation OMORs, referred to as Tier One Innovation OMORs and
357 Tier Two Innovation OMORs.

358
359 Most Innovation OMORs will be Tier One OMORs. Examples include, but are not limited to,
360 requests for the following:

- 361 • Addition of a new ingredient to a monograph that already has one or more ingredients
362 that have been found to be GRASE
- 363 • Addition of a new indication to a monograph that already has one or more ingredients
364 that have been found to be GRASE, and the new indication applies to one or more of the
365 GRASE ingredients
- 366 • Addition of a new fixed-dose combination of ingredients to a monograph that already
367 has one or more ingredients that have been found to be GRASE
- 368 • Addition of a new test method for a monograph that already has one or more
369 ingredients that have been found to be GRASE, and the new test method applies to one
370 or more of the GRASE ingredients
- 371 • Addition of a new route of administration for a monograph that already has one or
372 more ingredients that have been found to be GRASE, and the new route of
373 administration applies to one or more of the GRASE ingredients

**Over-the-Counter Monograph User Fee Program Performance Goals and
Procedures - Fiscal Years 2018-2022**

- 374 • Addition of a new dose or concentration for a GRASE ingredient for a particular
- 375 monograph
- 376 • Addition of a new monograph therapeutic category (each ingredient proposed for the
- 377 new therapeutic category will be a separate OMOR)
- 378 • All other Innovation OMORs not covered in Tier Two
- 379
- 380 Tier Two Innovation OMORs will be limited to requests for the following:
- 381 • Reordering of existing information in the Drug Facts label (DFL)
- 382 • Standardization of the concentration or dose of a specific finalized ingredient within a
- 383 particular finalized monograph
- 384 • An ingredient nomenclature change to align with nomenclature of a standards-setting
- 385 organization
- 386 • Addition of an interchangeable term under 21 CFR 330.1(i)
- 387 • Modification to existing DFL Directions for Use, in order to be consistent with a final
- 388 order/guidance pair on minor dosage form changes (see Section II.B.2)
- 389 • Addition of information (either required or optional) to be included under the “Other
- 390 Information” section of Drug Facts labeling, as limited by 21 CFR 201.66(c)(7)
- 391 • Other specific items may be added by FDA later as FDA gains experience with Tier Two
- 392 OMORs
- 393
- 394 The decision regarding whether a proposed Innovation OMOR meets one of the above criteria
- 395 for a Tier Two OMOR will be made by the review division after receipt of the OMOR.
- 396
- 397 b. Innovations May Only be Made to Ingredients that have had a Final Determination of
- 398 “Generally Recognized as Safe and Effective”
- 399
- 400 Innovations may only be made to ingredients that have had a final determination of “Generally
- 401 Recognized as Safe and Effective”, or GRASE. Under monograph reform, ingredients that are
- 402 GRASE are limited to the following:
- 403 • Ingredients that were GRASE in a Final Monograph at the time of enactment of
- 404 monograph reform
- 405 • Ingredients that, immediately prior to monograph reform, were proposed as Category I
- 406 in a Tentative Final Monograph
- 407 • Ingredients that have been found GRASE in a final order after enactment of monograph
- 408 reform
- 409
- 410 All other ingredients will require a final GRASE determination, with finalization of all relevant
- 411 monograph conditions of use for that ingredient for a particular therapeutic use, in order for
- 412 FDA to consider an Innovation OMOR relevant to that ingredient. Examples of these types of
- 413 ingredients that would require GRASE finalization include, but are not limited to:

**Over-the-Counter Monograph User Fee Program Performance Goals and
Procedures - Fiscal Years 2018-2022**

- 414 • Ingredients that, immediately prior to monograph reform, were Category III in a
- 415 Tentative Final Monograph
- 416 • Ingredients that, immediately prior to monograph reform, were proposed Category I in
- 417 an Advance Notice of Proposed Rulemaking
- 418 • Other ingredients that have not had a final GRASE determination
- 419

420 Ideally, if a requestor wants to request a change for an ingredient for which a final GRASE
 421 determination has not been made, the requestor would submit an OMOR for the final GRASE
 422 determination for the ingredient and all of the relevant monograph conditions of use first, and
 423 would submit the Innovation OMOR after FDA issues its final order regarding the GRASE
 424 determination for the ingredient. However, a requestor may submit a single OMOR package
 425 that contains both the complete data necessary for final GRASE determination for that
 426 ingredient and all its relevant conditions of use (referred to as a GRASE Finalization OMOR), and
 427 the complete data to support the proposed innovation. Cosubmission of a GRASE Finalization
 428 OMOR with an Innovation OMOR will extend the GRASE Finalization OMOR timeline from
 429 receipt to issuance of the proposed order by six months, with a consequent extension of the
 430 total GRASE Finalization OMOR timeline to final order by six months. If a requestor submits a
 431 GRASE finalization OMOR, and later submits an Innovation OMOR before the final order for the
 432 relevant GRASE finalization OMOR, the timeline of the subsequently submitted Innovation
 433 OMOR will be extended by six months.

434

435 c. OMOR Packages Expected to be Complete at Time of Submission

436

437 OMOR packages are expected to be complete at the time of submission, and FDA will make a
 438 determination of whether each package is acceptable for filing. As described in Section II.A.3.c,
 439 FDA will issue guidance regarding the content and format of OMOR packages. OMOR
 440 requestors are strongly encouraged to request and attend a presubmission meeting (as
 441 described in Section II.C.1) for their proposed OMOR, to discuss the expected content, format,
 442 and tier for a particular OMOR.

443

444 d. Timelines

445

446 The following table outlines the timelines for Innovation OMOR review, i.e. review of Industry-
 447 requested changes to finalized monographs, other than Drug Facts label (DFL) specified safety
 448 changes as outlined in Section II.D.

449

450 Currently, prior to enactment of proposed monograph reforms, it takes many years to make a
 451 change to a monograph, and the goal under monograph reform is to shorten that timeframe
 452 substantially, while still maintaining public comment between proposed and final orders, and
 453 maintaining FDA's standards for safety and efficacy. These substantially shortened timeframes
 454 are reflected in Table II.B.1.d.

**Over-the-Counter Monograph User Fee Program Performance Goals and
Procedures - Fiscal Years 2018-2022**

455
456 Eligibility determination for a new ingredient (a pre-OMOR activity):
457
458 Innovation OMORs for new ingredients will require an eligibility determination. Industry may
459 submit a request for ingredient eligibility determination well in advance of submission of the
460 OMOR. Minimum advance submission periods for eligibility determination requests are
461 specified in the following paragraphs.
462
463 If the ingredient is currently marketed for the same Use in a drug product under a US OTC NDA,
464 and the US OTC NDA drug product has documented sales of over 1 million units, the requestor
465 will submit the eligibility determination request at least 60 calendar days in advance of the
466 OMOR submission. For US OTC NDA products that meet these specific requirements, FDA will
467 issue an eligibility determination by 30 calendar days after receipt of the ingredient eligibility
468 determination request.
469
470 For any ingredient eligibility determination request that does not meet the specific
471 requirements in the immediately preceding paragraph, but that the requestor believes meets
472 eligibility requirements as stated in the applicable statute, the requestor will submit the
473 eligibility determination request at least 120 calendar days in advance of the OMOR
474 submission. For these other types of ingredient eligibility determination requests, FDA will issue
475 an eligibility determination by 90 calendar days after receipt of the eligibility determination
476 request.
477
478
479
480
481
482
483
484
485
486
487
488
489
490
491
492
493

**Over-the-Counter Monograph User Fee Program Performance Goals and
Procedures - Fiscal Years 2018-2022**

Table II.B.1.d: Timelines for Innovation OMORs (Industry-Initiated Over-the-Counter Monograph Order Requests OMORs for Monograph Changes)			
	Tier One Innovation: Eligible¹ New Ingredient	Tier One Innovation: Change to a Monograph Condition of Use (other than a New Ingredient), or Request for Other² Monograph Change	Tier Two Innovation
Filing determination	FDA makes fileability determination 60 calendar days after receipt of OMOR	FDA makes fileability determination 60 calendar days after receipt of OMOR	FDA makes fileability determination 60 calendar days after receipt of OMOR
Issuance of proposed order	If OMOR is filed, FDA issues proposed order 12 months after receipt of OMOR	If OMOR is filed, FDA issues proposed order 12 months after receipt of OMOR	If OMOR is filed, FDA issues proposed order 10 months after receipt of OMOR
Public comment period	Begins on the date of issuance of the proposed order, and lasts 45 calendar days	Begins on the date of issuance of the proposed order, and lasts 45 calendar days	Begins on the date of issuance of the proposed order, and lasts 45 calendar days
Assessment of volume and substantiveness³ of comments	Begins one calendar day after the end of the comment period, and lasts 60 calendar days.	Begins one calendar day after the end of the comment period, and lasts 60 calendar days	Begins one calendar day after the end of the comment period, and lasts 60 calendar days
Issuance⁴ of final order	17.5 months after receipt of OMOR	17.5 months after receipt of OMOR	15.5 months after receipt of OMOR
Abbreviations: OMOR = Over-the-Counter Monograph Order Request 1 Eligibility determinations will be required for proposals for the addition of new ingredients to a monograph, but not for changes to other monograph conditions of use for a finalized monograph. See paragraphs immediately preceding this table. 2 This includes all proposed changes to the monograph, except for safety changes described in Section II.D, the addition of new ingredients, Tier Two Innovation OMORs, and specific changes for which FDA has issued a final guidance stating that an OMOR is not required (see Section II.B.2). 3 Assessment of substantiveness of comments does not involve full review of the comments, but rather is intended to assess whether the comments will require substantial time or resources for full review. 4 If comments received are numerous or substantive, there will be a Comment Review Extension of the final order goal date. For Tier One Innovations, the extension will be 5 months; and for Tier Two Innovations, the extension will be 3 months.			

494
495
496
497
498
499
500
501
502
503
504
505
506

e. Comment Review Extension

If comments received during the comment period are numerous or substantive, there will be an extension of the final order goal date. For Tier One Innovations, the extension will be 5 months; and for Tier Two Innovations, the extension will be 3 months. This extension will be additive to those generated by any major amendment(s).

f. Performance Goals

The first year in which Innovation OMORs will be associated with timelines and performance goals will be Year 4 of OMuFA (Innovation OMORs received on or after October 1, 2020.)

**Over-the-Counter Monograph User Fee Program Performance Goals and
Procedures - Fiscal Years 2018-2022**

507 For Innovation OMOR submissions, the following performance goals will apply:

508 • Year 4: For 50% of OMOR submissions received in Year 4, FDA will issue a final order by

509 the specified goal date

510 • Year 5: For 75% of OMOR submissions received in Year 5, FDA will issue a final order by

511 the specified goal date

512

513 Although there will not be timelines and performance goals associated with Innovation OMORs

514 submitted in Years 1-3, requestors may still submit Innovation OMORs in Years 1-3. If resources

515 permit, FDA intends to review these early OMORs in order of receipt, but timelines and

516 performance goals will not apply.

517

518 g. Assumptions Regarding Expected Numbers of Innovation OMORs in First Five Years of

519 OMUFA

520

521 The assumptions for the first OMUFA cycle were that there would be no Innovation OMORs

522 submitted by industry over the first 3 years of OMUFA, that 5 Innovation OMORs would be

523 submitted in Year 4, and that 10 Innovation OMORs would be submitted in Year 5.

524

525 h. Major Amendments

526

527 OMORs are expected to be complete at the time of submission, and therefore, unsolicited

528 amendments are expected to be rare. (Unsolicited amendments are amendments other than

529 those submitted in response to a specific FDA information request.) Major amendments

530 (whether solicited or unsolicited) submitted by the original requestor prior to issuance of the

531 proposed order may extend the time to issuance of the proposed order by three months, and

532 consequently may extend the final goal date by three months. Major amendments submitted

533 by the original requestor after the end of the comment period and prior to issuance of a final

534 order may also extend the final goal date by three months. Major amendments may apply to

535 Innovation OMORs, industry-initiated requests for GRASE finalizations (as discussed in Section

536 II.F), and industry-initiated requests for certain safety changes to the monograph (as described

537 in Section II.D).

538

539 A major amendment may include, for example:

540 • a major clinical safety or efficacy study that was not previously submitted to the current

541 OMOR

542 • a major reanalysis of a study or studies previously submitted to the current OMOR

543

544

545

546

**Over-the-Counter Monograph User Fee Program Performance Goals and
Procedures - Fiscal Years 2018-2022**

547 i. In-Review Meeting

548

549 For filed Innovation OMORs and for filed Industry-requested GRASE Finalization OMORs, FDA
550 will schedule an in-review meeting to be held between the requestor of the OMOR and FDA.
551 This meeting will generally be held between 8 and 9 months after receipt of the OMOR. The
552 OMOR requestor may request that the meeting be held either face-to-face or via
553 teleconference.

554

555 FDA representatives at the in-review meeting are expected to include:

556

557

558

559

560 Not less than 12 calendar days prior to the scheduled in-review meeting, FDA will send a
561 premeeting document to the requestor. The premeeting document will include an agenda, a
562 brief list of substantive issues noted to date, and a brief description of information requests
563 that FDA will ask of the requestor. The total length of the premeeting document generally will
564 not exceed three pages.

565

566 Potential topics for discussion at the in-review meeting include:

567

568

569

570

571 Review of the OMOR will not be complete at the time of the in-review meeting, and thus
572 definitive information regarding the content of the future proposed order will not be discussed.

573

574

575

576

577

578

579

580

581

582

583

584

585

586

587

588

589

590

591

592

593

594

595

596

597

598

599

600

601

602

603

604

605

606

607

608

609

610

611

612

613

614

**Over-the-Counter Monograph User Fee Program Performance Goals and
Procedures - Fiscal Years 2018-2022**

587 Class One resubmitted original OMORs are limited to the following items, or combinations of
588 these specified items:

- 589 • Draft or final labeling
590 • Safety updates submitted in the same format, including tabulations, as the original
591 safety submission, with new data and changes highlighted. (However, resubmissions
592 with large amounts of new information including important new adverse experiences
593 not previously reported for the ingredient(s) will be Class Two resubmissions.)
594 • Assay validation data
595 • A minor reanalysis of data previously submitted to the OMOR
596 • Other minor clarifying information (determined by the FDA as fitting the Class One
597 category)
598 • Other specific items may be added by the FDA later as the FDA gains experience with
599 resubmitted OMORs
600

601 Class Two resubmitted original OMORs are resubmissions that include any other items,
602 including any items that the FDA decides would need presentation to an Advisory Committee.
603

604 The FDA and Industry do not expect any resubmitted original OMORs during the first five years
605 of a user fee agreement.
606

607 If any resubmissions of original OMORs occur, the following timelines will apply:
608

Table II.B.1.j: Timelines for Resubmitted Original OMORs		
	Class One Resubmission	Class Two Resubmission
Issuance of proposed order	FDA issues proposed order 4 months after receipt of resubmitted original OMOR	FDA issues proposed order 6 months after receipt of resubmitted original OMOR
Public comment period	Begins on the date of issuance of the proposed order, and lasts 45 calendar days	Begins on the date of issuance of the proposed order, and lasts 45 calendar days
Assessment of volume and substantiveness ¹ of comments	Begins one calendar day after the end of the comment period, and lasts 60 calendar days.	Begins one calendar day after the end of the comment period, and lasts 60 calendar days
Issuance of final order ²	FDA issues final order 9.5 months after receipt of Class I resubmitted original OMOR	FDA issues final order 11.5 months after receipt of Class I resubmitted original OMOR
Abbreviation: OMOR = Over-the-Counter Monograph Order Request 1 Assessment of substantiveness of comments does not involve full review of the comments, but rather is intended to assess whether the comments will require substantial time or resources for full review. 2 If comments received are numerous or substantive, there will be a Comment Review Extension of the final order goal date by 5 months, for both Class I and Class II resubmitted original OMORs		

609

**Over-the-Counter Monograph User Fee Program Performance Goals and
Procedures - Fiscal Years 2018-2022**

610 Comment Review Extension: If comments received during the comment period are numerous
611 or substantive, there will be an extension of the final order goal date by 5 months, for both
612 Class One and Class Two resubmitted original OMORs.

613

614 Performance Goal:

615

616 Year 5: For 50% of resubmitted original OMORs received in Year 5, FDA will issue a final order
617 by the specified goal date

618

619 2. Guidance Development for Innovation

620

621 Under the proposed policy reforms for the monograph, most innovations would occur through
622 submission of an OMOR by an Industry requestor. However, it is possible that a few types of
623 changes to the monograph could be accomplished through a process that would not require an
624 OMOR for each change. One area where such changes might occur is for minor dosage form
625 changes.

626 In order to clarify which types of minor changes to solid oral dosage forms might be possible
627 without an OMOR (when the monograph does not already provide for these types of changes),
628 FDA will issue a proposed administrative order outlining key requirements, and draft guidance
629 providing details of what sponsors will need to do in order to comply with the proposed
630 administrative order. This order and guidance are referred to together as an "order/guidance
631 pair". FDA will issue the proposed administrative order and draft guidance by April 1, 2022.

632 C. Enhancing Communication and Transparency for the Public and Regulated
633 Industry

634

635 1. Meeting Management Goals

636

637 Formal OMFUFA meetings between monograph sponsors/requestors and FDA will consist of
638 Type X, Y, and Z meetings. These meetings are further described below.

639

640 Type X meetings are those meetings that are necessary for an otherwise stalled monograph
641 drug development program to proceed, or meetings that are necessary to address an important
642 safety issue. A meeting requested by an Industry requestor within 3 months after FDA has
643 taken a refusal-to-file action on an OMOR submitted by that requestor would be a Type X
644 meeting. A meeting requested by an Industry requestor within 3 months after FDA has declined
645 to issue an administrative order requested by that requestor would be a Type X meeting.

646

**Over-the-Counter Monograph User Fee Program Performance Goals and
Procedures - Fiscal Years 2018-2022**

Type Y meetings are intended for milestone discussions during the lifecycle of Industry development programs for monograph ingredients and monograph conditions of use. Examples of appropriate circumstances for Type Y meetings include:

- Overall Data Requirements Meetings: After FDA has stated its intent to make a final GRASE determination for a particular monograph ingredient or monograph condition of use, an Industry sponsor may request a meeting to discuss the overall data requirements to support that GRASE determination. Similarly, an Industry sponsor interested in initiating an OMOR for an FDA action on a monograph ingredient or monograph condition of use may request a meeting to discuss the overall data requirements to support that OMOR.
- Presubmission Meetings: When an Industry sponsor is nearing completion of its development program for an OMOR package, the sponsor may request a meeting to present a summary of the data supporting the proposed OMOR, and of the proposed format for the OMOR package, to obtain FDA feedback on the adequacy of the proposed package. For an Innovation OMOR, the proposed Tier (One or Two) may also be discussed at the presubmission meeting. The presubmission meeting should be held sufficiently in advance of the planned submission of the order request to allow for meaningful response to FDA feedback and should generally occur not less than 3 months prior to the planned submission of the order request.

A Type Z meeting is any other type of meeting.

a. Responses to Meeting Requests

Procedure: FDA will notify the requestor in writing of the date, time, and place for the meeting, as well as expected FDA participants, following receipt of a formal meeting request. Table II.C.1.a below indicates the timeframes for FDA's response to a meeting request.

Table II.C.1.a: Meeting Request Response Time Goals	
Meeting Type	Response Time (calendar days)
X	14
Y	14
Z	21

- For any type of meeting, the requestor may request a written response to its questions rather than a face-to-face meeting or teleconference. FDA will review the request and make a determination regarding whether a written response is appropriate or whether

**Over-the-Counter Monograph User Fee Program Performance Goals and
Procedures - Fiscal Years 2018-2022**

a face-to-face meeting or teleconference is necessary. If FDA deems a written response appropriate, when FDA responds to the meeting request, FDA will notify the requestor of the date FDA intends to send the written response. This date will be consistent with the timeframes specified in Table II.C.1.b below for the specific meeting type.

- For Type Z meetings, while the requestor may request a face-to-face meeting, FDA may determine that a written response to the requestor's questions would be the most appropriate means for providing feedback and advice to the requestor. When it is determined that the meeting request can be appropriately addressed through a written response, FDA will, in FDA's response to the meeting request, notify the requestor of the date FDA intends to send the written response. This date will be consistent with the timeframes specified in II.C.1.b below for the specific meeting type.

b. Meeting Scheduling

Procedure: FDA will schedule the meeting on the next available date at which all applicable FDA personnel are available to attend, consistent with the FDA's other business; however, the meeting should be scheduled consistent with the type of meeting requested. Table II.C.1.b below indicates the timeframes for the scheduled meeting date following receipt of a formal meeting request, or in the case of a written response, the timeframes for FDA to send the written response. If the date requested by the requestor for any meeting type is greater than the specified timeframe, the meeting date should be within 14 calendar days of the requested date.

Table II.C.1.b: Meeting Scheduling or Written Response Times	
Meeting Type	Meeting Scheduling or Written Response Time
X	30 calendar days from receipt of meeting request
Y	70 calendar days from receipt of meeting request
Z	75 calendar days from receipt of meeting request

See Section II.C.1.h for meeting performance goals.

c. Meeting Background Packages

The requestor of the requested meeting will submit the background package for each meeting type no later than the date specified in Table II.C.1.c below.

**Over-the-Counter Monograph User Fee Program Performance Goals and
Procedures - Fiscal Years 2018-2022**

Table II.C.1.c: Timelines for Submission of Meeting Background Packages	
Meeting Type	Receipt of Background Package
X	At the time of the meeting request
Y	50 calendar days before the date of the meeting or expected written response
Z	47 calendar days before the date of the meeting or expected written response

710

711

d. Preliminary Responses to Requestor Questions

712

713

714

715

716

717

718

719

720

721

722

723

724

725

726

727

728

729

730

731

732

733

734

735

736

737

738

739

740

741

742

743

744

745

746

747

748

749

750

751

752

753

754

755

756

757

758

759

760

761

762

763

764

765

766

767

768

769

770

771

772

773

774

775

776

777

778

779

780

781

782

783

784

785

786

787

788

789

790

791

792

793

794

795

796

797

798

799

800

801

802

803

804

805

806

807

808

809

810

811

812

813

814

815

816

817

818

819

820

821

822

823

824

825

826

827

828

829

830

831

832

833

834

835

836

837

838

839

840

841

842

843

844

845

846

847

848

849

850

851

852

853

854

855

856

857

858

859

860

861

862

863

864

865

866

867

868

869

870

871

872

873

874

875

876

877

878

879

880

881

882

883

884

885

886

887

888

889

890

891

892

893

894

895

896

897

898

899

900

901

902

903

904

905

906

907

908

909

910

911

912

913

914

915

916

917

918

919

920

921

922

923

924

925

926

927

928

929

930

931

932

933

934

935

936

937

938

939

940

941

942

943

944

945

946

947

948

949

950

951

952

953

954

955

956

957

958

959

960

961

962

963

964

965

966

967

968

969

970

971

972

973

974

975

976

977

978

979

980

981

982

983

984

985

986

987

988

989

990

991

992

993

994

995

996

997

998

999

1000

1001

1002

1003

1004

1005

1006

1007

1008

1009

1010

1011

1012

1013

1014

1015

1016

1017

1018

1019

1020

1021

1022

1023

1024

1025

1026

1027

1028

1029

1030

1031

1032

1033

1034

1035

1036

1037

1038

1039

1040

1041

1042

1043

1044

1045

1046

1047

1048

1049

1050

1051

1052

1053

1054

1055

1056

1057

1058

1059

1060

1061

1062

**Over-the-Counter Monograph User Fee Program Performance Goals and
Procedures - Fiscal Years 2018-2022**

- 739 g. Assumptions Regarding Number of Meetings Industry Expects to Request per Year
740
741 Industry has estimated that approximately the following numbers of meetings will be
742 requested per year:
743
744 FY 2018: 6 meetings (not under timelines or performance goals)
745 FY 2019: 9 meetings (not under timelines or performance goals)
746 FY 2020: 12 meetings (see performance goal below)
747 FY 2021: 24 meeting requests (see performance goal below)
748 FY 2022: 40 meeting requests (see performance goal below)
749
- 750 h. Performance Goals
751
752 Requestors may submit meeting requests beginning in FY 2018. However, performance goals
753 regarding meeting management will become effective October 1, 2019. These goals are:
754
 - 755 • Year 3: For the first 12 meeting requests received in Year 3, FDA will meet 50% of the
756 total of meeting management goal dates (goal dates for response, scheduling,
757 preliminary responses [Type Y meetings only], and minutes). If more than 12 meeting
758 requests are submitted in Year 3, the remainder will not be under timelines.
 - 759 • Year 4: For meeting requests received in Year 4, FDA will meet 60% of the total of
760 meeting management goal dates (goal dates for response, scheduling, preliminary
761 responses [Type Y meetings only], and minutes)
 - 762 • Year 5: For meeting requests received in Year 5, FDA will meet 80% of the total of
763 meeting management goal dates (goal dates for response, scheduling, preliminary
764 responses [Type Y meetings only], and minutes)
765 Performance goals apply to the aggregate of all types of meeting management goals. However,
766 in FDA's OMuFA performance report, FDA will include information on the various subsets of
767 meeting management goals.
768
- 769 i. Conditions for Performance Goals for Meetings
770
771 For a meeting to qualify for OMuFA performance goals, all of the following conditions must be
772 met:
773
 - 774 • The meeting must concern issues related to the issuance of an administrative order for
775 the monograph, issues related to a potential request for a monograph order, or issues
776 related to FDA-initiated data requests for the monograph.
 - 777 • The requestor of the meeting must be subject to, or potentially subject to, OMuFA fees.
778 For example, the requestor may be a monograph establishment owner, a requestor of
an OMOR, or a requestor who intends to submit an OMOR. Other entities may request

**Over-the-Counter Monograph User Fee Program Performance Goals and
Procedures - Fiscal Years 2018-2022**

- 779 meetings to discuss monograph issues, but meetings with these other entities will not
780 qualify for OMFUA performance goals.
- 781 • A written request must be submitted to the review division.
 - 782 • The written request must provide:
 - 783 ○ A brief statement of the purpose of the meeting and the requestor's proposal for
 - 784 either a face-to-face meeting or a written response from FDA
 - 785 ○ A listing of the specific objectives/outcomes the requestor expects from the
 - 786 meeting
 - 787 ○ A proposed agenda, including estimated times needed for each agenda item
 - 788 ○ A statement of whether the requestor intends to discuss trade secret or
 - 789 confidential commercial information at the meeting
 - 790 ○ A listing of planned external attendees
 - 791 ○ A listing of requested participants or discipline representatives from the Center
 - 792 with an explanation for the request as appropriate
 - 793 ○ The date that the meeting background package will be sent to the Center. Refer
 - 794 to Table II.C.1.c for timeframes for FDA's receipt of background packages.
 - 795 • FDA must concur that the meeting will serve a useful purpose (i.e., the meeting is not
 - 796 premature or clearly unnecessary). However, requests for Type Y meetings will be
 - 797 honored except in the most unusual circumstances.
 - 798 • The requestor of the meeting and any of its affiliates must have no overdue unpaid
 - 799 OMFUA fee.
- 800
- 801 j. Meetings Guidance Development
- 802
- 803 FDA will develop guidance regarding formal meetings between FDA and sponsors or requestors
- 804 for OMFUA ingredients and drug products. FDA will issue draft guidance by February 1, 2019.
- 805 FDA will issue final guidance by July 1, 2020.
- 806
- 807 2. FDA Forecasting of Planned Monograph Activities
- 808
- 809 Procedure: Each year, FDA will publish a nonbinding listing of monograph issues FDA intends to
- 810 address in the coming three years. For issues for which FDA anticipates that submission of data
- 811 to FDA will likely be needed, FDA will include a date by which it will expect these data to be
- 812 submitted. FDA will publish the first list by October 1, 2018; and will publish subsequent lists no
- 813 less frequently than annually (by October 1 in each of the years 2019, 2020 and 2021.)
- 814
- 815 Performance goal: FDA will publish each annual forecasting list within 30 days of the goal date.
- 816
- 817
- 818

**Over-the-Counter Monograph User Fee Program Performance Goals and
Procedures - Fiscal Years 2018-2022**

819 D. Enhancing Industry's and FDA's Core Mission Efforts to Ensure and Improve
820 the Safety of OTC Monograph Drugs

821
822 Prior to the proposed monograph reforms, it has been very difficult and time-consuming to
823 effect changes to monographs, with changes often requiring many years. The significance of
824 this difficulty in changing monographs in a timely manner has been especially problematic
825 when the desired changes have been intended to change the labeling of monograph products
826 to enhance the likelihood of safe use of the product. As noted in sections on timelines for
827 Industry-initiated Innovation OMORs and Industry-requested GRASE Finalization OMORs, FDA
828 intends to reduce the time needed for action on monograph issues, going from the current
829 reality of many years for each change, to a timeframe of less than two years in most
830 circumstances, while still maintaining public comment between proposed and final orders, and
831 maintaining FDA's standards for safety and efficacy.

832
833 For certain Industry-requested safety changes to the Drug Facts labeling of monograph drug
834 products, FDA intends an even shorter timeline, as described below.

835
836 The following types of proposed changes to the Drug Facts label of monograph drug products
837 qualify for the shorter timeline:

838
839 Changes to the Drug Facts labeling of a monograph drug that are intended to add or strengthen
840 any of the following:

- 841 • a contraindication, warning, precaution, or adverse reaction
- 842 • a statement about risk associated with misuse or abuse
- 843 • an instruction about dosage and administration that is intended to increase the safe
- 844 use of the monograph drug product

845
846 OMORs for these types of changes will hereafter be referred to as "Specified Safety Change
847 OMORs." These industry-requested Specified Safety Change OMORs will be made through the
848 ordinary administrative order process proposed under monograph reform (and not through the
849 interim final order expedited procedure for administrative orders proposed under monograph
850 reform.)

851
852 In order to qualify for the shortened timelines, OMORs for these types of safety changes are to
853 be submitted as stand-alone packages, and are not to include requests for other types of
854 changes to a monograph. A filing determination will be made, and if an OMOR that is
855 represented by the requestor as fitting into one of the above DFL safety change categories is
856 determined to contain a request for another type of change to the monograph, the applicable
857 timeline will be consistent with that for the other type of request found in the OMOR.

858
859

**Over-the-Counter Monograph User Fee Program Performance Goals and
Procedures - Fiscal Years 2018-2022**

1. Timelines for Industry-Requested Specified Safety Change OMORs

Table II.D.1: Timeline for Industry-Initiated Request for Certain² Safety-Related Changes to the Drug Facts Labeling of Monograph Drug Products ("Specified Safety Change OMORs")	
Filing determination	FDA makes fileability determination 60 calendar days after receipt of OMOR
Issuance of proposed order	If OMOR is filed, FDA issues proposed order 6 months after receipt of OMOR
Public comment period	Begins on the date of issuance of the proposed order, and lasts 45 calendar days
Assessment of volume and substantiveness¹ of comments	Begins one calendar day after the end of the comment period, and lasts 60 calendar days
Issuance of final order³	11.5 months after receipt of OMOR
Abbreviation: OMOR = Over-the-Counter Monograph Order Request 1 Assessment of substantiveness of comments does not involve full review of the comments, but rather is intended to assess whether the comments will require substantial time or resources for full review. 2 Changes to the Drug Facts labeling of a monograph drug that are intended to add or strengthen any of the following: <ul style="list-style-type: none"> • a contraindication, warning, precaution, or adverse reaction • a statement about risk associated with misuse or abuse • an instruction about dosage and administration that is intended to increase the safe use of the monograph drug product 3 If comments received during the comment period are numerous or substantive, there will be an extension of the final order goal date by 3 months.	

2. Assumptions Regarding the Number of Specified Safety Change OMORs Industry Expects to Submit During the First Five Years of OmuFA

Across the first five years of OmuFA, Industry estimates that it will submit a total of two OMORs for the above types of safety-related changes.

3. Performance Goals

Timelines and performance goals will begin on October 1, 2020.

Requestors may submit OMORs for the above types of safety-related changes in Years 1-3, but timelines and performance goals will not apply in those years. However, FDA always strives to review safety data and make appropriate changes in a timely manner.

Performance Goals:

- Year 4: For 60% of OMOR submissions that request the above types of safety changes, and that are received in Year 4, FDA will issue a final order by the specified goal date
- Year 5: For 80% of OMOR submissions that request the above types of safety changes, and that are received in Year 5, FDA will issue a final order by the specified goal date

**Over-the-Counter Monograph User Fee Program Performance Goals and
Procedures - Fiscal Years 2018-2022**

883 4. Timelines for FDA-Requested Safety Changes

884

885 The above timelines and performance goals apply to Industry-requested specified safety
886 changes. Other Industry-requested changes to the monograph, even if possibly related to
887 safety, will be subject to the same timelines for other OMORs as outlined in Section II.B.1.d.
888

889 Under the proposed monograph reforms, two types of FDA-requested safety changes to the
890 monograph are included. One type will include a proposed order, followed by a comment
891 period, followed by a final order. Another type, to be used for certain serious safety concerns
892 defined in the policy reform statutory language, will include an interim final order (that will go
893 into effect immediately), followed by a comment period, followed by a final order. Once FDA
894 has issued an FDA-initiated proposed safety order, or an FDA-initiated interim final order for a
895 safety issue, FDA intends to follow the same timelines outlined in Table II.D.1 above regarding
896 the length of the comment period and lengths of time from the end of the comment period to
897 issuance of a final order.
898

899 5. Major Amendments

900

901 Major Amendments will be possible; see Section II.B.1.h for further information.
902

903 6. Comment Review Extension

904

905 Comment Review Extension: If comments received during the comment period are
906 numerous or substantive, there will be an extension of the final order goal date by 3
907 months. This extension will be additive to those generated by any major amendment(s).
908

909 7. Resubmitted Original OMORs

910

911 See Section II.B.1.j.
912

913 E. Enhancing Efficiency in Continuing FDA's Core Mission Work of Completion of
914 Final GRASE Determinations of Monograph Ingredients
915

916 FDA will continue work on finalization of GRASE determinations for ingredients that were
917 Category III in a TFM prior to monograph reform, and for ingredients that were proposed as
918 Category I in an ANPR prior to monograph reform. FDA will request that Industry submit data
919 packages to support these GRASE finalizations.
920

921 When an FDA-requested complete package for a final GRASE determination (referred to as a
922 GRASE Finalization Package) is submitted, FDA intends to follow the same timelines as outlined
923 for Industry-submitted OMORs for GRASE finalizations (see below).

**Over-the-Counter Monograph User Fee Program Performance Goals and
Procedures - Fiscal Years 2018-2022**

Due to the resource requirements for the many implementation activities for other aspects of monograph reform, FDA does not expect to begin to request packages until OMFU Year 4 or later, and even in Year 4 and the ensuing few years, will likely only have sufficient resources to review one or two packages per FY while still meeting other OMFU commitments. Once FDA begins to request these packages, FDA plans to request packages for up to 6 ingredients per year.

F. Enabling Efficient Completion of Final GRASE Determinations Requested by Industry

As discussed above, some GRASE finalization packages will be requested by FDA. Industry can also initiate a GRASE finalization process by submitting a GRASE Finalization OMOR. All OMOR packages are expected to be complete at the time of submission. The content and format of a complete OMOR package are to be discussed at a presubmission meeting as discussed in Section II.C.1.

1. Timelines

Table II.F.1: Timeline for Review of Industry-Initiated Over-the-Counter Monograph Order Requests for Final GRASE Determinations (GRASE Finalization OMORs)	
Filing determination	FDA makes fileability determination 60 calendar days after receipt of OMOR
Issuance of proposed order	If OMOR is filed, FDA issues proposed order 12 months after receipt of OMOR
Public comment period	Begins on the date of issuance of the proposed order, and lasts 45 calendar days
Assessment of volume and substantiveness¹ of comments.	Begins one calendar day after the end of the comment period, and lasts 60 calendar days
Issuance of final order²	17.5 months after receipt of OMOR
Abbreviations: GRASE = General Recognition of Safety and Effectiveness; OMOR = Over-the-Counter Monograph Order Request 1 Assessment of substantiveness of comments does not involve full review of the comments, but rather is intended to assess whether the comments will require substantial time or resources for full review. 2 If comments received during the comment period are numerous or substantive, there will be an extension of the final order goal date by 6 months.	

2. Assumptions Regarding the Number of GRASE Finalization OMORs Industry Expects to Submit in the First Five Years of OMFU

Based on discussions between Industry and FDA, an assumption was made that no Industry-initiated requests for GRASE finalizations for existing nonfinal ingredients are likely during the first cycle of OMFU, as Industry is expected to be more likely to submit Innovation OMORs and Specified Safety Change OMORs in the first cycle.

**Over-the-Counter Monograph User Fee Program Performance Goals and
Procedures - Fiscal Years 2018-2022**

951
952 3. Performance Goal
953
954 Timelines and performance goals for Industry-requested GRASE Finalization OMORs will begin
955 in Year 5.
956
957 Although there will not be timelines and performance goals associated with GRASE Finalization
958 OMORs submitted in years 1-4, requestors may still submit them.
959
960 Performance Goal:
961 FY 2022: For 50% of GRASE Finalization OMOR submissions received in Year 5, FDA will issue a
962 final order by the specified goal date
963
964 4. Major Amendments
965
966 Major Amendments will be possible; see Section II.B.1.h for further information.
967
968 5. In-Review Meeting
969
970 An in-review meeting will be scheduled for Industry-submitted GRASE Finalization OMORs. See
971 Section II.B.1.i.
972
973 6. Comment Review Extension
974
975 If comments received during the comment period are numerous or substantive, there will
976 be an extension of the final order goal date by 6 months. This extension will be additive to
977 those generated by any major amendment(s).
978
979 7. Resubmitted Original OMORs
980
981 See Section II.B.1.j.
982
983 G. Implementing a New Dispute Resolution System Agreed Upon as Part of
984 Monograph Policy Reform
985
986 Under the proposed monograph policy reforms, two (sequential) dispute resolution processes
987 are specified. The first is the current CDER formal dispute resolution request path, referred to
988 here as the CDER FDRR path. If a requestor proceeds through the entire CDER FDRR path, but
989 still wishes to dispute CDER's action, the requestor may request to proceed to a second path,
990 referred to here as the administrative hearing path.
991

**Over-the-Counter Monograph User Fee Program Performance Goals and
Procedures - Fiscal Years 2018-2022**

992 The first path is described in the draft guidance for Industry and review staff entitled *Formal*
993 *Dispute Resolution: Appeals above the Division Level*, hereafter referred to as the FDRR
994 guidance. This guidance will need some modification of its language to encompass actions
995 covered under OMUFA. If dispute resolution is requested prior to modification of the draft
996 guidance, FDA and Industry intend to follow applicable general procedures in the above existing
997 FDRR draft guidance.

998
999 Procedure (for FDRR draft guidance development): FDA will revise the draft guidance for
1000 Industry and review staff *Formal Dispute Resolution: Appeals above the Division Level*, to state
1001 the circumstances and procedures under which requestors of OMUFA may use the CDER FDRR
1002 process. The draft guidance will be revised by February 3, 2020.

1003
1004 Performance goal (for timelines described in the FDRR draft guidance):
1005

1006 FY 2021: For dispute resolution requests received in Year 4, FDA will meet 50% of the timeline
1007 dates described in the FDRR draft guidance

1008
1009 FY 2022: For dispute resolution requests received in Year 5, FDA will meet 75% of the timeline
1010 dates described in the FDRR draft guidance

1011
1012 After a requestor has proceeded through the entire CDER FDRR path, the sponsor may request
1013 to proceed to an administrative hearing path. The above performance goals will not apply to
1014 the administrative hearing path.

1015
1016 H. Carrying Out Other Aspects of Monograph Reforms

1017
1018 1. Consolidated Proceedings Guidance

1019
1020 For monograph drugs products, it is common for there to be multiple manufacturers or
1021 sponsors of a given drug product with the same active ingredient and other monograph
1022 conditions of use.

1023
1024 For Industry-initiated OMORs, it is highly desirable that all Industry sponsors that are relevant
1025 for a given OMOR consolidate their data into a single well-organized and complete submission
1026 package.

1027
1028 For Industry-initiated appeals of FDA decisions regarding the monograph, FDA intends to
1029 conduct a single consolidated appeals process for a given appealed FDA decision, with all
1030 relevant sponsors represented as a group.

1031

**Over-the-Counter Monograph User Fee Program Performance Goals and
Procedures - Fiscal Years 2018-2022**

1032 It will be the responsibility of Industry to organize itself for these consolidated processes.
 1033 However, FDA will issue guidance on its views regarding best practices for consolidated
 1034 proceedings for appeals. FDA will issue draft guidance by July 1, 2019, and will issue final
 1035 guidance by February 1, 2021.
 1036
 1037 2. Administrative Activities for Category I Ingredients and Other Monograph Conditions of
 1038 Use from Tentative Final Monographs
 1039
 1040 Under the proposed monograph reforms, TFM Category I ingredients will be treated as GRASE
 1041 under the monograph conditions of use specified in the TFM as it was immediately prior to
 1042 enactment of monograph reform. There will be administrative activities associated with these
 1043 finalizations and the associated public postings. FDA will complete these administrative
 1044 activities by October 1, 2018.
 1045
 1046 3. Conditions that Apply to Over-the-Counter Monograph Order Requests Filed Over
 1047 Protest
 1048
 1049 Under proposed monograph reforms, FDA may refuse to file certain OMORs.
 1050
 1051 FDA will make a filing determination within 60 calendar days after receipt of an OMOR. FDA will
 1052 issue a letter (a "Day 74 Letter") to requestors within 74 calendar days after receipt of an
 1053 OMOR. The Day 74 Letter will communicate FDA's filing decision and any filing issues that were
 1054 identified.
 1055
 1056 OMOR requestors may choose to file an OMOR over protest after a refusal-to-file decision by
 1057 FDA. The following conditions will apply to OMORs filed over protest:
 1058 • OMORs filed over protest will be subject to the same timelines and performance goals
 1059 outlined in Sections II.J.1 and II.J.2.
 1060 • OMORs filed over protest will not be eligible for in-review meetings with FDA
 1061 • FDA generally will not review amendments to OMORs filed over protest
 1062 • FDA generally will not issue information requests to requestors of OMORs filed over
 1063 protest
 1064 • The timelines for resubmitted original OMOR reviews will not apply to resubmission of
 1065 an OMOR that was filed over protest. Any such resubmission will be reviewed as
 1066 available resources permit.
 1067
 1068 I. Routine Inspections
 1069
 1070 For routine FDA inspections of monograph drug manufacturing facilities, FDA intends to
 1071 continue to follow a risk-based model for prioritization of inspections.
 1072

**Over-the-Counter Monograph User Fee Program Performance Goals and
Procedures - Fiscal Years 2018-2022**

1073 J. Creating a System to Measure the Success of Goals Laid Out in the User Fee
1074 Agreement

1075
1076 1. Summary of Performance Goals for OMUFA

1077
1078 As noted earlier, when there are very few instances of a given activity, adherence to
1079 performance goals should be interpreted accordingly. For example, if there are so few
1080 occurrences of an activity that missing only one or two goal dates would make it appear that
1081 the performance goal was not met, qualitative description of performance may provide more
1082 useful data to be used in improving future performance.

1083
1084 As discussed in Section II.A.2, the growth of effective review capacity will be limited in the first
1085 three years of OMUFA due to the necessary training of newly onboarded hires, and during
1086 those first three years, much of the effective review capacity will be consumed by current
1087 mandates such as the Sunscreen Innovation Act and an antiseptic consent decree, and by
1088 ongoing safety activities. There are also numerous OMUFA implementation and infrastructure
1089 establishment activities to be accomplished in those years, resulting in a likely “net-negative”
1090 effective review capacity in Years 1-3. Beginning in Year 4 (and to a very limited extent in Year
1091 3), FDA expects to have built sufficient effective review capacity to begin to implement
1092 timelines and limited performance goals.

1093
1094
1095
1096
1097
1098
1099
1100
1101
1102
1103
1104
1105
1106
1107
1108
1109
1110
1111
1112

Over-the-Counter Monograph User Fee Program Performance Goals and Procedures - Fiscal Years 2018-2022

1113 The following table summarizes performance goals for OMUFA activities for the first 5 years of
 1114 OMUFA:

1115

Table II.J.1: Summary of Performance Goals for OMUFA	
Activity	Performance Goal
Industry-Submitted Innovation OMORs	Year 4: For 50% of OMOR submissions received in Year 4, FDA will issue a final order by the specified goal date Year 5: For 75% of OMOR submissions received in Year 5, FDA will issue a final order by the specified goal date
Industry-Submitted Specified Safety Change OMORs	Year 4: For 60% of OMOR submissions received in Year 4, FDA will issue a final order by the specified goal date Year 5: For 80% of OMOR submissions received in Year 5, FDA will issue a final order by the specified goal date
Industry-Submitted GRASE Finalization OMORs	Year 5: For 50% of OMOR submissions received in Year 5, FDA will issue a final order by the specified goal date
Resubmitted Original OMORs	Year 5: For 50% of resubmitted original OMORs received in Year 5, FDA will issue a final order by the specified goal date
Meetings between FDA and regulated monograph industry	Year 3: For the first 12 meeting requests received in Year 3, FDA will meet 50% of the total of meeting management goal dates (goal dates for response, scheduling, preliminary responses [Type Y meetings only], and minutes). If more than 12 meeting requests are submitted in Year 3, the remainder will not be under timelines. Year 4: For meeting requests received in Year 4, FDA will meet 60% of the total of meeting management goal dates (goal dates for response, scheduling, preliminary responses [Type Y meetings only], and minutes) Year 5: For meeting requests received in Year 4, FDA will meet 80% of the total of meeting management goal dates (goal dates for response, scheduling, preliminary responses [Type Y meetings only], and minutes)
Issuance of nonbinding annual forecasting list of planned monograph actions over ensuing 3 years	FDA will publish the forecasting list within 30 days of each goal date (goal dates are Oct 1 of 2018, 2019, 2020, and 2021).
Dispute resolution	Year 4: For dispute resolution requests received in Year 4, FDA will meet 50% of the timeline dates described in the FDRR draft guidance Year 5: For dispute resolution requests received in Year 5, FDA will meet 75% of the timeline dates described in the FDRR draft guidance
Abbreviations: DFL = Drug Facts label; FY = fiscal year; FDRR = Formal Dispute Resolution Request; OMOR = Over-the-Counter Monograph Order Request	

Over-the-Counter Monograph User Fee Program Performance Goals and Procedures - Fiscal Years 2018-2022

2. Summary of Timelines for Industry-Initiated Over-the-Counter Monograph Order Requests

1116

1117

1118 The following table summarizes the timelines for Industry-initiated OMORs.

1119

	Tier One Innovation OMOR: Eligible¹ New Ingredient	Tier One Innovation OMOR: Change to a Monograph Condition of Use (other than a New Ingredient), or Request for Other² Monograph Change	Tier Two Innovation OMOR	GRASE Finalization OMOR	Specified Safety Change OMOR	Class One Resubmitted⁵ Original OMOR	Class Two Resubmitted⁵ Original OMOR
Filing determination	FDA makes fileability determination 60 calendar days after receipt of OMOR	FDA makes fileability determination 60 calendar days after receipt of OMOR	FDA makes fileability determination 60 calendar days after receipt of OMOR	FDA makes fileability determination 60 calendar days after receipt of OMOR	FDA makes fileability determination 60 calendar days after receipt of OMOR	n/a	n/a
Issuance of proposed order	If OMOR is filed, FDA issues proposed order 12 months after receipt of OMOR	If OMOR is filed, FDA issues proposed order 12 months after receipt of OMOR	If OMOR is filed, FDA issues proposed order 10 months after receipt of OMOR	If OMOR is filed, FDA issues proposed order 12 months after receipt of OMOR	If OMOR is filed, FDA issues proposed order 6 months after receipt of OMOR	FDA issues ⁵ proposed order 4 months after receipt of resubmitted OMOR	FDA issues ⁵ proposed order 6 months after receipt of resubmitted OMOR
Public comment period	Begins on the date of issuance of the proposed order, and lasts 45 calendar days	Begins on the date of issuance of the proposed order, and lasts 45 calendar days	Begins on the date of issuance of the proposed order, and lasts 45 calendar days	Begins on the date of issuance of the proposed order, and lasts 45 calendar days	Begins on the date of issuance of the proposed order, and lasts 45 calendar days	Begins on the date of issuance of the proposed order, and lasts 45 calendar days	Begins on the date of issuance of the proposed order, and lasts 45 calendar days

63

Over-the-Counter Monograph User Fee Program Performance Goals and Procedures - Fiscal Years 2018-2022

	Tier One Innovation OMOR: Eligible¹ New Ingredient	Tier One Innovation OMOR: Change to a Monograph Condition of Use (other than a New Ingredient), or Request for Other² Monograph Change	Tier Two Innovation OMOR	GRASE Finalization OMOR	Specified Safety Change OMOR	Class One Resubmitted⁵ Original OMOR	Class Two Resubmitted⁵ Original OMOR
Assessment of volume and substantiveness³ of comments.	Begins one calendar day after the end of the comment period, and lasts 60 calendar days.	Begins one calendar day after the end of the comment period, and lasts 60 calendar days	Begins one calendar day after the end of the comment period, and lasts 60 calendar days	Begins one calendar day after the end of the comment period, and lasts 60 calendar days	Begins one calendar day after the end of the comment period, and lasts 60 calendar days	Begins one calendar day after the end of the comment period, and lasts 60 calendar days	Begins one calendar day after the end of the comment period, and lasts 60 calendar days
Issuance of final order⁴	17.5 months after receipt of OMOR	17.5 months after receipt of OMOR	15.5 months after receipt of OMOR	17.5 months after receipt of OMOR	11.5 months after receipt of OMOR	9.5 months after receipt of resubmitted OMOR	11.5 months after receipt of resubmitted OMOR
Abbreviations: GRASE = generally recognized as safe and effective; OMOR = over-the-counter monograph order request ¹ See Section II.B.1.d regarding eligibility determination ² This includes all proposed changes to the monograph, except for safety changes described in Section II.D, the addition of new ingredients, Tier Two Innovation OMORs, and specific changes for which FDA has issued a final guidance stating that an OMOR is not required (see Section II.B.2). ³ Assessment of substantiveness of comments does not involve full review of the comments, but rather is intended to assess whether the comments will require substantial time or full review. ⁴ If comments received during the comment period are numerous or substantive, there will be an extension of the final order goal date. See Sections II.B.1.e, II.B.1.j, II.D.6, and II.F.6. ⁵ Assumes resubmitter addressed all deficiencies identified in the previous final order							

64

1120
1121
1122
1123
1124

Over-the-Counter Monograph User Fee Program Performance Goals and Procedures - Fiscal Years 2018-2022

3. Summary of Dates of Specified Activities under OMUFA

Table II.J.3: Summary of Dates of Specified¹ Activities under OMUFA

Activity	Date Associated with Specified Activity														
	1 Oct 2017	1 Oct 2018	1 Feb 2019	1 Apr 2019	1 Jul 2019	1 Oct 2019	3 Feb 2020	1 Apr 2020	1 Jul 2020	1 Oct 2020	1 Feb 2021	1 Apr 2021	1 Oct 2021	1 Feb 2022	1 Apr 2022
Assumed effective date	x														
Hiring annual goal assessment		x				x				x			x		
Monograph forecast annual posting		x				x				x			x		
TFM Cat I finalization activities complete		x													
Meetings draft guidance issued			x												
Meetings final guidance issued									x						
Public-facing IT dashboard contract awarded		x													
Public-facing IT dashboard functional						x									
IT platform for electronic submission receipt, archiving and reporting: RFP			x												
IT platform: initial contracts awarded				x											
IT platform: business requirements established								x							
IT platform fully functional															x
Content and format draft guidance issued				x											
Content and format final guidance issued										x					
Consolidated proceedings draft guidance issued					x										
Consolidated proceedings final guidance issued											x				

Over-the-Counter Monograph User Fee Program Performance Goals and Procedures - Fiscal Years 2018-2022

Activity	Date Associated with Specified Activity														
	1 Oct 2017	1 Oct 2018	1 Feb 2019	1 Apr 2019	1 Jul 2019	1 Oct 2019	3 Feb 2020	1 Apr 2020	1 Jul 2020	1 Oct 2020	1 Feb 2021	1 Apr 2021	1 Oct 2021	1 Feb 2022	1 Apr 2022
Meeting management TPGs begin						x									
Meeting management TPGs annual goal assessment										x			x		
Electronic submission draft guidance issued						x									
Electronic submission final guidance issued												x			
CDER-level dispute resolution updated draft guidance issued							x								
Pre-OMuFA paper document cataloging contract award							x								
Pre-OMuFA paper document cataloging complete														x	
Innovation OMOR TPGs begin										x					
Industry-initiated Specified Safety Change OMORs TPGs begin										x					
Industry-initiated GRASE Finalization OMOR TPGs begin													x		
CDER-level dispute resolution TPGs begin										x					
Solid oral dosage forms proposed administrative order and draft guidance issued															x

Over-the-Counter Monograph User Fee Program Performance Goals and Procedures - Fiscal Years 2018-2022

Table II.J.3: Summary of Dates of Specified ¹ Activities under OMUFA															
Activity	Date Associated with Specified Activity														
	1 Oct 2017	1 Oct 2018	1 Feb 2019	1 Apr 2019	1 Jul 2019	1 Oct 2019	3 Feb 2020	1 Apr 2020	1 Jul 2020	1 Oct 2020	1 Feb 2021	1 Apr 2021	1 Oct 2021	1 Feb 2022	1 Apr 2022
Abbreviations: ANPR = Advance Notice of Proposed Rulemaking; CAT = category; CDER = Center for Drug Evaluation and Research; COU = monograph conditions of use; GRASE = generally recognized as safe and effective; IT = information technology; OMOR = Over-the-Counter Monograph Order Request; OMUFA = Over-the-Counter Monograph User Fee Act; TFM = Tentative Final Monograph; TPGs = timelines and performance goals															
¹ : These are not all the activities that the FDA monograph review staff will be engaged in, but only those for which goal dates are specified under OMUFA. FDA will continue its many baseline monograph activities, such as: addressing ongoing and emerging safety issues; carrying out mandated activities under the Sunscreen Innovation Act and an antiseptic consent decree; training; and numerous other activities described elsewhere in this goals document															

**Over-the-Counter Monograph User Fee Program Performance Goals and
Procedures - Fiscal Years 2018-2022**

- 1127 4. Annual Performance Reporting
1128
1129 FDA will include in the public annual performance report to Congress an assessment of the
1130 activities listed in Table II.J.3 "Summary of Dates of Specified Activities under OMuFA."
1131
1132 III. Definitions and Explanations of Terms
1133
1134 (If needed, will be added later to be consistent with statutory language)

Mr. BURGESS. The Chair thanks Dr. Woodcock for your testimony and we will move into the question-and-answer portion of the hearing. I am going to begin by yielding my time to the principal author of the bill, Mr. Latta, recognized for 5 minutes for questions, please.

Mr. LATTA. Well, thank you very much. And I appreciate the chairman for yielding. And Dr. Woodcock, thanks very much for being with us today. We appreciate your testimony and the work that you have been doing at FDA.

If I could start with the first question, kind of touching on what you were just discussing. As we work together to draft this legislation, we are very mindful to ensure that FDA has the authority they need to regulate the safe packaging of over-the-counter drugs to prevent unintended consequences. As you were talking, this is children that actually would ingest drugs intended for adults. Does the discussion draft—again, just to go back into it, does the discussion draft provide FDA with sufficient authority? And would you also discuss the authorities you would be granted when the monograph reform becomes law and it benefits public safety, would you touch back into that, please?

Dr. WOODCOCK. Certainly. Well, first, we believe the language that said an administrative order may include requirements for the packaging of a drug, which may include requirements for unit dose packaging to encourage use in accordance with labelling. Such packaging requirements that we could have could include unit dose packaging, special requirements for products intended for use by children and other appropriate requirements. And we believe that language provides us enough authority to require safe packaging.

Mr. LATTA. Thank you. Also—here a lot of us, when you look at the dates that we are looking at, in some cases, we are going back to 1972, and the FDA began evaluating 26 therapeutic categories and had yet to finalize monograph for each of them.

Could you go into, again, the system that we are looking at, especially with the review of the OTC that it is slow, and that it is antiquated, and again, speaking to the proposal before us today how, especially under the administrative order process and procedure, that would be speeded up to get these drugs out there?

Dr. WOODCOCK. Certainly. So what occurs now, what you have in front of you, that first slide, talks about a single role. And this is an important one, external analgesic drug products. And it shows many of the steps that we have gone through simply to try and move a single rulemaking along. And each one of those require very large administrative effort, writing, many of them publishing in the Federal Register notice going through extensive clearances. This would be substituted by a new process that would take less than 2 years and would have defined timelines under the user fee part of the program. So we would commit to finishing things in a timely manner. All right?

And what we would do for these old ones—some of them would transition to legally marketed drugs, and that would, over time, go through a process where the industry would submit data, the old monograph issues would be taken off the table, they would submit current data, and we would have timelines within which we would review that, publish a draft, and then finalize an order. And the

reason we aren't—wouldn't just go to an approval like we do for a new drug or generic drug would be this is a public process. So if we publish a draft that allows anyone who might be interested in commenting and participating in that to comment before we finalize.

So there is a different, slightly additional step compared to approving a new drug, because once that order is final, then any manufacturer who wishes may enter the market if they conform to those conditions. But we do it directly and would do it directly instead of through publishing regulations, and the current regulations would go off the books.

Mr. LATTA. I wish the slides were working right now because what you have given us—obviously, you have the burdensome monograph process and the rulemaking. Looking at the first December 4th, 1979, and there is it 22 different dates on here. We get down to November the 19th, 1997. So we got to get this sped up, and we appreciate the work you have been doing, and we look forward to getting this bill passed.

Mr. Chairman, I thank you for yielding and I yield back. Thank you very much.

Mr. BURGESS. The gentleman yields back. The Chair thanks the gentleman. The Chair recognizes the gentleman from Texas, Mr. Green, 5 minutes for questions, please.

Mr. GREEN. Thank you, Mr. Chairman. And thank you, Dr. Woodcock. You are always—good to see you and we appreciate the good work you have done for many years and at the FDA. I want to start by asking you about the current OTC monograph system. The committee learned a bit about how the system works, or doesn't, work during our consideration of the Sunscreen Innovation Act. It was clear then and even more clear now that reforms are modernized and fund FDA OTC monograph activities are needed to better serve patients, consumers in the industry. You just elaborated on how monograph rulemaking takes too long and is an inefficient process for scientific decisions, and how the lack of speed and flexibility poses harm to patient safety. How will allowing the FDA to make scientific determinations on OTC ingredients through the administrative order process improve overall patient safety and allow for new innovations?

Dr. WOODCOCK. I brought a little visual aid with me as an example, OK? Some time ago, and this relates to the fact that with the rulemaking, you assume something is fixed, but there is always new scientific knowledge with drugs, right? And we need to get it that out there to patients. We discovered that acetaminophen, a common pain reliever and fever reducer, some people are allergic and have life-threatening skin reactions, and we wanted to put a warning on. So what we did, we couldn't modify the rule quickly, right? You see that. So what we did, we put out a drug safety communication in August of 2013 discussing 91 cases that had—associated with 12 deaths, and the allergy alert for severe skin reaction, we put March 2014. So now, if you look at Tylenol, OK, and you look at the label of it, it has this allergy statement on there and warning so people know.

If you look at others, that you can get, perhaps smaller manufacturers who aren't aware of this, they—we issued guidance on how

to do this labelling, but they—this does not have—this still does not have the safety label on it. And we issued a final guidance, a draft guidance in November of 2014, a final guidance in January of 2017. Most sponsors voluntarily complied, because that is all we could ask, because it is different than the regulation, if you follow me. So this is an OTC NDA drug, this is a monograph drug, and it is still out there without the warning. And that is the case for many products. Most problematically, I think, are the pediatric cough and cold where the manufacturers we have had to get them to voluntarily comply. We know, and Congress has passed several laws around pediatric—studying pediatric drugs, right, and yet the monograph system and all the old rules we made assume that children are like little adults and that their dosing should just be extrapolated. And so to change all that could take 10 years or more in regulation.

Mr. GREEN. Thank you. The monograph reform can and will streamline the process, but it won't address the resource challenges that the agency faces. You know in your testimony, the FDA struggles to meet the requirements of congressional mandates to keep pace with the science and meet public health needs for monograph products in a timely fashion for current resource levels. The FDA has a budget of about \$8 million and 30 full-time employees to oversee a \$32 billion industry through one of the most complex regulatory frameworks the agency has. Can you elaborate on how reform without user fees is utterly unworkable?

Dr. WOODCOCK. Yes. We have had some reform in the Sunscreen Innovation Act that Congress passed several years ago. Even right now, our resources are completely taken up by implementing the Sunscreen Innovation Act. We are under court order for certain deadlines for other monographs, and we have to pay attention to that. And then acute safety issues that we are dealing with. We literally have no other resources. So even where we've given additional authorities or different ways of implementing, we would have a great deal of trouble bringing that about without additional resources.

Mr. GREEN. Mr. Chairman, I only have 12 seconds left, but I know the FDA stakeholders and the Members worked together on this, and I think we had a good example of this committee, subcommittee doing PDUFA over the years since, what, 1992?

Mr. BURGESS. Uh-hum.

Mr. GREEN. And to have this funding ability for the FDA to not only have the authority, but can actually regulate and oversee it. So I yield back my time.

Mr. BURGESS. The gentleman yields back. The Chair thanks the gentleman. The Chair recognizes the gentleman from Texas, Mr. Barton, for 5 minutes of questions, please.

Mr. BARTON. I thank the subcommittee chairman.

Dr. Woodcock, how long have you been at the FDA?

Dr. WOODCOCK. Thirty years.

Mr. BARTON. Thirty years.

Dr. WOODCOCK. Yes.

Mr. BARTON. How many monographs have been approved during the time you have been there?

Dr. WOODCOCK. Probably seven. Maybe, we don't know, but that would be a reasonable ballpark.

Mr. BARTON. I know you are not personally responsible for this, but I graduated from college in 1972, 45 years. I have had two wives, four children, six grandchildren, been approved 17 times to be a Member of Congress and disapproved once to be a Senator. Do you think seven monographs in 45 years is acceptable?

Dr. WOODCOCK. No, obviously for each monograph there has been a great deal of activity, all right?

Mr. BARTON. I can go outside and yell and scream and cause a stir and have a lot of activity, but that doesn't pass a law.

Dr. WOODCOCK. Yes.

Mr. BARTON. I know it is not your personal problem. I didn't—I wasn't aware of this until I read the briefing. But if the system is broken, which obviously as Congressman Latta just pointed out—my gosh, does it take 45 years for the FDA to say, "Help, we need help"? I mean—this—when you are trying to find a cure for cancer and all the other great things, I don't know that this is the most important priority at the FDA, I wouldn't say that, but approving a monograph for manufacture of over-the-counter drugs shouldn't take a moon shot. Do you agree with that?

Dr. WOODCOCK. I agree with that. And we could do it under the new proposals that have been proposed. We can, I think, do this in a more timely manner. It is simply going through regulations and doing regulations.

Mr. BARTON. I mean, again, somebody in your agency has known for a long, long time this is a problem; a long, long time. I mean, I never chaired the Health Subcommittee, but I did chair the full committee. I have been on the committee for 32 years. Nobody ever came to me from the FDA and said, "Hey, we have got a problem here." I mean, don't you—Mr. Latta says that to approve a specific new drug, you have an average of 18 FTE reviewers working on that, but to do all of these monographs, you have only got 18 people reviewing them.

Dr. WOODCOCK. That is right.

Mr. BARTON. Don't you think somebody at some point in time in your position, or somebody who reports to you, could have said maybe we need a few more people; maybe we need a lot of people; maybe we need to change the rules; maybe you don't need 27-step processes. I would assume that the FDA supports the Latta-DeGette-Green bill.

Dr. WOODCOCK. That is true. We held a public meeting 3 years ago to discuss the problem. And we were very clear that the system was progressively becoming more unworkable as it was more and more difficult to get regulations through.

Now, the industry is very concerned about these safety problems, but earlier, because all these drugs remain on the market until the monograph was finalized, and perhaps, some of them would be taken off, it wasn't such a problem for the industry. But in the modern world, industry, I believe, support this.

Mr. BARTON. What, in your mind, is a reasonable time to get these monographs approved?

Dr. WOODCOCK. I believe for a public process, several years, and should be done.

Mr. BARTON. Two years?

Dr. WOODCOCK. Yes, sir.

Mr. BARTON. Is that the guideline in the bill, 2 years? Do we know? Anybody? OK, if it is not, I will put it in the bill.

Dr. WOODCOCK. But we weren't going to be able to do every single one at the same time in 2 years.

Mr. BARTON. I understand that.

Dr. WOODCOCK. We can talk about that. We will have to build up our staff, our infrastructure, our IT systems and so forth.

Mr. BARTON. Well, I appreciate your willingness to testify on this, and I commend the subcommittee chairman and the sponsors of the bill. Hopefully, it won't take us 45 years to move the bill, Mr. Chairman, and we can have a bill-signing ceremony, and then hold them to their word that they will start approving these in 2 years.

With that, I yield back.

Mr. BURGESS. The Chair thanks the gentleman. The Chair recognizes the gentleman from New Jersey, Mr. Pallone, 5 minutes for questions, please.

Mr. PALLONE. Thank you, Mr. Chairman. I am not trying to denigrate you, Dr. Woodcock or Mr. Barton, and I am certainly not going to get it into how many years we have all been here and what we have been doing, but I think part of the problem is that, you know, you are not allowed to initiate that. I mean, you can't write us letters and say you need more resources, you want to change the law. That is our oversight obligation. And so I would say, whether Democrats or Republicans are in power, we still have to do a lot more oversight. It is not really up to you to come to us. It doesn't work that way, the way I understand it.

But in any case, one of the most serious constraints of the current monograph system is the ability to move quickly to revive the monograph to address emerging safety issues and the current multistep monograph process requires the FDA to make any revisions or updates through a rulemaking process, and that is why these safety changes take so long, if they happen at all.

So I just want you, if you could, briefly discuss how emerging safety issues are addressed currently through the OTC drug monograph process. And what has prevented the agency thus far moving swiftly to address safety issues, such as those associated with the use of the cough and cold products in children, which you mentioned, actually.

Dr. WOODCOCK. Well, I believe our thinking has evolved on that since the cough and cold issue first came up, because when it first came up, the thought was well, the regulation says these are generally recognized as safe and effective, including for children. That is what it said in Government regulation, so what could we say? But it was clear that thinking had changed on children, and that children should be specifically studied, and their safety evaluated in children. Eventually, what we do now is we issue safety communications and issue guidance on labeling and so forth, even though it is somewhat different than what might be in the regulation, or the draft regulation, or whatever state the tentative final monograph—whatever state it is in.

So we can do that and that requires voluntary, as I said, participation by the industry. It is not binding on industry because it is guidance. And so I think everyone would prefer that safety changes we deal with, safety problems are dealt with promptly and very definitively, not in guidance or something that is voluntary. So we can take care of the problem, keep people safe rapidly as we get the information.

Mr. PALLONE. Well, thank you.

In the discussion draft that we are considering, the monograph process will be transitioned from rulemaking to an administrative order process, and the FDA would also be given expedited authority to update safety labelling information in light of serious adverse events. Would you explain how the transition to administrative order and to the expedited authority for safety labeling will help to respond to these emerging safety issues?

Dr. WOODCOCK. Well, the expedited safety labelling would an interim order whereby the FDA could put out an order rapidly, not subject to some of the public comment requirements and so forth that most orders would have, all right? And once that was out, it would be binding, it would be interim final so it would be binding. So we would notify the public, and the manufacturers would have to change their label and conform their label to the safety problem. Then you could have comments after that and we could discuss it more, but the safety issue would have been dealt with more definitively so people were protected.

Right now, it may take 8 years or more for us to get a rule change so that we can have new safety statements in the regulation.

Mr. PALLONE. All right. Thanks.

I wanted to ask you what lessons have been learned from PDUFA, GDUFA, that were incorporated into the Over-the-Counter Monograph Drug User Fee Act? And how will user fees benefits the OTC program industry in patients, for example?

Dr. WOODCOCK. Well, some of the things we learned is, for this program, we are going to have what we call "managed growth" is what we have been discussing with everyone, where the program starts sort of small, expectations are clear for everyone and it grows over time. And the user fees grow so that we can absorb and lay down the foundation. And we learned that from the generics program where we had to change like a huge number of things at once.

We also have learned that we should have a simple a fee structure as possible, with a few exceptions and tiers and all, because this is a very large industry, there are a very large number of players here and have all kind of different status, and the more exceptions and tiers and everything, maybe it will start looking look the Tax Code.

Mr. PALLONE. Thank a lot. Thank you, Mr. Chairman.

Mr. BURGESS. The gentleman yields back, the Chair recognizes the gentleman from Kentucky, Mr. Guthrie, 5 minutes for questions, please.

Mr. GUTHRIE. Thank you, Mr. Chairman. Thank you, Dr. Woodcock. Thanks for being here today and discussing this important matter. I have heard stories from manufacturers trying to do

the right thing at risk having a have misbranded product because they want to update their label in real time as the current process can take years, as Mr. Barton described. In order for a label or packaging change currently, manufacturers must go through notice and comment rulemaking and bureaucratic system of red tape that can take years. So thanks for bringing this to us, and us working together to try to move us forward.

Could you tell me—could you tell the committee how the administrative orders will ensure due process is maintained if there are differences of opinion since this is a public process?

Dr. WOODCOCK. Well, there will be administrative order that is not final that comes out first, then there will be a comment period. And that is because since this is a public issue, other manufacturers who may not have been participating, but may want to get into that space or the public consumers, advocates may want to comment on the order, and so there is that public process whereby the comment.

If we get substantive comments on the proposed order, then the time of finalization may be somewhat delayed as we deal with those issues, and we can do that in many ways, but that a public process. And then, there is a process that has been proposed for administrative appeal of decisions through an appeal process within the Center for Drugs, and then appeal, administrative appeal above that to a party who is third party, who is selected to hold a sort of hearing on it, and adjudicate any substantive issue that is a material difference that might occur. So there are layers of administrative appeal and recourse for people.

Mr. GUTHRIE. Thank you. And you mentioned sunscreens earlier. Could you please expand on how sunscreens will fit and can fit into this over-the-counter drug reform? My good friend, Ed Whitfield, who was a member of this committee, my former colleague from Kentucky who is no longer in Congress, who did a lot of work in this space, and I talked about it with him some. And so it just seems, with the rise in skin cancer, it seems to be difficult to get improved sunscreens on the marketplace. So how will this work for sunscreens?

Dr. WOODCOCK. My understanding of the contract draft is the Sunscreen Innovation Act will continue to operate, all right? So what was stipulated by Congress there—and we have met all the timeframes that were required under the Sunscreen Innovation Act—we have exceeded those timeframes, so those will continue to operate.

Once those sunscreens that are subject to that are done and through the process, then they will be folded into the order so that then we have a common system. Now one thing that remains a question, one of the innovations or improvements that is being proposed in this discussion for modernizing the whole monograph process is to have confidential meetings with manufacturers and an ability to do that. That is not part of the Sunscreen Innovation Act, so that could be put in to conform, conform that Act if monograph reform is passed. Was I clear?

Mr. GUTHRIE. I believe so. I appreciate that. Those are my questions. I yield back my time.

Mr. BURGESS. The Chair thanks the gentleman. The gentleman yields back. The Chair recognizes the gentleman from North Carolina, Mr. Butterfield, 5 minutes for questions.

Mr. BUTTERFIELD. Thank you, Mr. Chairman. Dr. Woodcock, I too would like to thank you for coming back again and giving us your testimony today. I am very interested in the potential public health benefits of reforming the OTC medicine regulations. Your testimony today highlighted several examples of safety concerns with OTC medicines, and how they were handled by your agency. How frequently—how frequently does the FDA encounter adverse events with OTC medicines?

Dr. WOODCOCK. I would say fairly frequently, to rise to a serious level, maybe once every several years.

Mr. BUTTERFIELD. Infrequently? Frequently or infrequently?

Dr. WOODCOCK. Fairly frequently. But given what they are and the exposure of the population to them, but once, perhaps, every 2 years, we are facing an issue that we would like to get out rapidly as public to notify them, and our hands are really tied, and we have to use this guidance process.

Mr. BUTTERFIELD. Two of the examples that you highlighted in your written testimony were related to pediatric issues with certain medicines. Would you say that a disproportionate safety concerns with OTC medicines are related to pediatrics?

Dr. WOODCOCK. I would say, in the last decade, that is true, decade or so, and the reason is starting in the late 1990s, I think everyone became aware you should study children, and not just treat them as tiny adults and just scale down the medicines. And so, with that realization came the realization that children may be being harmed, because back in the 1970s when all of this was started, the doses for children were just scaled down adult doses. And so we have been going on a whole campaign as you know under BPCA and PREA to study children with drugs. Here, it is going back and looking at these medicines, particularly, say, the cough and cold, and some of the other medicines, and saying, really, is this appropriate for children and what do we need to do about this?

Mr. BUTTERFIELD. Can you provide any examples of safety improvements that have been made to existing monographs, and how long those changes have taken to be implemented? I know we touched it on that earlier, but can you illuminate on that?

Dr. WOODCOCK. Let me consult my colleagues. Well, most recently it took 7 years for to us to get the liver warnings on acetaminophen. Acetaminophen is the number one cause of drug-induced liver failure in the United States. When we strengthened the warnings on acetaminophen, we were able to rapidly do the NDA acetaminophen and change those warnings very fast. In contrast, it took us 7 years for the monograph, and, of course, a lot of the acetaminophen use is monograph.

Mr. BUTTERFIELD. And finally, how do you envision the special mechanism for rapidly responding to urgent safety issues? How do you envision that working?

Dr. WOODCOCK. We envision that we could have an interim final order that could be issued very rapidly, all right? And that order would be in place and therefore manufacturers would have to con-

form to it, so they would have whatever labelling statement they would have put on, but subsequent to issuing that interim final order, there would be an administrative process so people could comment and there could be discussions, and it could be modified. However, we could put the interim final order in place very rapidly, thus keeping people safe while we were discussing the issue.

Mr. BUTTERFIELD. Thank you. Dr. Woodcock, there was a discussion earlier that perhaps the FDA has not been proactive enough to seek legislation to remedy some of these issues. It appears that you are the director for the Center for Drug Evaluation and Research of FDA.

Dr. WOODCOCK. That is correct.

Mr. BUTTERFIELD. Are you permitted under your rules to pick up the telephone and call the chairman of the committee on Energy and Commerce and ask for legislation?

Dr. WOODCOCK. No.

Mr. BUTTERFIELD. That would be unacceptable in your agency or any other agency in the Federal Government?

Dr. WOODCOCK. We are not allowed to lobby Congress is my understanding.

Mr. BUTTERFIELD. That is what I have learned in my 13 years. Thank you very much.

I yield back.

Mr. BURGESS. The Chair thanks the gentleman. The gentleman yields back. The Chair recognizes the gentleman from Virginia, Mr. Griffith, 5 minutes for questions, please.

Mr. GRIFFITH. Thank you very much, Mr. Chairman. All right. So it seems that we have a problem. Everybody agrees that we need to change things. We have a discussion draft in front of us. I have looked through it. But I would ask you, as our expert who always gives us good counsel, we don't always take it, but we always like to hear your opinion: Are there things in the bill that concern you, things that we ought to take a look at changing the language on? And I know some of it is not finalized yet. But as the bill currently exists, is there anything in there that causes you concern?

Dr. WOODCOCK. No, not serious concern. I think we would like to continue to give technical assistance on it, because, you know, the devil is in the details.

Mr. GRIFFITH. Always.

Dr. WOODCOCK. But we believe the broad outlines of this are where we need to be.

Mr. GRIFFITH. And likewise, is there anything that you would like to see in the discussion draft that is not currently in there?

Dr. WOODCOCK. I don't have a role in this, as I have told this committee before. But I recognize that there are many folks who want to talk about exclusivity. I don't believe that FDA has a role in those tradeoffs, those societal tradeoffs, but I believe that is something that needs to be resolved.

Mr. GRIFFITH. OK. And I appreciate that.

And not asking your opinion per se, but have you anticipated, or have you felt any, or heard any comments about the user-fee portions of this bill? Are there groups out there that have told you they really oppose this and that this would be an impediment to

bringing certain over-the-counter medicines, particularly in rural areas?

Dr. WOODCOCK. I have not heard that, all right? I recognize that some of the contract manufacturers—because the proposed fee right now is facility fee, which is the most straightforward and simplest way to do this if you are producing an OTC drug under the monograph. The issues have been raised about the contract manufacturers and their obligation to pay a fee.

Mr. GRIFFITH. OK.

Dr. WOODCOCK. I think that is one of the more controversial areas.

We feel that there is tremendous merit in maintaining a simple uniform fee. A large number of the OTC manufacturers are small business, and so everybody is—there is lots of small businesses involved here.

Mr. GRIFFITH. Right. And I wouldn't want to price them out. But at the same time, the other UFAs have been highly successful. Isn't that fairly much accepted?

Dr. WOODCOCK. Yes. And I believe they have been beneficial to industry as well, or they wouldn't have been reauthorized as they have been.

Mr. GRIFFITH. Yes, ma'am.

Thank you very much. I appreciate your testimony here today. And with that, Mr. Chairman, I yield back.

Mr. GUTHRIE [presiding]. The gentleman yields. Mr. Schrader is recognized for 5 minutes for questions.

Mr. SCHRADER. Thank you, Mr. Chairman. I appreciate it. I appreciate having you here, Ms. Woodcock. Thank you very much.

So how many of these steps are we anticipating removing as a result of the new process? What would you expect?

Dr. WOODCOCK. I would say practically all.

Mr. SCHRADER. That is welcome.

Dr. WOODCOCK. We want to put this behind us, basically. So part of this proposed legislation would put all the monograph stuff behind us, transfer all these into a new status, can start not over, but start afresh and have a—timelines and plans for moving forward.

Mr. SCHRADER. So would you be able to establish timelines? Is there a rough timeline template, to Mr. Barton's earlier question, that you would give us and maybe some benchmark performance measures between you start, you get down the road a little bit, and then hopefully ultimately get to a decision?

Dr. WOODCOCK. Yes. Well, there are goals, and they phase in because, as I said, we are talking about managed growth. And in the first 2 years of this program, the plan would be to build a new system. We also have to deal with those legislatively and court-mandated projects, the Sunscreen Innovation Act, and some court-mandated things that we have to finish, all right? But we would have to hire people. We need to create new standards and processes. We need to create a new IT system. We don't have any IT system for that.

Mr. SCHRADER. But once that is all—I appreciate that.

Dr. WOODCOCK. Yes.

Mr. SCHRADER. And there is probably a timeline you can give us for all that to occur.

Dr. WOODCOCK. Right.

Mr. SCHRADER. That would help us judge the progress and help you with resources and whatever. But once that is all established, it would be interesting to know what is the—I heard a 2-year, rough-out from start to finish.

Dr. WOODCOCK. Right.

Mr. SCHRADER. And it is interesting and helpful, I think, for the committee and for you to see if we are hitting those timelines. I am sure this is a new program. We are going to have to make adjustments as we go forward here.

Dr. WOODCOCK. Right. Well, we had proposed, or planned to have goals, OK, for everything. And so there would be a goal for when we do this and when we get that done, just like we do for the other user-fee programs. So there would be a structured set of goals and timelines and percentage, like, here is the timeline, and we would—our goal would be to do 70 percent in this time frame this year, and the next year it goes up to 80 percent, and so on.

It is pretty complicated, I can't go through it in 5 minutes. But for the existing monographs, what we would plan to do is put forth a dashboard that would be in advance, and that would—because the industry is going to have to submit for the existing what—what are now existing monographs. They are going to have to resubmit something. And then we would have a timeline of when we expected that to come in. And then there would be an orderly process with timelines for accomplishing that.

Mr. SCHRADER. Can you share that with us?

Dr. WOODCOCK. Absolutely.

Mr. SCHRADER. And I assume the industry understands they have to resubmit and, in general, they are OK with that, given the process?

Dr. WOODCOCK. That is the plan, because right now, we have this giant, sort of mulch of documents that have been sent in over the years. We want to use the current scientific information to make the judgment.

Mr. SCHRADER. Sure.

And the last question, all right. You are about 30 FTE, or something like that, in this program. With the new revenue coming in, what is your initial expectation to gear up to and where do you hope to be as a more level employee workforce?

Dr. WOODCOCK. Right. Ultimately we would hire 105 new employees.

Mr. SCHRADER. Wow. Great.

Dr. WOODCOCK. So then we would have, then, 135 doing this scientific work.

Mr. SCHRADER. Very good. Thank you very much. Good luck.

And I yield back, Mr. Chair.

Dr. WOODCOCK. Thank you.

Mr. BURGESS [presiding]. The Chair thanks the gentleman. The gentleman yields back.

The Chair recognizes the gentleman from Missouri, 5 minutes for questions, please.

Mr. LONG. Thank you, Mr. Chairman.

Dr. Woodcock, the over-the-counter monograph program is the key regulatory framework at the FDA for oversight of OTC medi-

cines which account for the bulk of medication consumed by Americans. I understand that the user-fee program you are setting up is still relatively small, particularly when compared to some of the much larger programs that we have approved earlier this year.

Could you discuss why the user fees are needed?

Dr. WOODCOCK. Certainly.

User fees are needed because we simply do not have enough staff to finalize all these, and then deal with innovation coming forward. We have 30 staff to deal with more than 100,000 products that are on the market and, currently, this burdensome rulemaking process. Even if we were to move to an order process that was streamlined in a very efficient, effective, the 30 staff could not make substantive progress against that in the next 5 years.

Mr. LONG. How are the user fees structured, and how are these fees collected?

Dr. WOODCOCK. The fees are going to be—for any facility that manufactures a monograph drug would have a flat fee. How much it would be depends on how many register. We are going to use our drug registration enlisting system, which is an existing system, to capture all the facilities. It might be between, like, \$14,000 or a little less or a little more, depending on how many facilities participate per annum.

Mr. LONG. OK. Well, you mentioned in your testimony that the OTC monograph process is one of the largest and most complex regulatory programs ever undertaken by the FDA.

Could you discuss how OTC monograph reform can address these regulatory challenges?

Dr. WOODCOCK. Certainly. By simplifying the process that we have to go through to finalize a—you know, to finish, in this case, it would be an order with the new process, is tremendously simpler than what we have to do with the monograph. And orders can be amended over time through a simple process. So we can keep up with the science. And hopefully with the user fees, we will have enough people to do that.

But I have to be clear, this user-fee program is not large enough to get all this done in first 5 years. We will get the program set up, and we will begin to work against it, and we will be accepting innovation. And that will all be good. And we will be dealing promptly with safety issues. But we won't be finished with every single one of these, because they do take a fair amount of scientific work. But we would never be finished with them. We will never finish this process if we do not change, do not modernize it.

Mr. LONG. Speaking of process, can you discuss the FDA's engagement with stakeholders during the process?

Dr. WOODCOCK. Certainly.

As I said, I think in 2014, we had a public meeting about this. And to Representative Barton's point, we did own up to the fact that the process was broken, although some people came and told us it was simply because we were lazy or whatever. But we did ask the public, including advocates, consumer groups, and others, you know, how—in the industry—how we could change and modernize this process. And we pointed out the different problems.

Since that time, as we have been talking to industry about how we might change the process, we have also talked to public stake-

holders, advocacy groups, consumer groups, professional groups, and so forth, to keep people in the loop, although I will admit, this is a rather obscure program, and many people are unaware of how this program operated and the problems that it had.

We have had several public Webinars, and we have also talked extensively to special stakeholders who have a particular stake in this, for example, the American Academy of Pediatrics.

Mr. LONG. Excuse me. How will FDA address emerging challenges to ensure that the OTC monograph program remains effective?

Dr. WOODCOCK. Well, I think one of the things we need to build in, which we have built into every single other user-fee program that we have, are assessments. As I said earlier, we are going to have goals and objectives. And so we will have put forth what we expect our timeliness to be, how much we expect to get done. And then we will assess against that. And if we are failing on those measures, we will own up to it.

Mr. LONG. OK. Thank you.

With that, Mr. Chairman, I yield back.

Mr. BURGESS. The gentleman yields back. The Chair thanks the gentleman.

The Chair recognizes the gentlelady from California, Ms. Eshoo, 5 minutes, for question, please.

Ms. ESHOO. Thank you, Mr. Chairman.

And I want to commend the authors of the legislation for addressing something that evidently has been overlooked for decades. I want to start with a question about what you can and cannot do. I know that you cannot come to Congress and lobby for money. I know that you can't come to Congress and have something printed out and say this bill needs to be introduced. But I have never heard, in 25 years, that anyone from any agency can't meet with Members to discuss a shortcoming within the agency policy-wise or anything surrounding what I just mentioned.

So would you clarify this, because I think it changes, for me, the complexion of this entire issue; not that it doesn't need to be addressed, but it is just stunning to me that it hasn't been.

So would you clarify, please?

Dr. WOODCOCK. Well, you know, different administrations have different priorities. Administrations basically decide how the interactions with Congress are.

Ms. ESHOO. Well, you need to be more specific about that, though. I really want to understand this, because it is important.

Where is the agency precluded from essentially putting a spotlight on something that obviously has an effect on the population in the country to say there is a shortcoming here and we need to work together to address this? I don't think that that is something that changes with administrations. I think that is just part of the ongoing work of the agency and the Congress.

Dr. WOODCOCK. We certainly can, as we did, hold public meetings. We can write white papers. We can do many things depending on—

Ms. ESHOO. But you are talking about internal to the agency and what you do there.

Dr. WOODCOCK. Right.

Ms. ESHOO. I am talking about the relationship between the agency and Congress.

Let me ask this: Is there any statute or rule that is written that prohibits the FDA from meeting with any Members or chairs of committees or subcommittees to point out that there is a shortcoming somewhere, it is troubling to the agency, and that we need to work together on whatever the issue might be?

Dr. WOODCOCK. No, not to my knowledge. I mean——

Ms. ESHOO. Well——

Dr. WOODCOCK [continuing]. We wish to put forth a legislative proposal that is put forward through the A-19 process by the administration, right.

Ms. ESHOO. Well, clearly this has really been overlooked, and my sense is that it rests more with the FDA than the Congress. But I am glad that this is being taken up.

Now, on the user fees, does 100 percent of the user fees that would be coming in fully fund the 130 positions that you have goals for?

Dr. WOODCOCK. We currently have funding—we currently fund 30 positions.

Ms. ESHOO. I know that, but you are anticipating 130.

Dr. WOODCOCK. Yes. Yes.

Ms. ESHOO. So will the user fee——

Dr. WOODCOCK. 135. Yes, 105 additional would be funded by user fees fully.

Ms. ESHOO. Fully.

Dr. WOODCOCK. Uh-huh.

Ms. ESHOO. On the risks relative to the incomplete monographs, you know, the risks that they pose, does that affect the pediatric population?

Dr. WOODCOCK. Yes.

Ms. ESHOO. It does.

And can you give us an example?

Dr. WOODCOCK. Well, in pediatric, cough and cold, in the early 2000s, we recognized that there was harm, significant harm, to children, OK, due to use of pediatric cough and cold medicines, right? But the monograph statements were that they were safe and effective. So it is difficult.

Ms. ESHOO. Were they ever corrected?

Dr. WOODCOCK. Well, not fully, not yet. What we have done is worked with——

Ms. ESHOO. I mean, I did BPCA, PREA. But in this area——

Dr. WOODCOCK. It doesn't apply.

Ms. ESHOO [continuing]. It doesn't apply.

Dr. WOODCOCK. So what we did, we worked with the industry. They voluntarily changed their labeling. But as I showed for the acetaminophen example, not every manufacturer voluntarily changes their label. And we don't have tools right now, because the regulation that is on the books, or the tentative final regulation, says "safe and effective."

Ms. ESHOO. My time has expired.

Thank you.

Mr. BURGESS. The Chair thanks the gentlelady. The gentlelady yields back. The Chair recognizes the gentleman from New Jersey, Mr. Lance, 5 minutes for question, please.

Mr. LANCE. Thank you very much.

Good morning to you. It is always a pleasure to be with you, Dr. Woodcock.

Dr. WOODCOCK. Thank you.

Mr. LANCE. Before I ask questions, I do want to indicate that it is my hope that the committee will examine the cosmetics issue. This has been discussed in opening statements by others. I am involved in that issue with Mr. Pallone, the ranking member of the full committee.

Native Americans use these products, and I have been working in a bipartisan capacity to advance consumer safety and provide a regulatory framework that furthers growth and innovation for American cosmetics manufacturers and small businesses. Consumers need to know that the products they are using are safe, and businesses need a 21-century FDA that responds as quickly as new, great ideas are being developed. The statutory scheme governing cosmetics has been unchanged virtually for 70 years. This is an area where the committee should break ground and find a bipartisan solution for consumers and stakeholders.

Mr. Chairman, on the issue we are discussing this morning, I have a letter that I would like to submit into the record from Colin Mackenzie, who is the head for all of the Americas from GlaxoSmithKline Consumer Healthcare. And I respectfully request that that be put in the record.

Mr. BURGESS. Without objection.

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

Mr. LANCE. Thank you very much.

Dr. Woodcock, off topic, but an issue of acute interest on the Hill right now, right-to-try legislation. I have been involved in this, and I am interested in hearing your perspective on the proposal that recently passed in the Senate.

Dr. WOODCOCK. Well, first of all, my personal opinion, which I have testified on before, is that the Federal Government should not stand between someone who is dying and wants to try a medication. However, I feel if I were that person, or a relative of that person I would want to know if the last several people taking that medication had survived or had died quickly or whatever. So I think for protecting people, it is important that there be some transparency about the outcomes of these uses if something were to pass.

Now, the FDA, as you know, approves about 99 percent, or 99.9 percent of all requests for uses of drugs. However, we are aware that certainly not all firms are willing to give out medicines because they may have a short supply or they may be concerned about the situation, or even the safety of the treatment for that particular individual. So it is, I believe, a complicated scenario. But I believe foremost, we should consider not only the rights of patients, but their safety.

Mr. LANCE. Thank you.

The OTC monograph reform bill we are considering provides for significant expansion of FDA's OTC drug review and oversight ca-

capacity. How will the boost in personnel, which we all favor, enable the FDA to resolve the OTC drug review backlog and timely consideration of applications for new innovative products?

Dr. WOODCOCK. Well, what we have envisioned, and what has been written down so far is sort of a staged improvement where, first, infrastructure and hiring and training and so forth take place. Then innovation begins to be taken up as well as early cases of finalizing these pending proceedings. And those will go overtime with time frames.

So what we envision is that we would start with the innovation along with dealing with the, quote, so-called backlog and the safety. Of course, immediately upon having this new program, we would be able to deal with safety problems much quicker, and we would.

Mr. LANCE. Well, thank you. And I wish you well in that. And, certainly, we want to be involved to the greatest extent possible.

Mr. Chairman, I yield back 32 seconds.

Mr. BURGESS. The Chair thanks the gentleman. The Chair now recognizes the gentlelady from Colorado, Ms. DeGette, 5 minutes for questions, please.

Ms. DEGETTE. Thank you, Mr. Chairman. I really want to thank you for going through regular order with this bill, because I think that this is one of those issues that has really been a bugaboo for a long time. The agency has tried to deal with it, Congress has tried to deal with it.

Dr. Woodcock, I just want to ask you a couple of questions. The first one is about the process that we have used to come up with the discussion draft on which we are having a hearing today. All of the group that everybody mentioned, the Republicans and Democrats on this committee who have been trying to work through this, we have been working with your agency for over a year on that. Is that correct?

Dr. WOODCOCK. Yes.

Ms. DEGETTE. And maybe you can talk a little bit more about some of the steps that the FDA took to get input for us on this OTC monograph reform bill from the various stakeholders.

Dr. WOODCOCK. Certainly.

Well, as I said, we had a public meeting on this in 2014 and, at that time, pointed out the fact that the monographs were not getting finished and the difficulties we were having, the difficulty of safety, and also the problem with innovation. And there was a great deal of support for doing something.

Subsequently with that, we met with the industry numerous times, a large number of times, trying to work out what such a program would look like so that Congress would have something to work with, right, and getting through a lot of the technical issues. So there were numerous meetings about both the policy changes, the legislative changes, that would enable us to have orders and so forth as well as what a user-fee program might look like.

At the same time, we posted meeting minutes of those meetings, and we had various public interactions at different times. And we met with some of the more involved stakeholders, some of whom will testify today as well.

Ms. DEGETTE. And in addition, as the bill was being drafted, I assume that your staff gave technical assistance to the committee staff on this—

Dr. WOODCOCK. That is exactly right. Uh-huh.

Ms. DEGETTE. So, really, the draft we are looking at today is sort of an amalgam of all of those processes that we have had up until today.

Dr. WOODCOCK. Uh-huh.

Ms. DEGETTE. I want to ask you about a specific provision of the discussion draft that allows the FDA to include requirements for the packaging of a drug to help protect children from harm, such as through unit-dose packaging or other requirements.

Does the packaging language include, in the discussion draft, give the FDA sufficient authority to require packaging information to protect children from risks, or is there more that needs to be done?

Dr. WOODCOCK. No, we believe this language is adequate.

Ms. DEGETTE. And why do you believe that?

Dr. WOODCOCK. Because it says other appropriate requirements. So it gives us fairly wide scope.

Ms. DEGETTE. Thank you very much, and thank you for all of your efforts and your agency's efforts.

I yield back, Mr. Chairman.

Mr. BURGESS. The Chair thanks the gentlelady. The gentlelady yields back. The Chair recognizes the gentleman from Florida, Mr. Bilirakis, 5 minutes for questions.

Mr. BILIRAKIS. Thank you, Mr. Chairman. I appreciate it.

Dr. Woodcock, in your testimony, you mentioned that roughly one-third of the monographs started decades ago are still not being finished.

Can you give us a sense of the size of this backlog? How big is it? How long do you think it will take to clear the backlog? What types of submissions are in the backlog?

Dr. WOODCOCK. Well, first of all, you have to understand, this backlog is a little different than, say, what you used to talk about the generic backlog, which we have dealt with. These products are still on the market, right. All these products are on the market. And the process of finalizing the monograph would perhaps remove some of those from the market, right, and establish the conditions under which they can be marketed and perhaps limit those.

So there are about 100 ingredients, I think—several hundred ingredients left out of 800 that haven't been finalized. And there are about maybe—many uses—more than—several hundred uses of those ingredients, because many ingredients are used for multiple different uses. It is difficult to have a count because, until we get to the final monograph, we don't know what will be in or out in each one of those. But that is the ballpark. It is about a third.

Mr. BILIRAKIS. About a third. And how long do you think it will take to clear the backlog?

Dr. WOODCOCK. Well, it will definitely, we believe, take beyond the 5-year period.

Mr. BILIRAKIS. OK. Your testimony shows that funding for FDA's monograph products is fairly flat, somewhere roughly between \$7- and \$8 million annually.

Have submissions being fairly flat year to year, or are they increasing?

Dr. WOODCOCK. Well, the activity has increased because of all the new scientific knowledge. And as I showed you this chart earlier, the churn that happens with any given monograph as we learn more scientific information. But this was fixed, really, in 1972. And so, we don't have any new submissions at all to this in the sense of new ingredients added, or whatever, except a few that might be foreign ingredients that could come within the time and extent pathway, which was what the Sunscreen Innovation Act dealt with.

Mr. BILIRAKIS. OK. Next question: In your testimony, you talked about the slow timeline for changes to the monograph. You used the example of a liver injury for generic Tylenol taking 7 years to update the warning. My goodness. How would monography reform shorten the time frame substantially? What changes would be required by statute? And what can FDA do to—what can they do administratively?

Dr. WOODCOCK. Yes. The goal would be that we could have an issue, an interim final rule on safety, on specific kind of safety changes. And we could issue that rather quickly, and then it would be binding. And then the discussion about it and any further adjudication could occur after that, and we would go to a final rule after we would get public comment. But say we find out a safety problem, a serious safety problem, can be dealt with with labeling. We issue an interim final rule. All the labels change so people are protected, and then we can have further scientific discussions and go to a final rule that would, you know, have had that chance for people to have a lot of discussion.

Mr. BILIRAKIS. OK. Very good. Thank you, Dr. Woodcock.

I yield back, Mr. Chairman. Thank you.

Mr. BURGESS. The Chair thanks the gentleman. The gentleman yields back. The Chair recognizes the gentlelady from Illinois, Ms. Schakowsky, for 5 minutes for questions, please.

Ms. SCHAKOWSKY. Thank you very much.

Dr. Woodcock, let me just say personally, first of all, how much I appreciate what you do and your testimony here. I think you are always transparent and candid and informed. And I thank you very, very much for that. And, you know, we can all look back and think, well, maybe we should have moved ahead further or faster on this issue. But here we are today, and I know that you will be working with us to make sure that we deal with over-the-counter drugs.

I wanted to reaffirm something that has been said a number of times, and that is that I am hoping very much that the committee moves forward on cosmetics. I have a bill, a Cosmetic Safety Act, that I have been working on for a long time. But, you know, when we have shampoos that cause people to lose their hair, a child to have lost all her hair, or a teen's eye shadow is tainted by asbestos, the FDA right now is unable to act. So never let it be said that we ignored the issue of cosmetics. And I think that is another thing we need to move forward on.

But back to OTC. We have talked a lot about the administrative problems, about how long it takes to regulate the cumbersomeness of the process. But I wonder if you could just succinctly list the

safety issues that we need to address that aren't being addressed right now?

Dr. WOODCOCK. OK. Well, we could start with the skin reactions to acetaminophen. We can add the safety problems with pediatric cough and cold medications. We can——

Ms. SCHAKOWSKY. Is that, in part, using the sweet gummy kinds of things that might attract children?

Dr. WOODCOCK. That is a safety issue related to, you know, the dosage form and overdoses in children. That is another issue that we would be dealing with. You know, there are quite a few. We finally finished the liver warning for acetaminophen, but there are other over-the-counter drugs that we probably need to move on safety.

Ms. SCHAKOWSKY. So do you think that once this process is in place, that there will be over-the-counter drugs that will be removed? You alluded to that in the last set of questions.

Dr. WOODCOCK. Well, the monograph system itself envisions removing, when we have a final monograph, certain ingredients out of the monograph. That is kind of how it works. They are all on the market, to start with. And as we go through this process, they get removed. So as we finalize these monographs, certain ingredients be no longer be permissible to be marketed in the United States. Most of them don't have serious safety issues. Some of them simply don't have any data that show they work.

Ms. SCHAKOWSKY. And so some would have to have more warnings?

Dr. WOODCOCK. They might have to have more warnings, or they simply might have to withdraw because they can't produce any data that show that they are effective.

Ms. SCHAKOWSKY. So this new process would be a before-the-fact look at these drugs, or no? Would they still go on the market anyway right away?

Dr. WOODCOCK. No. No drugs supposedly, since 1972, have gone on market. This process now only deals with drugs that are on the market in 1972 or before. What we are planning to put in place, if Congress, you know, agrees with this, is a process where we could move new ingredients into this process and have them regulated this way, which is much less burdensome for the industry, for products that are OTC products where multiple parties can market them.

Ms. SCHAKOWSKY. Let me ask you one more thing. As you know, the Consumer Product Safety Commission is charged with implementing and enforcing special packaging and child-resistant package requirements. I am just wondering how the FDA work and interact with the Consumer Product Safety Commission on these packaging requirements?

Dr. WOODCOCK. Certainly.

We work very closely with them. We recognize their standards. They set the standard for child-resistant packaging, say, for bottles and how you test for that and so forth. And were this to move forward, we could have a memorandum of understanding with them on how we would notify them about anything we were doing on packaging to make sure that they were aware of—you know, if we

were making some safety unit of use packaging, or whatever. We would let them know.

Ms. SCHAKOWSKY. Thank you.

I yield back. I appreciate you.

Mr. BURGESS. The Chair thanks the gentlelady. The gentlelady yields back. The Chair recognizes the gentlelady from Indiana, Mrs. Brooks, 5 minutes for questions, please.

Mrs. BROOKS. Thank you, Mr. Chairman. And I want to also thank Dr. Woodcock for coming before this committee again and explaining to us why it is so necessary to take these long, what I am learning, are overdue steps to update our over-the-counter monograph process.

I appreciate that you have talked about some of the challenges, and you just went through some specific problems, but wondered if there were any other examples of how the inefficiencies in the existing OTC drug monograph system have exposed Americans to risk from potentially unsafe, what you just talked about, I believe, or possibly ineffective drug products. Are there any specific examples you'd like to provide?

Dr. WOODCOCK. Well, until we get the monographs finalized, it is hard to call them ineffective until they are approved—a current system until they are shown by—you know, a regulation is published saying they are ineffective. So that is one of our conundrums. It fits very well with your question. They aren't officially ineffective until they are found ineffective in a final regulation.

Mrs. BROOKS. That is what has been so problematic to that point.

Dr. WOODCOCK. Yes. It is very difficult to get to that point, yes. And, you know, people can always submit more data and all these types of things. We propose them as ineffective and then back and forth. So it can be prolonged very long.

Mrs. BROOKS. Thank you.

We know that American patients, providers, and manufacturers have been benefited greatly from Congress' previous authorization of FDA user fees for prescription drugs, generic drugs, biologic and biosimilar drugs, animal drugs, medical devices. But we know that OTC drugs have—products have lagged behind.

So how do you believe that the user fees authorized in this legislation combined with congressional appropriations will give you the necessary resources to bring the OTC drug regulation on par with other drug and medical products? And then, secondly, in addition to the personnel increases, which you have talk about going from 30 to 135, what resources will this legislation provide FDA to improve the system?

Dr. WOODCOCK. Well, we plan to spend about \$26 million on investing in an IT system so that this becomes paperless instead of a paper-intensive process. And that would require about \$3 million a year ongoing for maintenance once it is built. So the \$26 million will be spread out over the first 4 years or so of the program. We would also invest in training of our people, developing processes and different matters like that.

But this level of program, as I said, will not result in the monographs all being in the new order system and having all final orders at the end of 5 years. It is not going to be that fast.

Mrs. BROOKS. No, I appreciate that. And you have certainly let us know that and have set the expectations.

Are you saying that right now, the current system relies on a paper process?

Dr. WOODCOCK. To a great extent, uh-huh.

Mrs. BROOKS. And so the building of an appropriate IT system which doesn't exist right now would be incredibly helpful?

Dr. WOODCOCK. Yes. And since we are going to put what I call the mulch behind all this past documentation that we have, it is all over the place, we can have an electronic gateway like we do for the other user-fee programs, so submissions are electronic. There are standardized formats. Many things that help everybody in a monograph system be efficient.

Mrs. BROOKS. And just out of curiosity, you talked about additional training that would be needed besides the 30 staff that are currently on board. Have they been involved in this process in a significant way?

Dr. WOODCOCK. Yes. Yes. And bracing themselves if they have to train all these new people, and try to complete some of the work at the same time.

Mrs. BROOKS. Thank you.

Thanks. I yield back.

Mr. BURGESS. The Chair thanks the gentlelady. The gentlelady yields back. The Chair recognizes the gentlelady from Michigan, Mrs. Dingell, 5 minutes for questions, please.

Mrs. DINGELL. Thank you, Mr. Chairman.

Dr. Woodcock, like everybody here, we are a fan and really grateful for all the work you are doing and sitting here through all these questions, many of which sound the same.

But I think we are all saying that we think the OTC system is broken. I don't think it is working for patients, for doctors, for people in the industry who are making innovative products. And your testimony said this, and the questions and answers we are getting keeps reaffirming that.

But just for the record, I, again, want to—it is true that there are far more OTC monograph products than brand of prescription drug products.

Dr. WOODCOCK. That is true.

Mrs. DINGELL. And despite this fact, FDA got only \$7.9 million last year to review OTC products while prescription drug spending totaled \$1.1 billion when user fees were included. Is that correct?

Dr. WOODCOCK. That is correct.

Mrs. DINGELL. So I do have this question, because when you are talking about the 5 years and you are talking about creating an IT system that doesn't exist, is it going to—can money help accelerate that 5 years? Will getting you more money—

Dr. WOODCOCK. Well, we can always do more with more. We can move faster with more, uh-huh.

Mrs. DINGELL. So it is maybe, at some point, you could give us how much you need to create that IT system which will accelerate it and maybe give us a little—that is not in any of the planned questions, but I think it is a question that is really popping here.

Will the draft legislation we are considering today give FDA the resources the agency needs to do a more effective job?

Dr. WOODCOCK. Definitely a more effective job, absolutely, especially combined—we need the authorities to do a more effective job. We can't use these authorities.

Mrs. DINGELL. So as you just said, the lack of funding is not the only issue. The draft legislation we are considering today also gives FDA the authority to use administrative orders to make changes to OTC monographs rather than the current notice and comment rulemaking process which has left many monographs unfinalized and critical safety issues unaddressed.

Does FDA believe that these changes in the draft legislation would make it easier to allow innovative products to make it to the market while also allowing the agency to address the safety issues faster?

Dr. WOODCOCK. Yes. There is a specific innovation pathway that has been built in with timelines and deliverables and so forth. And we definitely contemplate that there is innovation to be had in this space.

Mrs. DINGELL. Thank you.

I think this draft bill goes a long way. I want to take a step back a bit and give some context.

In 2014, Congress came together unanimously to pass the Sunscreen Innovation Act, because our Nation is facing a skin cancer epidemic, and the last time a new OTC sunscreen ingredient was approved was in the 1990s, which you know. This is a symptom of how broken the OTC system is overall, but it is more pressing and it is more urgent because there are 5 million Americans being treated for skin cancer every year. And the rate of melanoma is on the rise.

So while OTC reform is going to make it easier for all innovative products to safely and quickly get to market, we cannot forget the urgent need to ensure that Americans have access to sunscreen products that have been used safely for decades overseas. This is where the frustration comes from all of us.

Dr. Woodcock, Congress remains concerned about this skin cancer epidemic. Can we work with you and other stakeholders to ensure Americans have access to the latest sunscreen ingredients? And what do we need to do to make sure that is here and now?

Dr. WOODCOCK. Well, we have, you know, met, as I said, all the stipulations, actually exceeded them, in the Sunscreen Innovation Act. And what we are waiting for is data—safety data to be submitted. What the Sunscreen Innovation Act did not do is lower the standards for safety for OTC medicines. And so when we receive those data, we will be able to review them promptly because, as I said, the Sunscreen Innovation Act is one of our highest priorities.

Mrs. DINGELL. So how long is it going to take to get that aid up? What is the holdup? Why is this so complicated?

Dr. WOODCOCK. Under most of the things that FDA regulates, we don't do that research; the research is done by the sponsors because they have the medicines, the drugs, the formulations, and they submit that research to us. So we wait for them to conduct the research. We give them parameters about what the research should look like to meet the standards. And then it is on their time frames.

Mrs. DINGELL. Do we know their time frames?

Dr. WOODCOCK. We certainly are in contact with them about their activities. I personally have met with them fairly recently.

Mrs. DINGELL. Thank you.

I yield back the balance of my time, Mr. Chairman.

Mr. BURGESS. The Chair thanks the gentlelady. The Chair recognizes the gentleman from Georgia, Mr. Carter, 5 minutes for questions, please.

Mr. CARTER. Thank you, Mr. Chairman.

Dr. Woodcock, thank you for being here. Help me to understand something here. And I have been in between subcommittee meetings, so please excuse me if I have missed this. When you come up with a profile for a certain ingredient, does it apply to every product, every manufacturer that has that product out there?

For instance, ibuprofen. If you come up with a profile for ibuprofen, didn't you say if you have ibuprofen in your product, you have to have this on your monograph?

Dr. WOODCOCK. The monograph specifies the ingredient ibuprofen if that were in there, which it isn't. But it specifies the ingredient. It specifies the dosages that can be used, and the regimen. And then it specifies what conditions it can be sort of advertised for, right? And if you then market using those parameters, then you don't have to send in an application.

Mr. CARTER. If you market.

So tell me, if you find out something, if you find out that ibuprofen in a certain dosage causes hepatotoxicity, or is eating your stomach up and you want to warn against, so you go to every product out there that has a certain amount of ibuprofen in it, and you say, You need to add this to your monograph?

Dr. WOODCOCK. No. The monograph is an FDA regulation.

Mr. CARTER. OK.

Dr. WOODCOCK. And so we would have to change if—for an ingredient—

Mr. CARTER. But if you change it, do they have to—does every product—

Dr. WOODCOCK. Yes.

Mr. CARTER [continuing]. Out there have to change?

Dr. WOODCOCK. They would have to add the warning, that is correct.

Mr. CARTER. They would have to add the warning. So that seems simple enough.

Dr. WOODCOCK. And only if you didn't—if you got this slide. First of all, we have to have a final monograph in place. OK. And then we have to change it through rulemaking, through notice—

Mr. CARTER. How long does that process take?

Dr. WOODCOCK. Six, 8 years.

Mr. CARTER. Oh, please.

Dr. WOODCOCK. Here is one. This is the external—

Mr. CARTER. I have seen that. Why does it take that long?

Dr. WOODCOCK. Because—

Mr. CARTER. It doesn't take that long with prescription medications. They get them off the market quicker than that.

Dr. WOODCOCK. Oh, yes. We get them off the market lickety-split if they are dangerous, right?

Mr. CARTER. Absolutely.

Dr. WOODCOCK. Here, the issue is—say we have a final monograph in place, the Government has a regulation. The regulation states, this drug is generally recognized as safe and effective. And now we are saying, “Oh, it is not safe.” OK. But we have a regulation that says it is safe.

So for the lawyers in the room, they understand the problem, OK? We have to then—what we do now, because of that, we issue safety alerts, and we look for voluntary changes to the label. But we can’t mandate changes until—

Mr. CARTER. Why not?

Dr. WOODCOCK. Because it is a regulation.

Mr. CARTER. It is a regulation legislatively or through your rules that you promulgated?

Dr. WOODCOCK. Rules that we promulgate. And we have to promulgate a new rule. That is how the rules work before it gets changed.

Mr. CARTER. All right. Let me ask you something. What about off-label uses? You know that happens.

Dr. WOODCOCK. Uh-huh.

Mr. CARTER. I mean, you know, I practiced pharmacy for over 30 years, and I did that regularly. Do you ever address that?

Dr. WOODCOCK. Well, we address it in the sense that if an off-label use is leading to harm, we will send out safety alerts and tell people and so forth.

Mr. CARTER. So if a product has been on the market for years—let’s just take, for example, Diphenhydramine. You know, for many years, that was just an antihistamine that you used for bee stings or something like that.

Dr. WOODCOCK. Right.

Mr. CARTER. And I always recommended it to help somebody sleep, you know. And now you have got Benadryl PM, and you have got products—and they are marking for that now. So how long does that take, to get that new indication there?

Dr. WOODCOCK. Well, they are there already part of—right? They are already part of the sleep aids.

Mr. CARTER. They are now.

Dr. WOODCOCK. They are now.

Mr. CARTER. But initially they weren’t.

Dr. WOODCOCK. They always were, right?

Mr. CARTER. I am not sure about that. But nevertheless—

Dr. WOODCOCK. Yes.

Mr. CARTER [continuing]. You know.

Dr. WOODCOCK. OK. To get a new one is what you are asking about.

Mr. CARTER. Exactly.

Dr. WOODCOCK. There is no way to do that.

Mr. CARTER. An antihistamine. An antihistamine is indicated now for sinus drainage. I mean, you know, at one time when I was in school, which was just a few years ago. But at one time when I was in school, it was—you know, it was a side effect.

Dr. WOODCOCK. Right. Right.

Mr. CARTER. That is what we used it for.

So if a new indication comes out, how long does it take for you to get that new indication for them to be able to market it that way?

Dr. WOODCOCK. Under the monograph, there is no way to do that. Unless it was marketed for that purpose before 1972, then it isn't eligible for the monograph. They could file an NDA.

Mr. CARTER. Before 1972?

Dr. WOODCOCK. Uh-huh. This whole system is fixed in 1972 and in the past.

Mr. CARTER. I think we have discovered the problem.

Thank you, Dr. Woodcock.

Dr. WOODCOCK. Most welcome.

Mr. BURGESS. The gentleman yields back. The Chair thanks the gentleman.

Director Woodcock, I deferred my questions until the end, and I just have a couple.

First off, you mentioned at the start that you had 88 pending monographs; is that correct?

Dr. WOODCOCK. Yes.

Mr. BURGESS. Does the committee have that list? Are you able to share that with the committee?

Dr. WOODCOCK. We certainly could provide that to you.

Mr. BURGESS. And I think it would just provide some context of what we are working on.

And with Mr. Carter's line of questions, there used to be an over-the-counter asthma inhaler, and there is not. That was prior to 1972—

Dr. WOODCOCK. Right.

Mr. BURGESS [continuing]. That that product—

Dr. WOODCOCK. Was available.

Dr. WOODCOCK. Right.

Mr. BURGESS. So let me just ask the question, because I know I am going to get it from other people: Where do we stand with providing that active pharmaceutical ingredient that was in an over-the-counter asthma inhaler prior to 1972?

Dr. WOODCOCK. Right. Well, I can't comment on pending applications, so forth. That was not a monograph product. That was a new drug application product.

Mr. BURGESS. A new drug application?

Dr. WOODCOCK. Product, yes.

So there are products over the counter, like, say, Cortaid or whatever, your vaginal antifungal. Those were all switched from prescription drugs, and they still have a new drug application. They are not monograph products.

Mr. BURGESS. I see. I see.

Well, let me just make the plea that asthmatics do need an over-the-counter preparation. They shouldn't have to incur an emergency room charge in the middle of the night just to get a little bit of relief.

Mr. CARTER. Mr. Chairman, would the gentleman yield?

Mr. BURGESS. Briefly.

Mr. CARTER. Briefly.

I am sorry. What do you do in situations like sudaphedrine that has been approved but is being abused? Do you do anything in that situation?

Dr. WOODCOCK. Well, Congress took the step of moving that, restricting its—

Mr. CARTER. Why would Congress need to? I thought that was your job.

Dr. WOODCOCK. I don't think we have the authority to do that.

Mr. CARTER. So if you see that a drug that has been approved in the 1972 act is now being abused, you don't have the authority to do something about it?

Dr. WOODCOCK. We can move against things on safety grounds. That is right. But that was being—it was actually being used as an ingredient, that one, in manufacturing an abused drug.

Mr. CARTER. Is that not enough?

Dr. WOODCOCK. I would not like to give a legal opinion here.

Mr. BURGESS. And if the gentleman—reclaiming my time. I think there have been various State regulations that have been applied, and that is why in different States there is a different requirement as to whether or not you need to show a driver's license to purchase those products. However, when there was a product that was marketed as a weight-loss product that contained ephedrine, or some derivative of ephedrine, I think you all did move pretty quickly to remove that from the market.

Dr. WOODCOCK. We did. There were safety events related to that, uh-huh.

Mr. BURGESS. Well, I want to thank you for being here today. And just to address the comments that were made, actually on both sides of the dais. You know, where has the committee been? Where has the agency been? I mean, I have just been through my third reauthorization of the user-fee agreements. This concept was brought to me late in the spring. We were pretty far down the road on the user-fee agreements, and I made the decision nothing was going to deter us from getting the user-fee agreements across the finish line, and we did, recognizing that there would be some serious personnel repercussions at the agency if we did not do our work, but we did. I also committed that we would tackle this problem quickly after we got the user-fee agreements put together and delivered, and so here we are today.

I know I personally have made three trips to the Food and Drug Administration, your physical campus. And you received myself and staff one time when we were worried about the drug shortages a few years ago. I think I was there on Dr. Hamburg's first day. Dr. von Eschenbach was kind enough to have me out in the previous iteration of your headquarters. So the agency, I have always found, has been very welcoming to committee members. And there has never been, that I have detected, any reluctance of the agency to talk to members of the committee. Now, maybe there are rules that prohibit the direct communication as far as what will be considered as lobbying. But generally, the flow of information from the agency to at least myself as a Member of Congress, I have always found that door to be open, and I have been grateful for that.

I am grateful for your testimony here today. I think you have helped this process. And clearly, it is something that needs to be

addressed and needs to be fixed, and we will continue to pursue it and get it done.

We will conclude this panel. I am not going to recess in the interest of time. We do have another panel to follow. But again, thank you, Dr. Woodcock, and we will look forward to your next adventure here.

Dr. WOODCOCK. Thank you.

Mr. BURGESS. We will now hear from our second panel of witnesses. And, again, we do want to thank you our witnesses for being here today and taking the time to testify before the subcommittee.

Each witness will have the opportunity to give an opening statement followed by questions from Members. Our second panel, we will hear from Mr. Scott Melville, the president and CEO of Consumer Products Association; Ms. Kirsten Moore, project director, Pew Charitable Trust Healthcare Products; Mr. Michael Werner, partner, Holland and Knight, on behalf of Public Access to Sunscreens Coalition; Dr. Bridgette Jones, chair, Committee on Drugs, American Academy of Pediatrics; and Mr. Gil Roth, president, Pharma and Biopharma Outsourcing Association. We do appreciate you being here today.

Mr. Melville, you are recognized, 5 minutes for an opening statement, please.

STATEMENTS OF SCOTT MELVILLE, PRESIDENT AND CHIEF EXECUTIVE OFFICER, CONSUMER HEALTHCARE PRODUCTS ASSOCIATION; KIRSTEN MOORE, PROJECT DIRECTOR, HEALTHCARE PRODUCTS, THE PEW CHARITABLE TRUSTS; MICHAEL WERNER, PARTNER, HOLLAND & KNIGHT, ON BEHALF OF THE PUBLIC ACCESS TO SUNSCREENS (PASS) COALITION; BRIDGETTE L. JONES, M.D., CHAIR, COMMITTEE ON DRUGS, AMERICAN ACADEMY OF PEDIATRICS; AND GIL Y. ROTH, PRESIDENT, PHARMA AND BIOPHARMA OUTSOURCING ASSOCIATION

STATEMENT OF SCOTT MELVILLE

Mr. MELVILLE. Thank you, Chairman Burgess, Ranking Member, members of the subcommittee, thank you for the opportunity to provide testimony today on the over-the-counter monograph system and the importance of modernizing regulation to enhance the public health. My name is Scott Melville, and I am president and CEO of the Consumer Healthcare Products Association.

Since 1881, CHPA has served as the industry association representing leading manufacturers and marketers of over-the-counter medicines in the United States. CHPA member companies produce the vast majority of OTC medicines in our country, and provide millions of Americans with safe, effective, and affordable therapies to treat and prevent many common ailments and conditions. The availability of self-care treatment options saves money, reduces burdens on the healthcare system, and keeps consumers active and productive.

Given the importance of OTC medicines to consumers and our Nation's healthcare system, it is essential that the regulatory structure that oversees these medicines is one that is modern, effi-

cient, transparent, and accommodating to innovation. Now, the vast majority of OTC medicines in our homes today are regulated under the OTC monograph system, and our members strongly support the system. It oversees over 300 active ingredients and more than 100,000 nonprescription products ranging from antacids to diaper rash creams, from pain relievers to cough and cold products.

While the OTC system was created over 40 years ago, as we have heard earlier today from several speakers, the process is still not complete. Movement on unfinished items has ground to a halt, largely because the system is based on notice-and-comment rulemaking, a thorough but extremely time-consuming process that has slowed across all Government agencies and departments in recent years.

Change is needed to have a regulatory system that accounts for advances in science, accommodates innovation, permits timely updates to safety information, and creates a workable process for completing unfinished monographs.

CHPA has, therefore, worked with FDA and Members of the Congress to provide recommendations for a modernized monograph process by which FDA could make scientific determinations for these ingredients through an administrative order process rather than notice-and-comment rulemaking with necessary due process protections for dispute resolution and issue escalation. These improvements would empower the FDA to act more quickly when needed to address safety issues or other monograph changes while preserving the existing monograph structure, a structure that does not require unnecessary premarket review provided manufacturers utilize ingredients that have been determined to be generally recognized as safe and effective by the FDA.

We understand that this new system, if enacted by Congress, will require more effort on FDA's part, which is why our industry is willing to supplement Government resources with a modest user-fee program. We believe the fee agreement strikes the right balance and will help achieve a more nimble regulatory structure for monograph drugs that would be a win-win-win for consumers, manufacturers, and regulators.

In summary, the draft legislation we are discussing today is incredibly important, and, if enacted, will impact the health of nearly every American for decades to come. It is the product of months and even years of consideration and compromise between many stakeholders, including CHPA's manufacture members.

CHPA has some important technical comments on the discussion draft, and we look forward to continuing to work with members of this committee to finalize the text and support its introduction and consideration by the Congress in the very near future.

Thank you. I look forward to addressing any questions you might have.

[The prepared statement of Mr. Melville follows:]

**House Committee on Energy and Commerce, Subcommittee on Health
Prepared Testimony of Scott Melville, President and CEO Consumer Healthcare Products Association
September 13, 2017**

Chairman Burgess, Ranking Member Green, and Members of the Subcommittee:

Thank you for the opportunity to provide testimony today on the over-the-counter (OTC) Monograph system and the importance of modernizing regulation to enhance the public health.

My name is Scott Melville and I am the President and CEO of the Consumer Healthcare Products Association (CHPA).

Since 1881, CHPA has served as the industry association representing leading manufacturers and marketers of over-the-counter (OTC) medicines in the United States. CHPA member companies produce the vast majority of OTC medicines in our country and provide millions of Americans with safe, effective, and affordable therapies to treat and prevent many common ailments and conditions. The availability of self-care treatment options saves money, reduces burdens on the healthcare system, and keeps consumers active and productive. CHPA also shares educational tools and information with partners across the globe to ensure the safe and responsible use of OTC medicines.

Value of OTC Medicines

More and more consumers are taking their health into their own hands, and they are doing this with the help of OTC medicines. For the more than 240 million Americans who use OTC medicines every year, these remedies are a trusted and affordable way to get well, stay well, and feel well.

The availability of OTC medicine provides significant value to the U.S. healthcare system—\$102 billion in annual savings relative to alternatives and an important increase in access to medicine. This means that, on average, every dollar spent on OTC medicines results in \$6-7 in value for the U.S. healthcare system.

In addition to cost savings relative to alternatives, OTC medicines provide value through significantly expanded access to treatment for the most frequent and common illnesses. The availability of OTC medicines, off-the-shelf, without a prescription, provides symptomatic relief for an estimated 240 million people, 60 million of whom would not seek treatment if OTC medicines were not available. OTC medicines also contribute to increased economic productivity due to less time out of work for physician visits or to care for a sick child.

Commitment to Education and Safety

With more than 100,000 OTC products widely available, the CHPA Educational Foundation is dedicated to helping consumers lead happier, healthier lives through responsible self-care. Through public/private partnerships, national educational campaigns, and media efforts, the foundation educates consumers on how to safely use, store, and dispose of OTC medicines and dietary supplements. Information and materials represent the latest medical and scientific thinking and research and address specific areas where we know consumers need guidance and support.

Up and Away and Out of Sight is an educational program to remind families of the importance of safe medicine storage to prevent young children from getting into medicine. It is led by the Centers for Disease Control and Prevention (CDC) in partnership with the CHPA Educational Foundation, under the umbrella of the PROTECT Initiative.

Know Your Dose educates patients and consumers about safe and effective use of acetaminophen, the most commonly used drug ingredient in the United States. The campaign is organized by the Acetaminophen Awareness Coalition—a group of consumer organizations, health organizations, and healthcare provider organizations, including the CHPA Educational Foundation. The U.S. Food and Drug Administration's Safe Use Initiative and the CDC both serve as coalition advisors. The coalition provides information to consumers as they are making healthcare decisions in pharmacies, health clinics, physician offices, and online.

The foundation's Treat with Care program provides parents and caregivers the information they need to safely treat their children's cough and cold symptoms with pediatric OTC cough and cold medicines. Timed around cold and flu season, "Treat with Care" efforts have included print and radio public service announcements; ads and content in popular parenting media; and posters and brochures for doctors' offices, clinics and pharmacies.

Modernizing the Monograph System

Given the importance of OTC medicines to consumers and our nation's healthcare system, it's essential that the regulatory structure that oversees these medicines is one that is efficient, transparent, and accommodating to innovation. While some OTC medicines are regulated under new drug applications or abbreviated new drug applications, the vast majority of OTC medicines in our homes today are regulated under the OTC Monograph system, which our members strongly support. This system oversees over 300 active ingredients and more than 100,000 products, ranging from antacids to diaper rash creams, from pain relievers to cough and cold products.

The Monograph system has saved time and other resources for the FDA since there is no need to re-review each individual product with established ingredients, already proven safe and effective. For makers of these medicines, it also saves time, resources, and provides for more efficient market access – stimulating competition, thus providing Americans with a wide array of affordable choices and access.

While the OTC Monograph system was created more than 40 years ago, the process is still not complete. Movement on unfinished items has ground to a halt, largely because the system is based on notice and comment rulemaking – a thorough, but time consuming and expensive process, that has slowed across all government agencies and departments in recent years. Change is needed to have a regulatory system that accounts for advances in science, accommodates innovation, permits timely updates to safety information, and creates a workable process for completing unfinished monographs.

CHPA has therefore worked with FDA and Members of Congress to provide recommendations for a modernized Monograph process by which FDA could make scientific determinations for these ingredients through an administrative order process, rather than notice and comment rulemaking, with

necessary due process protections for dispute resolution and issue escalation. This would empower FDA to act quickly when needed to address safety issues or monograph changes, while preserving the existing monograph structure – a structure which does not require unnecessary pre-market review when manufacturers utilize ingredients that have been found to be generally recognized as safe and effective by the FDA.

We want to thank Chairman Burgess, Congressman Latta, Ranking Member Green, Congressman Guthrie, Congresswoman DeGette, Congresswoman Dingell and the entire Committee and its staff for working over many months to craft a discussion draft to bring the OTC Monograph system into the 21st Century.

Striking the Right Balance with User Fees

We understand that this new system, if enacted by Congress, will require more effort on FDA's part, which is why our industry is willing to supplement government resources with a modest user fee program. We believe the fee agreement strikes the right balance and will help to achieve a more nimble regulatory structure for monograph drugs that would be a win win win for consumers, manufacturers, and regulators.

In summary, the draft legislation we are discussing today is incredibly important and will, if enacted, impact the health of nearly every American for decades to come. It is the product of months – and even years -- of consideration and compromise between many stakeholders, including CHPA's manufacturer members. CHPA has some important technical comments on the discussion draft, we look forward to continuing work with members of this committee to finalize the text and support its introduction and consideration by the Congress in the very near future.

Thank you. I look forward to addressing any questions you might have.

Mr. BURGESS. The Chair thanks the gentleman.

Ms. Moore, you are recognized for 5 minutes for questions, please.

STATEMENT OF KIRSTEN MOORE

Ms. MOORE. Thank you very much, Chairman Burgess, Ranking Member Green, members of the subcommittee. Thank you for holding the hearing and for invitation to testify.

My name is Kirsten Moore, and I direct the Pew Charitable Trusts Healthcare Products project. Pew is a non-partisan, non-profit research and advocacy center, and I am here today in strong support of this legislation that would help update FDA regulations of over-the-counter products. By streamlining FDA's process, you have the opportunity to improve consumer safety and promote innovation.

My remarks will focus on the problems with the outdated OTC monograph system, its public health implications, and the benefits of the proposed legislation. Each year, more than 240 million Americans use OTC products. This marketplace is vast and diverse with up to 300,000 products ranging from cough and cold to sunscreen to pain relievers. And in theory, the active ingredients in these products are considered safe and effective when consumers follow the instructions on the label without direction from a healthcare provider. In practice, however, many contain ingredients that the FDA has not yet evaluated. There is no deadline by which FDA's ingredients reviews must be finalized, and several of these reviews have lasted decades.

Two main problems lead us to this point: First, FDA is hampered by a cumbersome and inefficient regulatory system in evaluating these products. It is a system that has not been updated since its introduction in 1972. Second, FDA has only 30 full-time employees and approximately \$8.2 million to oversee this growing marketplace. FDA evaluates safety and efficacy of OTC ingredients through a monograph system, which is described in greater detail in my written testimony. But important to note the changing a monograph is a multi-step process involving review by FDA, the Department of Health and Human Services, and often the White House Office of Management and Budget.

In contrast, FDA review of prescription drugs relies solely within FDA's jurisdiction. The additional steps for review for OTC products add considerable time and do not add to the key determinations of safety and efficacy.

Let me provide just one example of the current system's effects on public health. This April, FDA required that companies add the strongest form of warning label to children's prescription cough and pain medications containing codeine. The drug can cause potentially fatal breathing problems, especially in children under 12. These safety concerns led an advisory committee to recommend that FDA remove codeine from OTC products in 2015, but FDA has not made this change yet because of the inefficient monograph system. When patients are in harm's way, we need action, not bureaucracy.

This spring, Pew and several other public health stakeholders issued a set of principles for over-the-counter monograph reform.

These principles are broadly reflected in both the House and Senate language. And the bipartisan legislation that you are considering would produce a win-win—I will up it win-win-win—reducing regulatory burdens and protecting consumers in four key ways: First, by driving efficiency. The proposed reforms will replace cumbersome rulemaking with an administrative order process, again, aligning FDA’s decision-making authority for OTC products with the authority for prescription drugs. The legislation also would expedite the review process by giving the Secretary additional authority for data collection.

Second, improving safety. The proposal will ensure that if FDA has reason to believe a product is unsafe, it can take swift actions. Currently, products remain on the market when FDA has insufficient information about whether or not they are safe and effective, because they cannot be removed before a final monograph is issued.

Third, helping innovations. Under this legislation, FDA could more quickly accommodate innovation in OTC drug products, permitting new ingredients as well as new indications and formulations on existing ingredients.

And lastly, providing resources. The proposed agreement would provide FDA with the resources required to clear up FDA’s review backlog, address safety concerns for products currently on the market, and review future applications for innovative products in a more timely manner.

Pew supports the proposed legislation because it will lead to improvements in consumer safety and administrative efficiency. It strikes a sensible balance and reflects thoughtful compromise between stakeholders.

The current monograph system has had detrimental effects on consumers, and hinders FDA’s ability to ensure the safety and effectiveness of over-the-counter products.

We applaud this subcommittee for this bipartisan proposal, and urge Congress to capitalize on this momentum and pass this legislation as soon as possible.

Thank you.

[The prepared statement of Ms. Moore follows:]

Testimony before the Committee on Energy and Commerce, Subcommittee on Health, United States House of Representatives

Chairman Burgess, Ranking Member Green, members of the sub-committee, thank you for holding this hearing and for the opportunity to present testimony. My name is Kirsten Moore; I direct the Health Care Products project at The Pew Charitable Trusts. Pew is a nonprofit, nonpartisan research and policy organization with a longstanding interest in drug quality and safety. Today I am here to relay Pew's strong support for reforming the regulatory framework for over-the-counter (OTC) drug products. Modernizing the OTC monograph system is necessary to enhance efficiency, improve safety, promote innovation, and ensure that FDA has adequate resources – all of which ultimately help consumers.

Scope of Problem

OTC products range from antiperspirant and deodorant to sunscreen to cough and cold medication and pain relievers. The OTC drug marketplace includes over 300,000¹ unique products and has annual sales of \$32 billion.² FDA's monograph review framework for evaluating OTC ingredients is cumbersome, inefficient, and outdated – having not been revised since its inception in 1972. The multi-step rulemaking process is lengthy, and the agency's lack of resources hinders FDA's ability to ensure the safety and effectiveness of OTC products and to promote innovation.

Most over-the-counter drugs are not regulated like prescription medications. Manufacturers of prescription drugs must submit clinical data to FDA to show they are safe and effective for their intended use and population before marketing them. These data are submitted in the form of a new drug application that FDA can approve, deny, or make a request for additional data. The process is drug-product specific, and FDA approves the formulation and what goes on the label (for example, intended uses, warnings, and directions for the consumer). New OTC products can be reviewed through this process, either as nonprescription drugs or as prescription drugs that may be sold over the counter later. Examples include certain allergy medications, antacids, and fluoride toothpastes.

In contrast, the majority of OTCs rely on a “monograph” system, which entails evaluating the safety and effectiveness of active ingredients in the product rather than the product itself. A monograph is a published “recipe” used by product manufacturers that is typically organized into therapeutic classes or product categories, such as topical antimicrobials. The monograph for each category includes active ingredients, dosage form (for example, tablet or ointment), doses and dosage instructions, concentration, and mandatory labeling, and is published as a final rule in the Federal Register and codified in the Code of Federal Regulations. If a manufacturer follows the recipe exactly for an existing monograph, the company is not required to seek FDA approval for a new product. Many ingredients in OTC products have been on the market since before 1962, when Congress first required that new drug products be shown to be effective, as well as safe, before they were marketed. FDA, recognizing in the 1970s that it needed a way to evaluate the many ingredients in products that were already on store shelves, initiated a scientific review of all active ingredients in them. Advisory committees, composed of physicians, pharmacists, consumers, and industry representatives, recommended that each active ingredient be in one of three categories: Category I includes ingredients which have been subject to adequate clinical investigations and testing, and experts generally agree that they demonstrate safety and efficacy for intended use. Category II includes ingredients that are not generally recognized as safe and effective, but may continue to be marketed until a monograph is finalized, which can take years. Category III includes ingredients for which there is not enough information to determine whether they are generally recognized as safe and effective. Again, the product can remain on the market until FDA finds that there is enough evidence to make a final determination.

Making changes to a monograph is a multi-step process. All proposed changes to monographs are reviewed by FDA and the Department of Health and Human Services, and often the White House Office of Management and Budget, which estimates the cost and benefit of the change to the economy and consumers. FDA also receives and must respond to public comment throughout the monograph revision process. In contrast, new drug applications are reviewed solely by FDA on the basis of whether the product is safe and effective. The additional review steps for monographs add considerable time, and they risk prioritizing economic considerations over consumer health and safety. There is no deadline by which monographs must be finalized, and several have been under review for decades.

Public Health Implications of Outdated OTC Monograph System

Approximately 240 million people, including infants and the elderly, use OTC products annually.³ FDA's limited resources and authority to regulate OTC products in a timely and streamlined fashion hinder its ability to oversee their safety and effectiveness. This can lead to critical adverse events, and create unreasonable discrepancies between the agency's response to the same risks in OTC products versus prescription drugs.

In 2002, FDA held an advisory committee meeting to discuss the problem of liver injury related to the use of OTC acetaminophen products.⁴ The advisory committee recommended a specific liver toxicity warning and changes to OTC packages so that products containing acetaminophen could be more easily identified.⁵ It took the agency seven years to finalize a rule amending the labeling requirements for OTC drugs in order to inform consumers about the risk of liver injury when using acetaminophen (and four years even to issue an initial proposed rule).^{6,7} In contrast, it took FDA only two years to convene an advisory committee and require new Boxed Warning on all *prescription* drug products that contain acetaminophen.^{8,9}

Similarly, FDA was able much more quickly to address the risks of prescription anti-inflammatory drugs compared with the identical active drug sold as an OTC product. In 2002, FDA held an advisory committee meeting to discuss the gastrointestinal (GI) and renal toxicity risks associated with the use of OTC nonsteroidal anti-inflammatory drugs (NSAIDs).¹⁰ The advisory committee agreed that a change to the current label was necessary to address these risks, but again, it took the agency seven years to publish a final rule requiring the change.¹¹ It took the agency less than a year to require a Boxed Warning for prescription NSAIDs.¹²

More recently, in April 2017, FDA required companies to add the strongest form of warning to children's prescription cough and pain medications containing codeine, a controlled substance. The agency was responding to concerns that the drug can cause potentially fatal breathing problems, especially in children younger than 12 years.¹³ In 2015, an FDA advisory committee identified 24 deaths and 64 cases worldwide of serious breathing problems in the previous 50 years among children who took medications containing codeine. Twenty-one of those who died were children younger than 12.¹⁴ Despite the evidence, FDA has not yet made the change to remove codeine from the monograph for OTC children's cough and cold products.

These examples illustrate the unnecessary delay incorporated into a multi-step rulemaking system, which compromises FDA's ability to respond swiftly to address new safety information and protect consumers. This is particularly concerning as there is no presumption of a health care professional intermediary in an over-the-counter environment, so consumers lack vital information about safe or appropriate use of products. FDA, industry, and public health stakeholders are united in their conviction that OTC monograph reform is critical to protect public health, and are in strong support of this proposed legislation.

OMUFA Draft Language Improves FDA's Ability to Prioritize Public Health

Earlier this year, Pew joined with the American Academy of Pediatrics, the American Academy of Allergy, Asthma & Immunology, American Academy of Dermatology Association, the American Public Health Association, the National Association of County and City Health Officials, Society for Maternal-Fetal Medicine and March of Dimes to issue a set of principles for over-the-counter monograph reform.¹⁵ These principles call for:

- (1) replacing the cumbersome rulemaking process with a more efficient mechanism for creating and updating monographs;
- (2) allowing FDA to act promptly to address emerging safety issues; providing FDA with sufficient resources to accommodate OTC drug innovation;
- (3) creating an efficient data collection system for FDA; and
- (4) establishing FDA as the final arbiter of scientific evidence on the safety and effectiveness of ingredients and changes to monographs.

These principles are broadly reflected in both the House and Senate language which have been circulated. We will highlight several significant improvements under the proposed legislation.

Efficiency

OTC monograph reform will enhance efficiency by replacing the cumbersome rulemaking process with an administrative order process, aligning the decision-making authority FDA has for OTC products with the authority the agency already has for prescription drugs. Under the proposed system, agency scientists would be able to make important safety and effectiveness decisions about OTC ingredients. Monograph reform would also expedite the review process by giving the Secretary authority to standardize the content and format for electronic data submissions and set forth a procedure for collecting and analyzing such data. This improves on the current system, in which reviewers must sort through and then systematize a volume of disorganized, often fragile, paper documents into a package that can be properly reviewed.

Safety

Monograph reform will improve FDA's ability to respond to safety threats and ensure the agency has complete information about OTC products. Allowing the agency to change the rules for OTC products by administrative order would allow it to react rapidly to emerging safety issues regarding the use and misuse or abuse of OTC drug products. Currently, products for which FDA has insufficient information remain on the market, but OTC reform would allow FDA to complete its review and remove products from the market if sufficient evidence of safety and effectiveness is lacking. Furthermore, requiring firms to submit all information in their possession, including negative data (as is required for prescription drug submissions), would enhance safety by ensuring that FDA is the final arbiter of scientific evidence on the safety and effectiveness of ingredients and changes to monographs, as is already the case for prescription drugs and medical devices. To ensure safety, any new exclusivity provisions should not apply to safety-related changes, enabling universal adoption of such changes and, user fees should not be assessed for adding new safety information, so that firms are likely to update products accordingly.

Innovation

With an improved regulatory regime, FDA would more quickly be able to accommodate innovation in OTC drug products, permitting new ingredients, and new indications and new formulations for existing ones, potentially giving patients who are unable to take pill forms to access medications through other routes of administration.

Resources

Achieving these potential commercial and public benefits will require additional FDA resources. Establishing a user fee program for OTC products will significantly enhance FDA's ability to effectively oversee this marketplace. Approximately 18 scientific reviewers oversee about 800 active ingredients for over 1,400 distinct therapeutic uses,¹⁶ with more than half of these reviewers dedicated to review of sunscreen ingredients.¹⁷ For context, FDA dedicates approximately 18 FTEs to review one application to market a new prescription drug.¹⁸ The proposed agreement would provide FDA with the resources required to substantially expand the OTC review and oversight capacity – from 31 FTEs (this number includes legal, policy and support staff as well as scientific reviewers) in 2018 to 110 FTEs in FY2022. This boost in personnel will enable FDA to clear up the monograph review backlog, address safety concerns for products currently on the market, and review future applications for innovative products in a timely manner.

OMUFA is a Compromise

Pew supports this bipartisan proposed legislation as written, because it will lead to improvements in public safety and administrative efficiency. However, it is noteworthy that the new exclusivity provided to certain OTC products that do not undergo clinical trials under this measure would exceed the 6-months' additional exclusivity that Congress provided to companies that carry out tests of their drugs in a pediatric population. Pew also recommends incorporating language authorizing the Secretary to require packaging to be redesigned if needed to resolve safety concerns.

Other concerns with this legislation may be resolvable as stakeholders gain experience in a new system, thus Pew recommends incorporating a mechanism that facilitates future negotiations between industry and FDA, so that they can resolve remaining inefficiencies without the need for new legislation. For example, the proposed process for dispute resolution over OTC ingredients requires multiple notifications and potential delays and is more complex than the process for resolving disputes over prescription drugs. Industry and FDA should have an opportunity to agree to a more streamlined dispute resolution process than is contemplated by the current legislation. In addition, the proposed language allows a manufacturer to file an application over protest, even when FDA has already reviewed and deemed that file insufficient with regard to evidence. These provisions undermine the goal of increased efficiency, both by requiring FDA to use resources on review of insufficient applications and by delaying the agency's ability to turn to applications from sponsors who have submitted complete files.

Conclusion

The current monograph system, unchanged since 1972, has had detrimental effects on consumers and compromises FDA's ability to ensure the safety and effectiveness of OTC products. We applaud this subcommittee for its bipartisan work on the current proposal. The Pew Charitable Trusts urges Congress to capitalize on this momentum and pass this legislation as soon as possible.

¹ Food and Drug Administration, "Drug Applications for Over-the-Counter (OTC) Drugs," accessed Aug. 25, 2017, <http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/over-the-counterdrugs/default.htm>.

² Consumer Healthcare Products Association, "OTC Retail Sales 1964-2015," accessed Aug. 25, 2017, http://www.chpa.org/PR_OTCRetailSales.aspx.

³ Approximately 240 million people in the United States use OTC products annually in the seven categories (allergy, analgesics, anti-fungals, cough/cold/flu, upper and lower gastrointestinal, and medicated skin) that represent the significant majority of OTC products purchased in the United States. Consumer Healthcare Products Association, "The Value of OTC Medicine to the United States," (2012).

⁴ U.S. Food and Drug Administration, "Non-prescription Drugs Advisory Committee; Notice of Meeting," 67 Fed. Reg. 161 (August 20, 2002).

⁵ U.S. Food and Drug Administration, "June 29-30, 2009: Joint Meeting of the Drug Safety and Risk Management Advisory Committee with the Anesthetic and Life Support Drugs Advisory Committee and the Nonprescription Drugs Advisory Committee: Meeting Announcement," last modified July 30, 2013, <https://wayback.archive-it.org/7993/20170722143526/https://www.fda.gov/AdvisoryCommittees/Calendar/ucm143083.htm>.

⁶ U.S. Food and Drug Administration, "Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Required Warnings and Other Labeling," 71 Fed. Reg. 77314 (Dec. 26, 2006).

⁷ 21 CFR § 201.326.

⁸ U.S. Food and Drug Administration, "June 29-30, 2009: Joint Meeting of the Drug Safety and Risk Management Advisory Committee with the Anesthetic and Life Support Drugs Advisory Committee and the Nonprescription Drugs Advisory Committee: Meeting Announcement," last modified July 30, 2013, <https://wayback.archive-it.org/7993/20170722143526/https://www.fda.gov/AdvisoryCommittees/Calendar/ucm143083.htm>.

⁹ U.S. Food and Drug Administration, "FDA Drug Safety Communication: Prescription Acetaminophen Products to be Limited to 325 mg Per Dosage Unit; Boxed Warning Will Highlight Potential for Severe Liver Failure (January 13, 2011)," last modified July 31, 2017, <https://www.fda.gov/Drugs/DrugSafety/ucm239821.htm>.

¹⁰ U.S. Food and Drug Administration, "Nonprescription Drugs Advisory Committee; Safety Issues Related to ASA and NSAIDs, September 20, 2002," accessed September 8, 2017, <https://www.fda.gov/ohrms/dockets/ac/02/transcripts/388212.pdf>.

¹¹ 21 CFR § 201.326.

¹² U.S. Food and Drug Administration, "Public Health Advisory - FDA Announces Important Changes and Additional Warnings for COX-2 Selective and Non-Selective Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) (April 7, 2005)," last modified Aug. 16, 2013, <https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm150314.htm>.

¹³ U.S. Food and Drug Administration, "FDA Drug Safety Communication: FDA Restricts Use of Prescription Codeine Pain and Cough Medicines and Tramadol Pain Medicines in Children; Recommends Against Use in Breastfeeding Women" last modified April 20, 2017, <https://www.fda.gov/Drugs/DrugSafety/ucm549679.htm>.

¹⁴ U.S. Food and Drug Administration, "FDA Briefing Document: Joint Pulmonary-Allergy Drugs Advisory Committee and Drug Safety and Risk Management Advisory Committee Meeting; The Safety of Codeine in Children 18 Years of Age and Younger" Dec. 10, 2015, <https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Pulmonary-AllergyDrugsAdvisoryCommittee/UCM475975.pdf>.

¹⁵ The Pew Charitable Trusts, "Pew and the American Academy of Pediatrics Outline Principles for Over-the-Counter Drug Regulation Reform," accessed Sept. 11, 2017, <http://www.pewtrusts.org/en/research-and-analysis/analysis/2017/05/05/pew-and-the-american-academy-of-pediatrics-outline-principles-for-over-the-counter-drug-regulation>.

¹⁶ Renu Lal, Pharm.D., "User Fees and the Future of the OTC Monograph System," *FDA/CBER SBIA Chronicles*, July 6, 2016, <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/UCM510074.pdf>.

¹⁷ U.S. Food and Drug Administration, "Report in Response to the Sunscreen Innovation Act (P.L. 113-195) Section 586G," accessed Sept. 11, 2017, <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/UCM503441.pdf>.

¹⁸ Renu Lal, Pharm.D., "User Fees and the Future of the OTC Monograph System."

Mr. BURGESS. The Chair thanks the gentlelady.

Mr. Werner, you are recognized for 5 minutes for your opening statement, please.

STATEMENT OF MICHAEL WERNER

Mr. WERNER. Thank you, Mr. Chairman and Ranking Member Green. My name is Michael Werner. I am a partner at the law firm of Holland & Knight and a public policy advisor to the Public Access to SunScreens Coalition, the PASS Coalition. Thank you for inviting me to testify today regarding efforts to improve and strengthen the approval process for over-the-counter OTC products, including sunscreen ingredients.

The PASS Coalition is a multistakeholder coalition composed of public health groups, dermatologists, sunscreen manufacturers, and leading advocates for skin cancer patients. The PASS Coalition was formed to ensure Americans have access to the latest sunscreen technology to curb the skin cancer epidemic in the United States. And to address this problem, Congress, led by this subcommittee, the FDA, the coalition and other stakeholders came together to enact the bipartisan Sunscreen Innovation Act, the SIA, in 2014, to ensure Americans get access to new sunscreens. And working together, we identified regulatory barriers to the consideration of OTC sunscreen ingredients, and created historic reforms to address them. And the Act was enacted by the House and Senate unanimously.

The PASS Coalition supports the efforts of this subcommittee to extend similar reforms to other OTC product categories. We also support the establishment of a user-fee program to provide FDA with the resources it needs to implement these reforms. Based on our experience over the last 3 years in implementation of the SIA, and our productive conversations with FDA leadership, including Dr. Woodcock, we believe there are several improvements needed to continue to enhance the review process for pending and new sunscreen ingredients. And the OTC reform legislation being considered by this subcommittee provides the opportunity to codify these improvements and achieve the promise of the SIA.

Mr. Chairman, skin cancer remains a public health crisis in the United States. According to the Surgeon General, over 5 million Americans are treated for skin cancer every year, and each year there are more new cases of skin cancer than breast cancer, prostate cancer, lung cancer and colon cancer combined. And in the U.S., a patient is diagnosed with melanoma every 8 minutes and an American loses her life every hour from the disease. So clearly, Americans need access to all available safe and effective sunscreen products.

The last time a new OTC sunscreen ingredient was approved in the U.S. was decades ago. And since 2002, eight new sunscreen ingredients have been submitted for review under the FDA so-called time and extend process. And these ingredients have been widely available in Europe, Asia and elsewhere for decades. Clearing this backlog of applications will ensure that Americans have greater access to broad spectrum sunscreens and get better protections against both UVA and UVB rays.

As you have heard this morning, FDA has met all the timelines required by the Act. But unfortunately, none of the eight pending sunscreen ingredients has yet received a final decision, and they are not available in the United States.

Based on recent conversations with FDA, there is agreement that some changes to the SIA for the eight pending ingredients are needed, and that any new OTC pathway should accommodate sunscreen ingredients.

So as Congress considers OTC reform legislation, the PASS Coalition respectfully submits the following principles for consideration. First, eight sunscreen ingredients that have already received proposed administrative orders should continue to be considered under the SIA. New sunscreen ingredients should go to the OTC reform framework. Second, any new OTC drug approval pathway should be flexible enough to accommodate new sunscreen ingredients with U.S. or international market experience and should not require the sponsor to file a new drug application for its active ingredient to be considered for an OTC administrative order. Third, any OTC reform legislation should authorize FDA to meet individually on a confidential basis with sponsors of sunscreen ingredients to allow for open discussion of commercial confidential information and trade secrets.

And finally, the FDA's testing standards for these products should be periodically reviewed and assessed. Inclusion of provisions that incorporate these principles will ensure Americans have access to safe and effective sunscreen ingredients that are available across the world. The draft legislation that we have seen contain many of these provisions, and we look forward to continuing to working with the subcommittee.

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

[The prepared statement of Mr. Werner follows:]



**Testimony of Michael Werner, JD
Partner, Holland & Knight
On behalf of
The Public Access to SunScreens (PASS) Coalition
House Committee on Energy and Commerce
Subcommittee on Health
September 13, 2017
Summary**

The Public Access to SunScreens (PASS) Coalition is a multi-stakeholder coalition composed of public health groups, dermatologists, sunscreen manufacturers, and leading advocates for skin cancer patients. The PASS Coalition was formed to ensure Americans have access to the latest sunscreen technology to curb the skin cancer epidemic in the United States.

According to the U.S. Surgeon General, over 5 million Americans are treated for skin cancer every year, costing American taxpayers \$8.1 billion annually. Based on the skin cancer epidemic in the U.S., Americans must have access to all available safe and effective sunscreen products, especially those that have been available for years in Europe and elsewhere and have been shown to offer a public health benefit to the populations that have been using these products.

In a joint effort to address the skin cancer epidemic, Congress, FDA, the PASS Coalition, and other stakeholders came together to enact the bipartisan Sunscreen Innovation Act (SIA; Public Law 113-195) in 2014, which included several provisions to improve Americans' access to OTC sunscreen ingredients. FDA has met all the timelines required by the SIA. Unfortunately, none of the eight pending sunscreen ingredients have yet received a final decision.

The PASS Coalition supports the efforts to enact reforms to the OTC drug approval process. As Congress considers OTC reform legislation, the PASS Coalition has several principles for this Committee to consider in drafting your reform legislation. These principles have been developed based on feedback from the FDA, Congress, and other public health groups and industry stakeholders.



**Testimony of Michael Werner, JD
Partner, Holland & Knight
On behalf of
The Public Access to SunScreens (PASS) Coalition
House Committee on Energy and Commerce
Subcommittee on Health
September 13, 2017**

Good morning, Chairman Burgess, Ranking Member Green, and members of the Subcommittee, my name is Michael Werner. I am a partner at the law firm of Holland & Knight and a public policy advisor to the Public Access to SunScreens Coalition (PASS Coalition). Thank you for inviting me to testify today regarding efforts to improve and strengthen the approval process for over-the-counter (OTC) products, including sunscreens.

The PASS Coalition is a multi-stakeholder coalition composed of public health groups, dermatologists, sunscreen manufacturers, and leading advocates for skin cancer patients. The PASS Coalition was formed to ensure Americans have access to the latest sunscreen technology to curb the skin cancer epidemic in the United States. The PASS Coalition's mission is to work collaboratively with all stakeholders, including the FDA, the White House, Congress, health providers, consumer organizations, and sunscreen manufacturers, to establish a transparent review within a predictable timeframe for pending time and extent applications (TEAs) for OTC sunscreen ingredients. We are also committed to ensuring that FDA has the resources it needs to conduct the pre-market review of sunscreen ingredients.

In a joint effort to address the skin cancer epidemic, Congress, FDA, the PASS Coalition, and other stakeholders came together to enact the bipartisan Sunscreen Innovation Act (SIA; Public Law 113-195) in 2014. By working together and across the aisle, Congress, FDA and stakeholders identified a number of regulatory barriers to the consideration of OTC sunscreen ingredients and created historic reforms to address these barriers for sunscreen ingredients. The SIA was ultimately enacted by both the House and Senate by voice vote.

The PASS Coalition supports the efforts of the House Energy & Commerce Committee, and your counterparts in the Senate, to extend similar reforms achieved for sunscreens to other OTC product categories. We also support the establishment of a user fee program to provide FDA with the resources to implement these reforms. Based on our experience over the last three years implementing the SIA and productive conversations with Dr. Woodcock and Deputy Commissioner Anna Abram, we also believe that there are several improvements that are necessary to help continue to improve the review process for pending sunscreen ingredients. The OTC reform legislation being considered by the Subcommittee provides the opportunity to codify these improvements to finally achieve the promise of the SIA.

Public Health Impact of Skin Cancer

Mr. Chairman, skin cancer is a public health crisis in the United States. On July 29, 2014, the U.S. Surgeon General issued *A Call to Action to Prevent Skin Cancer* stating: "Even though most skin cancers can be prevented, rates of skin cancer, including melanoma, are increasing in the United States." According to the U.S. Surgeon General, over 5 million Americans are treated for skin cancer every year, costing American taxpayers \$8.1 billion annually.

The alarming rate of skin cancer means that each year there are now more new cases of skin cancer than the combined incidence of breast cancer, prostate cancer, lung cancer, and colon cancer. Melanoma, attributed primarily to UV exposure, is the deadliest of the skin cancers as a result of its ability to move quickly and spread to distant organs in the body and is rising dramatically across demographics. In the United States, a patient is diagnosed with melanoma every eight minutes and an American loses her life every hour from the disease. Despite recent tremendous advancements in treatment science, the melanoma death rate for patients with metastatic disease has remained static over the past 30 years, and according to the American Cancer Society the incidence of this deadly disease continues to rise at alarming rates. From 1975-2011, rates of melanoma in young men and women ages 20-39 years increased by 34% in men and by 84% in women.

These figures show that Americans must have access to all available safe and effective sunscreen products, especially those that have been available for years in Europe and elsewhere and have been shown to offer a public health benefit to the populations that have been using these products.

The Surgeon General's 2014 *Call to Action* concludes with this powerful recommendation: "We must act with urgency to stop the ever-increasing incidence of skin cancers in the United States."

United States Sunscreen Backlog

The last time a new OTC sunscreen ingredient was approved in the United States was the 1990s. Since 2002, eight new sunscreen ingredients have been submitted for review under the FDA's TEA process. Meanwhile, these ingredients have been widely available in Europe, Asia, and Central and South America for decades. That's why the PASS Coalition supported enactment of

the bipartisan SIA by the Congress. Clearing the backlog of sunscreen applications will ensure that Americans have greater access to broad-spectrum sunscreens, which provide better protection against both UVA and UVB rays.

Overview of Sunscreen Innovation Act Reforms

The SIA represented the culmination of fruitful collaboration between external stakeholders, including the PASS Coalition, the FDA, and Congress, who all saw the need to improve Americans' access to OTC sunscreen products to reduce the incidence of cancer in this country.

As a brief reminder, the SIA incorporated several major provisions, including:

- allowing FDA to make scientific decisions on OTC ingredients with administrative orders instead of rulemaking;
- establishing timelines for FDA review of the safety and efficacy of sunscreen active ingredients;
- allowing robust opportunities for public comment and the submission of safety and effectiveness data;
- ensuring a sunscreen ingredient with at least five years of safe and effective use in a comparable jurisdiction is eligible for consideration as under existing FDA regulations;
- requiring FDA to issue final guidance on the safety and effectiveness data required for FDA to review new sunscreen ingredients.

FDA has met all the timelines required by the SIA. Unfortunately, none of the eight pending sunscreen ingredients have yet received a final decision.

In 2016, the PASS Coalition contracted with two independent scientists, Edward Sargent, Ph.D., M.P.H., a toxicologist, and Jeffrey B. Travers, M.D., Ph.D., F.A.A.D., a dermatologist, to review FDA's draft guidance and examine proposed orders for the eight pending sunscreen ingredients. The purpose of the independent scientific review was to provide the Coalition with an analysis of FDA's actions and to help the Coalition develop recommendations for an appropriate testing regimen based on the risk profile of the pending sunscreen ingredients and the growing incidence of skin cancer. The independent scientific review resulted in recommendations with validated testing procedures to balance the benefits of additional broad spectrum sunscreen protection versus the risk of skin cancer in addition to those described in FDA's draft guidance. The conclusions of Drs. Sargent and Travers were peer reviewed and published in the Journal of Regulatory Toxicology and Pharmacology in August 2016 and was entitled "Examining the differences in current regulatory processes for sunscreens and proposed safety assessment paradigm."

Based on recent conversations with FDA, there is agreement that some changes to the SIA for the eight pending ingredients would be beneficial to establish an opportunity for meetings with sponsors of new sunscreen ingredients to discuss validated testing procedures that would support a determination of general recognition of safety and effectiveness.

OTC Reform Legislation

The PASS Coalition supports the efforts to enact reforms to the OTC drug approval process. Many of the same structural issues that the SIA sought to address for sunscreens also apply to other categories of products, particularly the requirement for FDA to make OTC drug decisions through rulemaking and the need for a predictable and transparent review process.

As Congress considers OTC reform legislation, the PASS Coalition has several principles for this Committee to consider in drafting your reform legislation. These principles have been developed based on feedback from the FDA, Congress, and other public health groups and industry stakeholders.

First, the eight sunscreen ingredients that already have received proposed sunscreen administrative orders should continue to be considered under the SIA. The first of these pending sunscreen ingredients was submitted in 2002 and has been under FDA review for 15 years. Each ingredient was required to be approved for at least 5 years in a comparable jurisdiction, which means that some of the pending ingredients have over 20 years of international experience. OTC reform legislation should allow sponsors of the eight pending to complete consideration of its ingredients under the SIA. New sunscreen ingredients, as with all other OTC drugs, should go through the OTC reform framework.

Second, any new OTC drug approval pathways must be flexible enough to accommodate new sunscreen ingredients with U.S. or international experience. The OTC reform process should allow sponsors to use U.S. or international safety and effectiveness data as the basis to meet FDA's standard for products generally recognized as safe and effective, similar to the framework established in the TEA process and codified in eligibility requirements of the SIA.

Third, any new OTC drug approval pathway should not require the sponsor of a sunscreen application to file a New Drug Application (NDA) for its active ingredient to be considered for an OTC administrative order. We believe that the NDA process is particularly burdensome for new sunscreen ingredients, and the FDA should have alternate pathways at their disposal to consider these new applications to maximize the ability of safe and effective products to come to

market as soon as possible. For instance, the NDA process evaluates only finished products, however sunscreen active ingredients are included in a variety of seasonal finished products to block UVA and/or UVB radiation from the sun. This is the same rationale used by FDA when it established the TEA process.

Fourth, any OTC reform legislation should authorize FDA to meet individually on a confidential basis with sponsors of sunscreen ingredients to allow for open discussions of confidential commercial information or trade secrets. FDA has expressed a willingness to consider validated alternative testing procedures in support of a determination of general recognition of safety and effectiveness outside of what the agency included in its final guidance on safety and effectiveness data. An individual meeting will also assist in the establishment of testing protocols for tests that have never been performed on a sunscreen ingredients before.

Finally, given the importance of innovation in the OTC space for getting patients the safe and effective products they require, the FDA's testing standards for these products should be periodically reviewed and assessed. As I mentioned previously, independent studies have already concluded that improvements to the testing regimes for sunscreen ingredients can and should be made to incorporate new scientific evidence and appropriately reflect the potential risks of these ingredients with the proven public health benefits of skin cancer prevention.

Ultimately, we believe that the OTC legislation currently being developed by Congress is the proper vehicle for these and other changes to be made to the current OTC framework. Inclusion of provisions that incorporate these principles will ensure Americans have access to sunscreen ingredients that are available across the world. Given the number of new products, labeling changes, and other issues pending regarding the tens of thousands of OTC products in the United

States, the time is now for Congress to act to improve the way these products are considered and approved.

Thank you for the opportunity to testify before you today. I look forward to your questions.

Mr. BURGESS. The Chair thanks the gentleman.

The Chair recognizes Dr. Jones, 5 minutes for your opening statement, please.

STATEMENT OF DR. BRIDGETTE L. JONES

Dr. JONES. Thank you. Good morning, Chairman Burgess and Ranking Member Green. Thank you for the opportunity to speak here today about the importance of modernizing the regulation of over-the-counter drugs for America's children.

My name is Dr. Bridgette Jones. I am a practicing allergy, asthma, immunologist and pediatric clinical pharmacologist at Children's Emergency in Kansas City, Missouri. I also conduct clinical research to improve the safety and efficacy of drugs for children. I am here today to represent the American Academy of Pediatrics, or the AAP.

In my practice, I frequently need to discuss with parents the risks and benefits of using OTC medicines to treat common pediatric ailments, such as allergies and asthma. As a pediatrician advising parents, I want to know that the products I recommend have been tested in children to ensure that they are safe, effective and labeled appropriately for their use. Therefore, we must have a process to regulate them that is responsive to the most recent medical science.

The current OTC regulation process at the FDA is not nimble to adapt to emerging evidence, safety concerns or product innovation. Burdensome regulatory processes cause unnecessary delays. The OTC monograph was, in large part, developed based on evidence from 50 years ago. Some of these drugs continue to be mainstays of pediatric practice, but others we know from more recent evidence provide little or no benefit to children. Put simply, the current system does not serve the needs of children.

The only way to ensure reliable and safe OTC medicines for families is to change how the monograph system works and provide significant new resources for the endeavor. Therefore, the AAP strongly supports the efforts of Congress to reform the process and create a user-fee program to fund FDA's monograph work.

The monograph regulating cough and cold medicines for children is a good example of how of process does not work. The data that led FDA to label these medicines for children does not meet today's standards, and data gathered since then clearly shows certain cough and cold products to be completely ineffective for children. Nevertheless, these products are still commonly marketed to children despite safety risks. While FDA agreed to revive the monograph more than a decade ago, today, FDA has yet to publish even draft changes despite evidence that these products result in thousands of pediatric overdose-related emergency department visits each year.

It is our hope that through a reformed OTC monograph system, the FDA will act, at long last, to modernize the cough and cold monograph. We also must ensure that innovation made possible by OTC reform does not have unintended negative consequences. One area where we anticipate greater industry innovation is in the development of novel formulations for OTC products. It is possible that industry may work on developing gummy formulations of

drugs, much like supplement manufacturers have done in recent years, with their marketing of gummy vitamins.

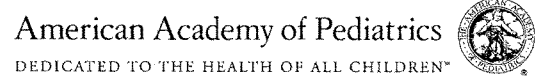
Gummy formulations of OTC drugs, whether intended for children or for adults, would greatly concern pediatricians because we know that when a product looks and tastes like candy, children will eat it. If a child consumes gummy acetaminophen, for instance, outside the watchful eye of parents, it could lead to a trip to the emergency room or worse. Therefore, FDA must have clear authority to regulate the packaging of OTC drugs, including requirements for unit dose packaging, such as blister packs to prevent abuse or misuse and protect against unsupervised ingestion.

While the Consumer Product Safety Commission has existing authority to require that certain drugs come in child resistant packaging, tested to ensure that it is difficult for children to open, CPSC cannot require specific types of packaging. Therefore, FDA must be able to do so, and since CPSC only requires a small handful of OTC monograph drugs to be sold in child resistant packaging, greater collaboration between FDA and CPSC is critically important.

Mr. Chairman, the latest discussion draft is largely reflective of the AAP's principles for OTC monograph reform. We strongly support the packaging language. Additionally, we look forward to continuing to work with the committee to ensure that the FDA and CPSC establish processes for notification when the FDA takes action that might warrant CPSC's reevaluation of its own packaging regulations.

Thank you for the opportunity to speak here today about this important issue.

[The prepared statement of Dr. Jones follows:]



Testimony of Bridgette L. Jones, MD, FAAP

On Behalf of the American Academy of Pediatrics

Before the U.S. House of Representatives

Committee on Energy and Commerce

Subcommittee on Health

"Modernizing FDA's Regulation of Over-the-Counter Drugs"

September 13, 2017

Chairman Burgess and Ranking Member Green, thank you for the opportunity to speak here today about the importance of modernizing the regulation of over-the-counter drugs (OTC) for America's children. My name is Dr. Bridgette L. Jones. I am a practicing pediatrician who specializes in the treatment of children with asthma and allergic disease. I also conduct clinical pharmacology research to improve the safety and efficacy of drugs for children. I hold a faculty appointment as Associate Professor of Pediatrics at the University of Missouri-Kansas City in the divisions of Pediatric Clinical Pharmacology, Toxicology and Therapeutic Innovation and Allergy/Asthma/Immunology at Children's Mercy in Kansas City, MO. I am board certified in Pediatrics and Allergy/Asthma/Immunology and have completed fellowship training in Pediatric Clinical Pharmacology. I am here today in an official capacity to represent the American Academy of Pediatrics (AAP). The AAP is a non-profit professional membership organization of over 66,000 primary care pediatricians and medical and surgical pediatric subspecialists dedicated to health and well-being of children. I serve as the chair of the AAP Committee on Drugs.

Every day in the United States, pediatricians get urgent calls from anxious parents, often in the middle of the night, asking about the best way to treat their sick child. Sometimes the answer is a prescription drug, sometimes the answer is non-drug supportive treatment, and sometimes the answer is an OTC medicine they can access at their local drug store. In my practice, I frequently need to discuss with parents the risks and benefits of using OTC medicines to treat common pediatric ailments such as allergies and asthma. Because parents often rely on OTC drugs to treat their children, it is essential that they can feel confident in knowing that those products are safe and effective. As a pediatrician advising parents, I want to know that the products I recommend have been tested in children and labeled appropriately for their use. As such, we must have a process set up to regulate them that is modern and responsive to the best and most recent medical science.

The current OTC regulation process at the Food and Drug Administration (FDA) is antiquated and not nimble enough to adapt to emerging evidence and to changes in how pediatricians practice medicine. The monograph that dictates how OTC drugs can be marketed was in large part developed based on the state of the evidence from over 40 to 50 years ago. Some of these drugs continue to be mainstays of pediatric practice, but others provide little or no benefit to children. Much of the pediatric drug labeling included in the OTC monograph was based on evidence that no longer meets today's rigorous standards for safety and efficacy or was based on incorrect assumptions about how adult data should inform the labeling of drugs in children.

Because we know that children are not just little adults, the AAP believes that drugs used in children should be appropriately studied specifically for their use. While we have made great strides in improving new prescription drug therapies for children through the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act, we have a long way to go to bring this record of success to OTC drugs.

The process for revising the OTC monograph is cumbersome and slow, and therefore the FDA cannot act quickly to respond to developments in the science, public health and safety concerns, or product innovation. The process is resource intensive while being significantly underfunded. It does not serve the needs of children and, for that matter, does not serve the needs of the public at large. The only way to ensure that consumers are afforded reliable, safe, and quality medicines is to change how the monograph system works and provide significant new resources for the endeavor. It is for this reason, the AAP supports reforms to the current OTC monograph system and the creation of a user fee program to fund FDA's monograph work. Over the past year, the AAP has worked closely with the Pew Charitable

Trusts and other public health and medical associations to speak up for the needs of patients as FDA, industry, and Congress have worked to develop a modernized approach to OTC regulation.

OTC Cough and Cold Medicines for Children

An illustrative example of how the current OTC monograph does not meet the needs of children can be found in the case of cough and cold medicines for children. The OTC drug review—the process FDA used to review cough and cold drugs and other grandfathered OTC products on the market prior to the enactment of FDA’s modern standards for safety and efficacy—was a massive and complicated undertaking. While FDA reviewers did their best to evaluate the safety and efficacy of these products, the data available to them was often extremely limited. And in the case of drugs for children, much has changed in the area of pediatric therapeutics since the 1970s. We have moved from an era where drugs were seldom studied in children, and pediatric drug studies were often considered to be unethical, to today, where failure to study drugs in children can be considered unethical.

The data that led FDA to label cough and cold medicines for children does not come close to meeting today’s standards for pediatric data. Not only that, but additional data gathered since that time has clearly shown certain cough and cold products to be completely ineffective in the pediatric population. Nevertheless, these products are still commonly marketed to children and often in combination with other products that can increase the safety risks. The monograph process has proven ineffective in ensuring that OTC drugs marketed to children and families have data to justify their use.

Over a decade ago, numerous pediatric experts submitted a citizen petition to FDA regarding the labeling of OTC monograph drugs for the treatment of cough and cold in children. The petition highlighted safety concerns but also—in the case of some products—a demonstrated lack of efficacy in the pediatric population. FDA held an advisory committee meeting in response to the petition. The committee voted unanimously that it was no longer appropriate for adult data on cough and cold products to be extrapolated to establish efficacy of the drugs in children under 12. The committee also voted to recommend that cough and cold drugs not be used in children under 6 years of age, consistent with the AAP’s recommendation at the time. After this critical and decisive meeting, FDA embarked on a process to revise the pediatric cough and cold monograph to better reflect the current state of the evidence.

Sadly, it’s now 2017 and FDA has yet to publish even draft changes to this monograph, despite pleas from Congress, pediatricians, and the public. We are convinced that this lack of progress is not for lack of effort on the part of FDA. Rather, progress has not been realized because the monograph process simply does not work.

FDA was unable to act decisively in the face of mounting evidence that these products were resulting in thousands of pediatric overdose-related emergency department visits each year—all for products with modest or non-existent efficacy in children. Currently, for FDA to change a warning in the monograph it must go through a lengthy notice and comment rulemaking process to modify federal regulations. This unwieldy process comes with numerous bureaucratic steps and layers of review. FDA’s only recourse for cough and cold drugs was to initiate a rulemaking process that has never concluded. This must change. If FDA identifies safety issues associated with a monograph drug, it needs the authority to require prompt label changes without going through a prolonged and burdensome regulatory process including the lengthy Office of Management and Budget review. Considerations of safety, effectiveness and

innovation, not economics, should drive FDA's process for modifying OTC drug monographs. Additionally, the agency needs appropriate resources to conduct safety surveillance for monograph products and allow quick action when safety issues arise.

FDA must have the authority and resources necessary to identify monograph products that lack appropriate data. Using a risk-based approach, FDA should be able to either require products to immediately come off the shelves or to give manufacturers a period of time during which they must submit new efficacy data to FDA to justify their continued marketing after which a product lacking such data would be removed from the monograph. Today's monograph process is ill-equipped to handle this task. Modernizing the monograph process will ensure FDA's ability to address products that do not meet appropriate efficacy standards.

Product Innovation

While the new drug application (NDA) process is the gold standard for the approval of new and innovative drugs, there are certainly instances where industry-initiated changes to the monograph are appropriate. Such changes can lead to improved drug formulations, increased safety, and other benefits for patients.

For instance, industry has for years been requesting that the monograph be amended to provide acetaminophen dosing instructions for children under the age of two. Even though there are well-accepted guidelines for acetaminophen dosing for children aged 6 to 24 months, the label of "infant" and "children's" acetaminophen (oral suspension) still asks parents of children under 2 to "ask a doctor" for dosing directions. Parents unable to quickly reach a physician may be tempted to make a guess of an appropriate dose, putting their infant at risk. The AAP supports such a change in labeling, and if the monograph process worked better, surely this change would have happened years ago.

Much like the long-delayed FDA action on the cough and cold citizen's petition, the existing backlog of industry-requested monograph changes currently awaiting FDA review is unacceptable. The uncertainty and complexity of the review process likely also reduces industry's incentive to invest research and development resources into monograph products. Congress should act to create a reformed monograph system that would add certainty to the evaluation of industry-initiated monograph revisions.

Safe Packaging for Children

While we generally support the goal of increasing industry innovation in the OTC drug market, we must ensure that this innovation meets the needs and expectations of consumers and does not have unintended negative consequences. With a reformed, more responsive, and better resourced system, one area where we anticipate greater industry innovation is in the development of novel formulations for OTC drug products. It is possible that the industry may work on developing gummy formulations of drugs, much like supplement manufacturers have done in recent years with their marketing of gummy bear vitamins.

Gummy formulations of OTC drugs—whether intended for children or for adults—would greatly concern pediatricians because we know that when a product looks and tastes like candy, children will eat it. If a child consumed a number of gummy medicines outside the watchful eye of parents, it could lead to injury, a trip to the emergency room, or worse. It is therefore vitally important that FDA have sufficient authority to regulate the packaging of OTC drugs.

Unfortunately, FDA's current authority over packaging is unclear, and as such we believe that this legislation must explicitly grant FDA authority to require specific types of packaging to prevent harm to children. For instance, if FDA did decide that approving a gummy drug product was appropriate, we would insist that FDA have the authority to require that drug to be sold in unit-dose packaging, such as blister packs, that would only allow access to one dose at a time. As a hypothetical example, a bottle of 100 loose, colorful and tasty gummy acetaminophen, if left open by an adult, would be nightmare scenario for a pediatrician from a poison prevention perspective. The margin between a therapeutic dose of acetaminophen and an amount that could kill a child is small. Without unit dose packaging, that open bottle of candy-like acetaminophen could be attractive and potentially fatal to a child. FDA must not wait until a product is already on the market and injuries, or even deaths, have occurred in children before requiring appropriate packaging.

Allowing FDA to require unit-dose packaging or other appropriate packaging would not interfere with the existing authority the Consumer Product Safety Commission (CPSC) has to require child-resistant packaging under the Poison Prevention Packaging Act because CPSC cannot require specific types of packaging like blister packs. What CPSC can do, and should continue to do, is to require drugs to be sold in what's called "special packaging," or packaging that is tested to ensure that it is sufficiently difficult for children to open. However, while CPSC regulations currently require all prescription drugs to come in this special packaging—and even requires the same for all prescription drugs that switch to OTC status—CPSC only requires a small handful of specific drugs regulated under the OTC monograph to be sold in child-resistant packaging.

For this reason, it is essential that FDA and CPSC have established processes for communicating about their regulatory activities. If FDA, for instance, were preparing to approve a new formulation of a drug that CPSC does not currently require come in child-resistant packaging—and this new formulation raised concerns about possible child poisoning—it would be important for the FDA to be in communication with the CPSC so that the Commission could decide whether updating its packaging regulations would be warranted.

We look forward to continuing to work with you and your staff to ensure that the legislation gives FDA the clear authority it needs to require specific types of packaging to prevent harm to children. Similarly, we look forward to continuing to work with you to ensure that the FDA and CPSC have established processes for notification when the FDA takes regulatory action on an OTC product that might warrant CPSC reevaluation of its packaging regulations.

Thank you for the opportunity to speak here today about the importance of safe and effective over-the-counter medicines for children. We look forward to working with you, FDA and other stakeholders as this process moves forward.

Mr. BURGESS. The Chair thanks Dr. Jones.

Mr. Roth, you are recognized for 5 minutes for an opening statement.

STATEMENT OF GIL Y. ROTH

Mr. ROTH. Chairman Burgess, Ranking Member Green, members of the subcommittee, thank you for the opportunity to submit testimony today about the proposed Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2017. I am Gil Roth, president of Pharma and Biopharma Outsourcing Association, or PBOA.

PBOA is a leading trade association for contract manufacturing organizations and contract development and manufacturing organization known has CMOs and CDMOs in the Pharma and Biopharma space. PBOA's core mission is to advance a regulatory, legislative and general business interest of the CMO and CDMO sector.

I am here today to express PBOA's support for the newly released OMUFA draft, to urge this committee and the Congress to advance this draft, and to express my thanks for ensuring that this draft takes into account the unique needs of the CMO/CDMO community. Your willingness to ensure our seat at the table greatly appreciated and PBOA strongly believes resulted in the release of a better OMUFA draft deserving of bipartisan support.

You may be wondering what a CMO and CDMO actually is and how the companies contribute to the development of drugs, or in this case, over-the-counter drugs. CMO/CDMOs are the true experts in manufacturing. The members, who are predominantly domestic, provide manufacturing formulation technology, packaging and other services that enable drug companies to develop and commercialize medicines. They help make more one-third of all doses dispensed to patients in America, producing both innovator drugs and generics, small molecules and biologics, pills to injectables, OTCs and biosimilars. CMOs/CDMOs empower their customers to bring lifesaving, cost effective quality medicines to patients. I have been involved with the CMO sector since 1999, have witnessed the industry's rapid growth and the key role it plays in the American healthcare system.

I would like to commend the committee for your continued focus on the important issues we will examine today. The FDA has long outstanding commitments to produce and finalize over-the-counter monographs worked up again a year after I was born. And as has been noted in the current fiscal year, the FDA has allocated \$8 million to such efforts, some that can yield only minimal dedicated staffing, little progress. Industry, the FDA and the Congress can agree that the monograph process overall is outdated, and further, that there is recognition that monograph review cannot expand without additional resources.

The legislation under consideration should help solve those issues. It will provide resources to FDA to finalize long, unfinished monographs, giving manufacturers a degree of certainty. As with other user fee programs, the transparency and goals dictated by the commitment letter should provide industry with increased predictability.

OMUFA's path for innovation to establish ingredients is overdue and could benefit manufacturers and marketers alike, including CMOs that specialize in unique dosage forms. Although PBOA was not included in the negotiations between industry and FDA, we are pleased that the legislative text under discussion today includes a fee model that reflects a differential value of OTC monograph products to CMOs and CDMOs, and that it provides a degree of relief from the facility fees proposed to fund OMUFA overall. And again, we are very appreciative of this committee's role in ensuring that all stakeholder voices were heard as you develop this OMUFA draft.

We hope that PBOA and the CMO/CDMO businesses that it represents will be included the future FDA user fee negotiations, particularly ones that are considering contributions from the manufacturing sector in the form of facility fees. We look forward to continuing to participate in the legislative process relating to OMUFA, and the day when this good legislation is signed into law.

Thank you, again, for the opportunity, and we are available for questions.

[The prepared statement of Mr. Roth follows:]

ONE-PAGE SUMMARY

TESTIMONY OF GIL Y. ROTH

PHARMA & BIOPHARMA OUTSOURCING ASSOCIATION

MODERNIZING FDA'S REGULATION OF OVER-THE-COUNTER DRUGS

BEFORE THE HOUSE ENERGY AND COMMERCE SUBCOMMITTEE ON HEALTH

SEPTEMBER 13, 2017

- CMO/CDMOs play a key role in the American healthcare system. What do they do, and who is PBOA?
- FDA's current OTC Monograph program is outdated and under-resourced.
- The proposed OMUFA bill should help solve those issues, with greater funding, more transparency and commitments, and a path to innovations for established ingredients.
- PBOA's members are pleased that the legislation under discussion includes a fee model that reflects the differential value of OTC monograph products to CMO/CDMOs.
- We hope that PBOA and CMO/CDMOs will be included in future FDA user fee negotiations.

128

TESTIMONY OF GIL Y. ROTH

PRESIDENT

PHARMA & BIOPHARMA OUTSOURCING ASSOCIATION

MODERNIZING FDA'S REGULATION OF OVER-THE-COUNTER DRUGS

BEFORE THE HOUSE ENERGY AND COMMERCE SUBCOMMITTEE ON HEALTH

UNITED STATES HOUSE OF REPRESENTATIVES

SEPTEMBER 13, 2017

Mr. Chairman, Mr. Ranking Member, Members of the Subcommittee: thank you for the opportunity to submit testimony today about the proposed “Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2017”.

I am Gil Roth, President of the Pharma & Biopharma Outsourcing Association. PBOA is the leading trade association for Contract Manufacturing Organizations and Contract Development and Manufacturing Organizations (known as CMOs and CDMOs) in the pharma/biopharma space. PBOA’s core mission is to advance the regulatory, legislative and general business interests of the CMO/CDMO sector. I am here today to express PBOA’s support for the recently-released OMUFA draft, to urge this Committee and the Congress to advance this draft, and to express my thanks for ensuring that this draft takes into account the unique needs of the CMO/CDMO community. Your willingness to ensure our seat at the table was greatly appreciated, and, PBOA strongly believes, resulted in the release of a better OMUFA draft deserving of bipartisan support.

First, you might be wondering what a CMO/CDMO actually is and how these companies contribute to the development of drugs, or in this case, over-the-counter drugs. CMO/CDMOs are the true experts in manufacturing. Our members provide manufacturing and other services that enable drug companies to develop and commercialize medicines. They account for more than one-third of all doses dispensed to patients in America, producing innovator drugs and generics, small molecules and biologics, pills and injectables, OTC and biosimilars. CMO/CDMOs empower their customers to develop and commercialize life-saving, quality, cost-effective medicines for patients. I have been involved in the CMO sector since 1999 and have

witnessed the industry's rapid growth and the key role it plays in the American healthcare system.

I would like to commend the Committee for your continued focus on the important issues we will examine today. The FDA has long outstanding commitments to produce and finalize Over-The-Counter (OTC) monographs, work that began in the 1970s. In the current fiscal year, the FDA allocated \$8 million to such efforts, a sum that can yield only minimal dedicated staffing and little progress. Industry, the FDA, and Congress agree that the monograph process is outdated. Further, there is recognition that monograph review cannot expand without additional resources.

The legislation under consideration should help solve those issues. It will provide resources to FDA to finalize long-unfinished monographs, giving manufacturers a degree of certainty. As with other user fee programs, the transparency and goals dictated by the commitment letter should provide industry with increased predictability.

OMUFA's path for innovations to established ingredients is overdue and could benefit marketers and manufacturers alike, particularly CMOs that specialize in unique dosage forms.

Although PBOA was not included in the negotiations between industry and FDA, we are pleased that the legislative text under discussion includes a fee model that reflects the differential value of OTC monograph products to CMO/CDMOs, and that it provides some relief from the facility

fees proposed to fund OMUFA. And, again, we are very appreciative of this Committee's role in ensuring all stakeholder voices were heard as you developed the OMUFA draft.

We hope that PBOA and the CMO/CDMO businesses it represents will be included in future FDA user fee negotiations, particularly ones that are considering contributions from the manufacturing sector, in the form of facility fees. And we look forward to continuing to participate in the legislative process relating to OMUFA, and to the day where this good legislation is signed into law.

Mr. BURGESS. The Chair thanks the gentleman. I thank all of our witnesses for their testimony. We will move into the Member question portion of the hearing. I am going to yield to Mr. Guthrie of Kentucky 5 minutes for your questions, please.

Mr. GUTHRIE. Thank you very much.

Thank you, Mr. Melville. The issue of new sunscreen approvals are important to me and our key component is package. I have worked on the Sunscreen Innovation Act in the past and have worked to ensure in this package that we work to further addressing the continued holdup we see of these products at the FDA.

Mr. Melville, can you outline for us today the positive benefits that you see in monograph proposal for sunscreen products?

Mr. MELVILLE. Well, yes, has been mentioned earlier. Sunscreens are considered drugs because the health claims that are made on sunscreens in the United States. The regulators of over-the-counter drugs, they are within the monograph today, they are in the monograph system. And over the years, have gone through a very long and extensive process with many stops and starts. As science has evolved over the years, new ingredients have been available elsewhere in the United States. But there hasn't been a process, as Dr. Woodcock mentioned, to really innovate under the monograph system, with the exception of a process called time and extent applications. That has never proven to be a very effective approach to market, very time-consuming. And therefore, the monograph reforms being discussed today would open up a new opportunity, bring new ingredients to the market through the monograph system, not using notice and comment rulemaking as has been traditionally been used, but using the administrative order process, which would be a much more effective, a much more efficient process.

So, I think for monograph drugs that are sunscreens, you would have two choices today under this law, you could continue, as Mr. Werner said, to operate under the Sunscreen Innovation Act that Congress passed and implemented 4 years ago, or you could elect to operate under the new monograph structure. And I think long-term new ingredients would all be utilized in the new structure. So it is very positive for sunscreens.

Mr. GUTHRIE. Thank you. Mr. Werner, I did hear your testimony. You mentioned the need for new over-the-counter review process to be flexible, enough to accommodate sunscreen, and how sunscreen active ingredients are slightly different than, say, Advil or Tylenol. Could you explain that?

Mr. WERNER. Sure. Thank you. So first of all, yes, the new over-the-counter process has to be flexible enough to accommodate sunscreens. A couple of big reasons that those are different is number one, the new drug application process isn't really feasible for sunscreen products for any number of reasons, but not of the least of which is that that would give you an approval for a final product and a final formulation. And sunscreens, sunscreen ingredients are used in lots of different products, number one. And number two, sunscreens typically change with the season. They might change their scent, they might change their lotion, et cetera. So the process has to provide for an alternative pathway to approval in the OTC

space besides the new drug application, and the bill's draft legislation certainly does that.

The other thing is, just like current law, sunscreen manufacturers should be able to use their safety and effectiveness data from elsewhere around the world where the products are being used as part of their application package to demonstrate safety and effectiveness for the FDA purpose. That is another way that the products are slightly different, and it is another way that this legislation absolutely accommodates those products.

Mr. GUTHRIE. Thank you. Mr. Roth, in your testimony, you mention that contract manufacturing organizations may specialize in unique dosage forms. Can you please explain this process further, and explain how that process would be affected by over-the-counter monograph reform?

Mr. ROTH. Well, some CMOs essentially work in traditional dosage form models, and a great portion of the market is comprised by those, but other ones do work in unique dosage forms and semisolids and other topical delivery systems, et cetera. And for some of those types of dosages, it is possible that innovations in the monograph might lead to products that they would then be open to manufacturing, where just changing the type of pill might not be as big an innovation. So for a niche technology provider like some of our member companies, this could open the door to new OTC monograph products that they would produce for their customers.

Mr. GUTHRIE. Thank you. Mr. Chairman, I yield back my time.

Mr. BURGESS. The Chair thanks the gentleman. The Chair recognizes the gentleman from Texas, Mr. Green, 5 minutes.

Mr. GREEN. Thank you, Mr. Chairman.

Ms. Moore, Mr. Melville, one of the discussed benefits of the over-the-counter monograph reform has been potential for streamline regulatory process to encourage innovation in the OTC drug market. The discussion draft also proposes an additional market incentive that would provide 24 months of exclusivity to an innovative, over-the-counter product. The committee has supported targeted exclusivity in certain product areas as a way to create a market where one does exist, such as, for instance, antibiotics or in areas where we want to engender greater competition, such as with the generic drug products.

Whether or not this incentive was the right incentive in these examples, the exclusivity that was crafted was with a clear public goal in mind. My question to Ms. Moore as I mentioned, the discussion draft would propose awarding 24 months of exclusivity to innovative over-the-counter products. A vastly longer period than the 180 days awarded to the first generic market entrants, or are the 6 months provided by the pharmaceutical manufacturers who complete the necessary pediatric studies.

In considering marketed activity for all over-the-counter products, what public health considerations could Congress have in mind to insure that there is a proper balance between that innovation and public health? A very long question.

Ms. MOORE. I would—I think—well, first, just to pause and reflect that the current draft is really well thought-through compromise on the part a lot of parties, so we appreciate that. I think

that the issue of exclusivity is always one of the more sensitive issues in this kind of legislation. And we appreciate the fact that different goals and different benefits have been evaluated under different types of legislation.

I think, in this case, for over-the-counter products, because we are hoping to spur a fair amount of innovation in this marketplace, it would be worthwhile—we understand that Congress and industry and other stakeholders have agreed to a certain timetable. We think it would be worthwhile to evaluate whether that timetable, that 2 years, as you point out, really is striking the right balance between spurring innovation for products that could improve health, and actually improving patient's access to products that could improve their health.

Mr. GREEN. Thank you. Much shorter answer than the question.

Mr. Melville, I heard from members in the industry that exclusivity is warranted for OTC monograph products in order to justify paying user fees are alternatively that regardless of the streamlining of monograph's process, that through executive order, they would still not be sufficient incentive for countries to innovate. Setting aside whether or not exclusivity is a proper incentive, what is the public health justification for awarding 24 months of exclusivity to an over-the-counter product? It seems to me that this long of a period has a potential for blocking patient access to new formulations that would increase or encourage patient utilization and adherence.

Mr. MELVILLE. So Mr. Green, I think one of the great benefits of the over-the-counter drug industry and the products that our members bring to market is it gives consumers a choice. They can choose a brand of product, they can choose a store brand product. The average price of one of our products is \$108. So they are very, very affordable products. The monograph system is currently enforced. It deals with drugs and with ingredients that have been on the market as has been said earlier, since 1972. There hasn't been a lot of innovation.

To spur innovation, a manufacturer would have to come to the table with essential human data, data that the drug will work on humans, will be safe and effective on humans. That is very costly. And if you don't give a period of exclusivity to reward the innovator, the next day, there could be a private label of that product on the market.

Mr. Chairman, our association represents both branded manufacturers and private label manufacturers. In fact, our chairman right now is the business head for the largest store brand manufacturer in the United States. They are strongly supportive of 2 years of exclusivity, because they recognize the investment that it takes to innovate, and they recognize that that is their future pipeline, and that consumers will benefit from that, so they will have a choice.

Mr. GREEN. Thank you.

Like my colleagues, I also want to encourage regulatory reform. The over-the-counter drug market is appropriately encouraging innovation. However, we consider incentives such as marked exclusivity. It is almost like an issue in our subcommittee. We must also ensure that our desire for innovation does not overtake the need for the patient access.

Mr. Roth, we work closely with contract manufacturing organizations and contract development manufacturing organizations, make OTC user fees that are appropriate tailored to those specific types of companies. Can you elaborate on how the fee model and our discussion draft reflects the deferential value of OTC products to CMO and CDMOs?

Mr. ROTH. Certainly. The—it is the result of conversations we have had internally within industry, that reflects the much lower margins that CMOs have, particularly when it comes to working with OTC products, even in relation to the prescription and generic products that they manufacture. So in working with our industry partners, we developed a tiering model that we think would better reflect the respective values that a CMO accrues from this, both from the products and from this program overall in comparison with the private label and the store marketing companies. Does that answer your question?

Mr. GREEN. I think that is pretty close.

Thank you, Mr. Chairman. I have run out of time.

Mr. BURGESS. You are correct.

The Chair recognizes the gentleman from Virginia, Mr. Griffith, 5 minutes for questions, please.

Mr. GRIFFITH. Thank you, Mr. Chairman. Thank you all for being here today. I open up it for whoever wants to jump in here. The first question is all pretty simple stuff, is there anything that we have in the discussion draft that causes you all concern? Anybody? Start which ever end. Whoever is passionate and wants to jump in first. Anybody have any comments? Dr. Jones?

Dr. JONES. No.

Mr. GRIFFITH. Yes, sir. Go ahead.

Mr. MELVILLE. I do—we strongly support having explicit authority for FDA over packaging, and that is in the statute. The specific language and how it can be applied, I think, is still being discussed. There are three ways that FDA can apply some of new authorities that it gets under the statute. It can act under an imminent hazard and move very, very quickly to remove a product from market. There is some interim order authority that it can use to update labelling, as Dr. Woodcock mentioned earlier. We strongly support that. Then there is a traditional administrative order process, which is a great enhancement over current law.

It allows for a period of public discussion before an order would take effect. We believe packaging decisions, because they are very complex, require that sort of discussion before they would take effect. So we think the packaging authority should be limited to the administrative order process.

Mr. GRIFFITH. All right. That is helpful to know. That is why I asked the question. So thank you. And then the second half of that question is, is there something that you think we ought to have in there that is not in there and part of that goes back to what you were saying, Mr. Melville. Does anybody else have something that they think we ought to put on the table to discuss while we—because it sounds like there is a bipartisan agreement by most members of at least the subcommittee that we have got to do something, so let's make sure we cover all the bases that we can.

Anybody have anything that we should put into the discussion draft that is not currently there?

Mr. WERNER. As we said in our testimony, we do think that it would be useful if we could incorporate some way to assess testing standards in for sunscreens, the FDA has published guidance on this, and, certainly, the bill goes a long way towards by guaranteeing meetings between sponsors and the agency that goes a long way toward the coming to some kind of an agreement about what the appropriate standards are, but since this is such a new—this is such a new area, we thought it would be appropriate for there to be some way, perhaps upon reauthorization of the bill, that we could evaluate how that is going.

Mr. GRIFFITH. All right. I appreciate that.

Dr. Jones, I am going to switch gears and turn to you in a slightly different vein. I haven't asked my two questions on this subject. I appreciate what you do. I have a now 11-year-old who has been under an allergists care since he was about 4 months old, got all kind of issues going on. And so I would have to say while in a perfect world, we appreciated your comments about making sure things are tested on kids. Every kid is a little bit different, as I am sure you are aware. And I am sure that at some point, you have off-label drugs because you couldn't find something else that would work for that particular child. Is that correct?

Dr. JONES. Yes. That is correct. Although there has been significant strides in the ability to study drugs in children over the last several years with BPCA and PREA. As pediatricians, we still know that 50 to 60 percent of the drugs that we currently have to use in children are used off label. So we do not have direct evidence that tells us the dosage for those medications, and whether those medications are actually effective. But when you see a child with a certain condition, and you know that this drug has some evidence that it may work in adults or other populations, you are somewhat forced to use those medications in off-label situations. But I think with BPCA and PREA, we are making significant strides, and I hope that that will continue.

Mr. GRIFFITH. And it is always good to get more information from whatever source you can to make sure that you are using that off-label drug when you have to, in the best way that you can. Isn't that also correct?

Dr. JONES. Yes. I think as any medical provider, it is your due diligence to your patients to make sure that you have combed the literature and done as much research as you can when you have to make that difficult decision in using off label medications.

Mr. GRIFFITH. And I only have time for a yes or no, but more information is better than less information, yes or no?

Dr. JONES. Yes.

Mr. GRIFFITH. Thank you very much, I yield back.

Mr. BURGESS. The Chair thanks the gentleman. The gentleman yields back.

I recognize myself for 5 minutes for questions. And Dr. Jones, I appreciated your testimony. And I do seem to recall maybe 2 or 3 years ago, a difficulty with the labeling of infant preparations of acetaminophen, and a child being given a child's dose of the infant concentration actually—paradoxically, it seems the infant prepara-

tion was more potent or more concentrated than the one that was labeled for children. And I believe there were some therapeutic misadventures with acetaminophen because of that concentration difference. Is that correct?

Dr. JONES. Yes, yes.

Mr. BURGESS. And one of the things that we might strive to avoid in the future would be just that type of confusion that a new parent might encounter, this is what I have been giving to my infant. Now that they are larger, I will give them a child's dose of the infant preparation and it wouldn't be appropriate.

Dr. JONES. Yes. I think that is a very great example. So for acetaminophen, as pediatricians, we know what the correct dose is for that medication, but due to limitations with being able to add language to the monograph, we cannot put that information on the packaging and on the labeling. So if a child is less than 2 years of age, it simply says contact your healthcare provider to provide how to dose that medication.

So if you are a parent in the middle of the night and it your baby has a fever, and they are less than 2 years of age, you do not have any instructions there that tell you how to dose that medication. And so that is when you get into safety issues where a parent might have to guess the dose if they are not able to contact their healthcare provider or they may have to take their child out in the middle of the night to an emergency room so they can be dosed. So I think those are significant safety concerns that hopefully will be addressed with this new legislation.

Mr. BURGESS. Yes, that would be my hope as well. Dr. Jones and Mr. Melville, you both referenced cross jurisdictions with the Consumer Product Safety Commission, I think Dr. Woodcock mentioned it as well. And clearly, that is one of the things that will have to be taken into account. I had not even considered that the dispensing mechanism being a gummy bear would pose a special challenge as far as the packaging is concerned, and clearly it would.

So that is—Mr. Melville, it just goes to your point, one of the reasons we are here today is we do have to be nimble, we do have to be much more agile, the regulatory agency needs to be much more agile than is currently capable being at the monographs.

Mr. MELVILLE. If I could follow up. I think Dr. Jones makes a great point, and pediatric acetaminophen is a good example. Our industry petitioned the FDA to add "under two" labeling on the label, and FDA wasn't able to move forward quickly on that because of the notice and requirement rulemaking requirement under the current monograph system. So today it does not exist, but our industry did move forward and the two concentrations of acetaminophen that Dr. Jones referred to were both permitted under the monograph. The industry voluntarily withdrew one of those because they saw in real world that there was some confusion. So there is only one concentration today, and it is the more diluted concentration.

We also voluntarily added flow restrictors to pediatric acetaminophen, so that children if they did get into a bottle that was open, was not sealed appropriately they would not be able to get a lethal dose of that. So the industry has moved forward to innovate to

make sure to improve the safety of these products. It is a work in progress for sure. And we look forward to the authority that FDA would have so we can work with them and get some of these improvements and make sure that they are applied not just voluntarily, but to all participants in the industry.

Mr. BURGESS. Well, then it begs the question because you brought up about cumbersome activity of the ruling comment type of structure that we are in now. So it made me wonder in the future, is there going to be an app for that?

Mr. MELVILLE. Who knows. Technology is certainly changing things. I mean, certainly today consumers have to look at the label to get all the information they need to be able to use that product safely. And with technology and advances, are there uses of technology that can enhance safety, add different labels, have a hologram that maybe has multiple languages. There are certain—I think the sky is—the options are limitless for using technology to enhance the safe use of over-the-counter medicines. We look forward to working with FDA on those initiatives.

Mr. BURGESS. And as every do-it-yourselfer knows, there is frequently a YouTube video on just how to provide the instruction that you need.

Mr. MELVILLE. And that concerns us greatly.

Mr. BURGESS. I am sure that it does. It opens another avenue.

Well it has been a fascinating discussion. I do want to thank all of our witnesses for being here today. Thank you for your testimony. I see no further Members wishing to ask questions.

Pursuant to committee rules, I remind Members they have 10 business days to submit additional questions for the record. And I ask the witnesses to submit their responses within 10 business days of receipt of those questions.

Without objection, the subcommittee is adjourned.

[Whereupon, at 12:53 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]



Colin I. Mackenzie
Region Head, Americas
GSK Consumer Healthcare

184 Liberty Corner Road
Warren, New Jersey 07950

colin.i.mackenzie@gsk.com
www.gsk.com

September 13, 2017

The Honorable Michael Burgess, M.D.
Chairman, Subcommittee on Health
Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Gene Green
Ranking Member, Subcommittee on Health
Energy and Commerce Committee
2322A Rayburn House Office Building
Washington, DC 20515

Dear Chairman Burgess and Ranking Member Green:

On behalf of GSK and our over 15,000 employees in the United States, thank you for holding today's hearing entitled "Modernizing FDA's Regulation of Over-the-Counter Drugs" to consider draft legislation updating the Over-the-Counter (OTC) Monograph system.

As you may know, OTC medicines play a vital role in our nation's healthcare system, providing access, affordability, empowerment and trust. OTC medicines allow individuals and families to meet their everyday healthcare needs, including 96% of U.S. adults reporting that OTC medicines make it easy for individuals to care for minor medical ailments and 93% of U.S. adults preferring to treat their minor ailments with OTC medicines before seeking professional care.

At GSK, our mission is simple. We want to help people do more, feel better, and live longer. GSK Consumer Healthcare embodies the company's overall mission by being the largest manufacturer globally for OTC products reaching over one billion people and assists in the ability for Americans to address these routine healthcare challenges. Our brands are organized into five categories: Pain Relief, Respiratory, Oral Health, Nutrition/Gastro Intestinal, and Skin Health.

OTC Monograph Reform will help foster the growth and availability of these vital medicines. GSK believes that policy reforms could make the system even more flexible, responsive, and accommodating to innovation. Ultimately, this will broaden choice for consumers so they can better meet their individual needs for OTC medicines.

We thank you for your collective leadership in holding today's hearing, and we hope that the Subcommittee moves forward with consideration of this legislation. Ultimately, modernizing the OTC Monograph system will ensure that FDA and industry can update products with safe, effective ingredients in the market today, and so that FDA has the resources to approve safety labeling changes and innovation in the OTC market.

If GSK can ever be of assistance to you or your staff, please do not hesitate to contact Michael Calvo, Manager, Federal Government Relations, at (202) 715-1041 or via email at michael.j.calvo@gsk.com.

Sincerely,

Colin Mackenzie

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) 225-2827
Minority (202) 225-3641

October 19, 2017

Dr. Janet Woodcock
Director
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Woodcock:

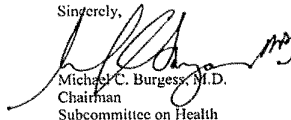
Thank you for appearing before the Committee on Energy and Commerce on September 13, 2017, to testify at the hearing entitled "Modernizing FDA's Regulation of Over-the-Counter Drugs."

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. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on November 2, 2017. Your responses should be mailed to Jay Gulshen, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to jay.gulshen@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Committee.

Sincerely,


Michael C. Burgess, M.D.
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

[Dr. Woodcock did not answer submitted questions for the record by the time of printing.]

**Questions for the Record from Ranking Member Frank Pallone
House Committee on Energy and Commerce
Subcommittee on Health
“Modernizing FDA’s Regulation of Over-the-Counter Drugs”
September 13, 2017**

**Dr. Janet Woodcock, M.D.
Director, Center for Drug Evaluation and Research
Food and Drug Administration**

FDA Engagement

There was considerable discussion at the hearing regarding when FDA first identified over-the-counter (OTC) drug monograph reform as a priority for the agency, and what steps the agency has taken to inform Congress and the public about the need for monograph reform. I would like to request further background regarding the agency’s prioritization of monograph reform as a policy issue and what steps the agency has taken to effectuate monograph reform.

Q1: Will you please provide more detailed information regarding how the FDA’s thinking on the OTC drug monograph has evolved over the years, and when the agency first identified the need for OTC monograph reform?

Q2: I understand that the agency held public meetings in 2014 and 2016, as well as a recent webinar. Will you please further outline the outreach FDA conducted around OTC monograph reform, including the timeline, the types of outreach conducted, and what stakeholders the agency engaged?

Confidential Meetings

Congress acted back in 2014 to pass the Sunscreen Innovation Act (SIA) with the goal in mind of speeding access to over-the-counter sunscreen ingredients. Despite this reform effort, I understand that members of the PASS Coalition, which represents a wide range of stakeholders interested in the approval of new sunscreen ingredients, are seeking additional reforms as a part of the over-the-counter monograph reform process.

Q1: How many meetings has FDA held with members of the PASS Coalition or other sunscreen manufacturers since the passage of SIA? Can you explain why sponsors of sunscreen ingredients cannot meet with FDA on a confidential basis today? Does the agency support allowing for confidential meetings for pending sunscreen ingredients?

Q2: Over-the-counter monograph reform also contemplates certain meeting management goals for meetings between over-the-counter sponsors and FDA. The PASS Coalition has proposed a 90-day timeline for meetings related to pending sunscreen ingredients. Would FDA be able to meet this timeline for confidential

meetings between sunscreen ingredient manufacturers and the agency? If not, please explain why.

- Q3: Would FDA need any additional resources to be able to meet the requirements and timeframe outlined in the OTC Monograph User Fee Act for confidential meetings for sunscreen ingredients?

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) 225-2027
Minority (202) 225-3841

October 19, 2017

Mr. Scott Melville
President and CEO
Consumer Healthcare Products Association
1625 Eye Street, N.W., Suite 600
Washington, DC 20006

Dear Mr. Melville:

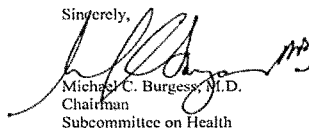
Thank you for appearing before the Committee on Energy and Commerce on September 13, 2017, to testify at the hearing entitled "Modernizing FDA's Regulation of Over-the-Counter Drugs."

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. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on November 2, 2017. Your responses should be mailed to Jay Gulshen, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to jay.gulshen@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Committee.

Sincerely,



Michael C. Burgess, M.D.
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

House hearing record responses

Exclusivity: Q1: As you know, in determining appropriate incentives to generate human data in the pediatric space, Congress deemed six months of exclusivity to be sufficient. In considering how exclusivity would delay patient access to innovative OTC drug formulations, what is the public health justification for awarding 24 months of exclusivity?

A: Exclusivity for OTC monograph drug innovations will provide Americans with a wider range of choices and greater competition. For instance, this incentive will encourage development of easier to take or apply dosage forms such as a film you could swallow without water or a spray that provides easier coverage or application compared to an existing cream. New technology for drug delivery has the potential to improve efficacy and safety of OTC products. It provides a meaningful path to develop combination therapies where appropriate, which would reduce the need to use multiple medicines at the same time or may offer other dosing advantages, including for safety. It will incentivize adding ingredients with an established track record of safety and effectiveness to a monograph such as ingredients with documented safe experience in other parts of the world. Today, that is very challenging. New indications haven't been added to the monographs in decades. An incentive will encourage clinical research to identify new indications for existing ingredients.

Innovations such as these require significant investment in generating human data. Innovating companies need an incentive to invest in that data before it can be immediately used by their competitors. For a product launch to succeed, it requires a sufficient new benefit to break-through to the retail shelf. The fact is many launches do not succeed in the marketplace, so to take a business risk, the product needs time on the market. This is because developing consumer awareness and acceptance takes time. Building acceptance so a retailer will keep the product on the shelf requires more than a year. Further, the more successful a new product is, the more incentive retailers have to launch their store brand version. For instance, a retailer would typically begin store brand planning roughly 6 months before a national brand even launches, and set their more precise store brand strategy a few months after the national brand is on shelf. That limits the amount of time the innovator has to recoup at least some of their R&D investment and expenses needed to raise awareness. Finally, new products in monographs will enter established categories – they are competing with existing options. Consumers have pre-existing price expectations, as they shopped the category before. For instance, an average American family buys an OTC pain reliever 6 times a year. Ultimately, the individual can see the price of the product on the shelf and make a conscious decision on whether the innovative product provides sufficient value above the other choices.

In contrast, 6 month pediatric exclusivity was intended to encourage research in unapproved or new pediatric uses of an active ingredient in response to a written request from FDA. The 6 months is added to existing exclusivity for an active moiety.

Need for reform: Q1: Will you discuss why members of your association feel that reform is necessary?

A: Our member companies believe reform is needed to increase the efficiency and responsiveness necessary to protect consumer health and to create a pathway for innovation that accommodates consumer needs. While the existing OTC Monograph system is a smart, balanced framework for regulating OTC medicines containing ingredients with a proven history of safe use and efficacy, it relies on notice and comment rulemaking. Rulemaking has become an increasingly slow and unresponsive administrative process across government. As a result, the Monograph system has become cumbersome. Today, it can take several years or more to formally update product labels with new safety information through rulemaking, approve new ingredients for monograph eligibility, or make other important changes for consumers. Moreover, the current system does not provide a mechanism for innovation.

Q2: Although some have suggested that user fees should not be necessary for OTC reform as the intention is to streamline the monograph process to make it more agile and timely, we heard very clearly from Dr. Woodcock about the critical need for additional resources for the OTC monograph program. CHPA has been very clear in the association's support for user fees. Will you further discuss why the members of your association agree with the need for user fees to support monograph reform?

A: CHPA member companies acknowledge that a reformed and improved monograph system requires dedicated resources to operate efficiently. For instance, the discussion draft will provide:

- Efficiency: administrative orders will replace notice and comment rulemaking.
- There will be an accelerated pathway for safety labeling changes.
- There will be a meaningful innovation pathway, including exclusivity for essential human data.
- FDA will annual post a projection to preview upcoming monograph work over the next 3 years, allowing better planning and prioritization.
- Sponsors will have the opportunity to scheduled closed meetings to discuss research and testing plans.
- As with other user fee programs, FDA, through the Administration, has already transmitted a goals letter to Congress outlining items on which they will report and goals they will seek to reach during the 5 years of authorization of the program.

These meaningful improvements will lag, and the goals not be met, without dedicated resources provided through user fees. While we would certainly support reform without paying fees, precedents in other areas suggest this is simply not likely. Further, even if significantly increased appropriations could be provided in a given year, shifting priorities and history suggest that would be too unpredictable year on year. Multi-year dedicated resources are necessary to meet the goals of reform.

It is also important to note that all firms who manufacture, process, and market under the OTC Monograph system gain value from it. This system does not require pre-market approval, is available to national brand firms, private label manufacturers, retailers under their own brand names, packagers, and contract manufacturers. In addition, under the discussion draft, companies who choose to innovate with products that require changes in Monograph conditions would pay an additional submission fee.

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

October 19, 2017

Ms. Kirsten Moore
Project Director
The Pew Charitable Trusts
901 E Street, N.W.
Washington, DC 20004

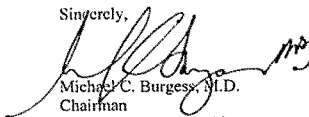
Dear Ms. Moore:

Thank you for appearing before the Committee on Energy and Commerce on September 13, 2017, to testify at the hearing entitled "Modernizing FDA's Regulation of Over-the-Counter Drugs."

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. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on November 2, 2017. Your responses should be mailed to Jay Gulshen, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to jay.gulshen@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Committee.

Sincerely,

Michael C. Burgess, M.D.
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

Responses from The Pew Charitable Trusts to
Questions for the Record from Ranking Member Frank Pallone
House Committee on Energy and Commerce
Subcommittee on Health
“Modernizing FDA’s Regulation of Over-the-Counter Drugs”
September 13, 2017

Improving Safety in OTC Products

In your testimony, you mentioned several examples in which the FDA process for addressing safety issues, such as through updating labeling or inclusion of warnings, was far faster for prescription drugs compared to over-the-counter drugs. One such example was for the liver toxicity associated with the use of over-the-counter acetaminophen products. In this instance, FDA was able to require the inclusion of a new boxed warning for all prescription acetaminophen products within two years, whereas it took the agency seven years to update the labeling for over-the-counter products.

Q1: Are there other instances where FDA has been able to act on safety issues more quickly in the prescription drug space versus the over-the-counter space? How will transitioning to a new administrative order procedure, as contemplated in the discussion draft, help to hasten label changes compared to the current system?

One example – in addition to the acetaminophen, nonsteroidal anti-inflammatory drug, and codeine examples in Pew’s testimony – is hydroquinone. This drug has been approved as a prescription drug for the topical treatment of moderate to severe melasma (skin discoloration) of the face. The prescription drug label lists warnings about potential carcinogenicity, birth defects, and ochronosis (skin darkening).

Hydroquinone is also marketed over the counter as a skin bleaching agent, which is a much broader use than the indication for which the prescription drug is approved. There is no requirement that the OTC drug bear the same labeling as the prescription drug, including product warnings. FDA published a tentative final monograph (TFM) affirming hydroquinone’s GRASE (“Generally Recognized as Safe and Effective”) status in 1982. Subsequently, new evidence emerged linking hydroquinone to serious side effects such as cancer and ochronosis. In 2006, FDA proposed a new rule that would withdraw the TFM and classify the compound as not GRASE. FDA has been unable to finalize this rule and hydroquinone continues to be marketed as an OTC.

When changes need to be made to prescription drug labeling, FDA has the authority, and the resources, to work with drug sponsors to make those changes. In contrast, at least three steps are needed to create or update a monograph (see Figure 1, below). All proposed changes to monographs are reviewed by FDA and the Department of Health and Human Services, and often the White House Office of Management and Budget, which estimates the cost and benefit of the change to the economy and consumers. FDA also receives and must respond to public comment throughout the monograph revision process. The additional review steps for monographs add

considerable time, and they risk prioritizing economic considerations over consumer health and safety. There is no deadline by which monographs must be finalized, and several have been under review for decades.

FIGURE 1

The Monograph Process

Announcement	The first step is often to issue an advance notice of proposed rule-making. This tells the public, industry, and agencies involved in the rule-making process that FDA is planning to change an existing monograph or create a new one. This notice is not required, but FDA may issue it to invite comments and information about the safety and efficacy of the ingredients in a particular product category
Proposed monograph	The tentative final monograph is a proposed rule outlining the details of the "recipe" for the product category or the change that is being suggested to an existing monograph. FDA indicates which potential ingredients it considers to be Category I, II, or III, along with its reasoning. The tentative final monograph is made available for public comment. This step can occur multiple times, as new scientific information emerges or product usage changes
Final	Once the comments have been reviewed and debated, FDA publishes a final rule with its conclusions, enabling manufacturers to change their products' labeling or ingredients. However, a final monograph can be reopened, which begins the process anew.

Source: Food and Drug Administration

Complicating the burdensome monograph process are significant resource challenges: FDA has fewer than 30 full-time employees working with a budget of less than \$10 million annually to regulate the \$32 billion OTC industry.¹ Most of the agency's resources for over-the-counter drug products have been dedicated to fulfilling mandates from Congress (regarding sunscreens) and the courts (antibacterial soaps), constraining its ability to prioritize emerging public health needs.

¹ Donal Parks, "User Fee Considerations in the Context of Over-the-Counter Monograph Drugs" (presentation at FDA public meeting: Over-the-Counter Monograph User Fees, Silver Spring, Maryland, June 10, 2016), <http://www.fda.gov/downloads/Drugs/UCM510584.pdf>.

The proposed legislation would allow FDA to make changes to monographs outside of the notice-and-comment rulemaking process, and would provide the flexibility and resources to respond quickly to safety and efficacy concerns.

Q2: Could you also elaborate on the benefits of requiring firms to submit all positive and negative information in their possession would put the OTC process on par with prescription drugs in terms of safety and efficiency?

As a part of a new drug application (NDA), sponsors—of either prescription or OTC drugs—must submit to FDA all data gathered during animal studies and clinical trials. This requirement ensures that an NDA sponsor cannot cherry pick the data that it shares with FDA.

However, under the current system, those OTC drug manufacturers who are not required to submit NDA applications are not required to provide the agency with all available data. This means that FDA must perform its own review of the literature for publicly-available data and, in some cases commission new research, requiring the use of agency resources, and potentially causing the delay of agency action in the wake of a new safety concerns.

Without access to all of the data, FDA is limited in its ability to evaluate the safety and effectiveness of these products which are used regularly by millions of Americans.²

² Deloitte Center for Health Solutions, “2012 Survey of Health Care Consumers: Key findings, strategic implications,” <https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/us-lshc-2012-survey-of-us-consumers-health-care.pdf>.

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) 226-2827
Minority (202) 225-3641

October 19, 2017

Mr. Michael Werner
Partner
Holland & Knight
800 17th Street N.W., Suite 1100
Washington, DC 20006

Dear Mr. Werner:

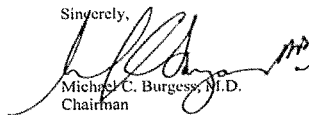
Thank you for appearing before the Committee on Energy and Commerce on September 13, 2017, to testify at the hearing entitled "Modernizing FDA's Regulation of Over-the-Counter Drugs."

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. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on November 2, 2017. Your responses should be mailed to Jay Gulshen, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to jay.gulshen@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Committee.

Sincerely,


Michael C. Burgess, M.D.
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

**Questions for the Record from Ranking Member Frank Pallone
House Committee on Energy and Commerce
Subcommittee on Health
“Modernizing FDA’s Regulation of Over-the-Counter Drugs”
September 13, 2017**

**Mr. Michael Werner
Partner, Holland and Knight
on behalf of the Public Access to Sunscreens (PASS) Coalition**

Confidential Meetings

In your testimony you noted that Congress acted back in 2014 to pass the Sunscreen Innovation Act with the goal in mind of speeding access to over-the-counter sunscreen ingredients. Despite this reform effort, I understand that members of the PASS Coalition, which represents a wide range of stakeholders interested in the approval of new sunscreen ingredients, are seeking additional reforms as a part of the over-the-counter monograph reform process. In particular, I would like to better understand the additional benefits the PASS Coalition is seeking through confidential meetings.

Q1: You note in your testimony, that over-the-counter reform should authorize FDA to meet on a confidential basis with sunscreen ingredient sponsors. Can you explain to this Committee why sponsors of sunscreen ingredients cannot meet with FDA on a confidential basis today? Further, can you discuss why confidential meetings are so critical to your members?

Response: Currently, FDA’s view is that all meetings under the current time and extend application (TEA) process under the OTC drug monograph system should be public. However, information submitted and considered during this process, especially for innovators in the OTC space, may be proprietary and therefore inappropriate for public disclosure. Although such data is “confidential until publication of a proposed monograph,” current regulations still require “published and unpublished data and information pertinent to a designated category of OTC drugs” submitted to an FDA advisory panel to be eventually released to the public, regardless of where that product is in the development process (21 CFR 330.10(a)(2)). This is problematic because sponsors have to be careful in what is submitted to FDA and comments that become part of the record (either by FDA in providing feedback or by the sponsor) must not include confidential business information.

Thus, it is important that sponsors of sunscreen ingredients are able to participate in open discussions with FDA that potentially include the use of confidential commercial information or trade secrets to ensure the agency has the necessary data to make a full and informed decision on the safety and effectiveness of sunscreen ingredients. In addition, confidential meetings would allow FDA to

have flexibility to consider validated alternative testing procedures in support of a determination of general recognition of safety and effectiveness outside of what the agency included in its final guidance on safety and effectiveness data. This is particularly important since FDA's sunscreen data and testing guidance recommends use of tests never before used with sunscreen ingredients. We anticipate that sponsors will need to engage in detailed discussions with FDA about their clinical protocols designed to meet these new standards. We do want to clarify that we believe such non-public meetings do not have to follow New Drug Application (NDA) formats.

Q2: Over-the-counter monograph reform also contemplates certain meeting management goals certain meetings between over-the-counter sponsors and FDA. Recognizing that the ability of the agency to meet these meeting management goals requires resources, do your members support providing FDA with the resources necessary to meeting any specified meeting goal timelines for sunscreen ingredients?

Response: Yes, from its inception, the PASS Coalition's mission has included working to ensure the FDA has the resources it needs to review sunscreen ingredients. The PASS Coalition supports the current proposals to bolster FDA resources for OTC product review including the newly proposed user fee program. The Coalition understands that nearly 20 full time employees (FTEs) are required to review a single OTC monograph, and that the agency requires additional resources to review the wide range of products that should and need to be reviewed in addition to crucial products incorporating OTC sunscreen ingredients.