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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, D.C.

The subcommittee met, pursuant to call, at 11:17 a.m., in Room 2322, Rayburn House Office Building, Hon. Michael Burgess, M.D. [chairman of the subcommittee] presiding.

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 Dingell, Latta, and Costello.

Staff Present: Mike Bloomquist, Deputy Staff Director; Kelly Collins, Staff Assistant; Zachary Dareshori, Staff Assistant; Paul

Edattel, Chief Counsel, Health; Jay Gulshen, Legislative Clerk, Health; Elena Hernandez, Press Secretary; Edward Kim, Senior Health Policy Advisor; 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, Outreach and Member Services; 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.

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.

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 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.

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 click 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 it 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.

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 drugstores.

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 accommodating 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, the --

Mr. Burgess. I don't think your microphone is on.

Ms. DeGette. It is on. I will use my big girl voice.

So 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.

The Chairman. 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 an 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.

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 to order -- 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.

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, Representative 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 monograph 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 an 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.

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 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, DIRECTOR, CENTER FOR DRUG EVALUATION AND RESEARCH, FOOD AND DRUG ADMINISTRATION**

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, okay? 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 similar 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 rulemaking 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 role, 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:]

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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, okay? 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, okay, 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 is 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 -- I never chaired the House 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. 2 years?

Dr. Woodcock. Yes, sir.

Mr. Barton. Is that the guideline in the bill, 2 years? Do we know? Anybody? Okay, 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 safely 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 draft -- we issue safety communications and issue guidance on labelling 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 Monogram 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 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 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. Woodcook, 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 conform 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.

RPTR ALLDRIDGE

EDTR ROSEN

[11:15 a.m.]

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. Okay. 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. Okay.

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. Yeah. 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 two-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, okay, 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 okay 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 medicines 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. Okay. 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 stakeholders, 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. Okay. 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. -- 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. Yeah, 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, okay, 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. -- 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 the 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 follows:]

******** COMMITTEE INSERT ********

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 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 innovate 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. Okay. 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. Okay. 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. Okay. 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. Okay. 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's 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. Okay.

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. -- 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. Okay. And

then we have to change it through rulemaking, through notice --

Mr. Carter. How long does that process take?

Dr. Woodcock. 6, 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, yeah. 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. Okay. But we have a regulation that says it is safe.

So for the lawyers in the room, they understand the problem, okay? 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 it 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. Yeah.

Mr. Carter. -- you know.

Dr. Woodcock. Okay. 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. -- 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-counters 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, yeah.

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 Health Care 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 CEO, CONSUMER HEALTHCARE PRODUCTS ASSOCIATION; KIRSTEN MOORE, PROJECT DIRECTOR, THE PEW CHARITABLE TRUSTS, HEALTH CARE PRODUCTS; MICHAEL WERNER, PARTNER, HOLLAND & KNIGHT, ON BEHALF OF THE PUBLIC ACCESS TO SUNSCREENS (PASS) COALITION; DR. BRIDGETTE JONES, CHAIR, COMMITTEE ON DRUGS, AMERICAN ACADEMY OF PEDIATRICS; AND GIL 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 --

Mr. Burgess. Sir, let me just ask you. Your microphone --

Mr. Melville. 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 Health Care 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, efficient, 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:]

******** INSERT 2-1 ********

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 Health Care 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.

RPTR DEAN

EDTR ROSEN

[12:21 p.m.]

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 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. 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:]

******** INSERT 3-1 ********

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:]

******** INSERT 3-2 ********

Mr. Burgess. The chair thanks Dr. Jones.

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

**STATEMENT OF GIL 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:]

******** INSERT 3-3 ********

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 chose 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 take 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 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 preparation 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. Yeah, 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 12:56 p.m., the subcommittee was adjourned.]