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EXAMINING FDA'S GENERIC DRUG AND BIOSIMILAR

USER FEE PROGRAMS

THURSDAY, MARCH 2, 2017

House of Representatives,

Subcommittee on Health,

Committee on Energy and Commerce

Washington, D.C.

The subcommittee met, pursuant to call, at 10:00 a.m., in Room 2123 Rayburn House Office Building, Hon. Michael Burgess [chairman of the subcommittee] presiding.

Present: Representatives Burgess, Guthrie, Lance, Griffith, Bilirakis, Long, Bucshon, Mullin, Collins, Carter, Walden (ex officio), Green, Engel, Schakowsky, Butterfield, Matsui, Castor, Sarbanes, Schrader, Kennedy, Cardenas, Eshoo, DeGette, and Pallone (ex officio).

Also present: Representative Welch.

Staff present: Mike Bloomquist, Deputy Staff Director; Karen Christian, General Counsel; Jordan Davis, Director of Policy and External Affairs; Paige Decker, Executive Assistant and Committee Clerk; Paul Edattel, Chief Counsel, Health; Blair Ellis, Digital Coordinator/Press Secretary; Adam Fromm, Director of Outreach and Coalitions; Jay Gulshen, Legislative Clerk, Health; Zach Hunter, Director of Communications; Katie McKeough, Press Assistant; Carly McWilliams, Professional Staff Member, Health; Alex Miller, Video Production Aide and Press Assistant; Dan Schneider, Press Secretary; Danielle Steele, Policy Coordinator, Health; John Stone, Senior Counsel, Health; Josh Trent, Deputy Chief Health Counsel, Health; Hamlin Wade, Special Advisor, External Affairs; Luke Wallwork, Staff Assistant; Jeff Carroll, Minority Staff Director; Tiffany Guarascio, Minority Deputy Staff Director and Chief Health Advisor; Dan Miller, Minority Staff Assistant; Olivia Pham, Minority Health Fellow; Samantha Satchell, Minority Policy Analyst; Andrew Souvall, Minority Director of Communications, Outreach and Member Services; Kimberlee Trzeciak, Minority Health Policy Advisor; and C. J. Young, Minority Press Secretary.

Mr. Burgess. I want to welcome everyone to the subcommittee hearing, and I ask that all guests take their seats and the subcommittee will now come to order. The chair recognizes himself for 5 minutes for the purpose of an opening statement.

Today's hearing marks the Health Committee's first public discussion on the reauthorization of several key user fee programs at the United States Food and Drug Administration. This hearing will focus on the generic drug and biosimilar user fee programs, and we will turn our attention to the reauthorization of the Prescription Drug User Fee Act and the Medical Device User Fee Amendments later this month. All four of these programs will expire in September, and thus must be reauthorized for fiscal years 2018 through 2022. Chairman Walden and I are committed to moving the user fee legislation through committee following regular order, with time to spare.

I want to welcome Dr. Woodcock back to the subcommittee. I would also like to commend the Food and Drug Administration and industry for the various briefings that they have provided members and members' staffs throughout the negotiation process and for transmitting the proposed agreements to Congress in a timely manner pursuant to the process laid out in statute.

Committee staff has been working on a bipartisan basis with the Senate Health Committee to review the agreements in detail

and to develop the necessary authorizing language for consideration. I appreciate the technical assistance that the Food and Drug Administration has provided, not to mention the expertise of our legislative counsels. It is because of these efforts that we are well on track for a timely reauthorization.

Since 1992, with the initial authorization of the Prescription Drug User Fee Act, revenues generated from regulated industry fees have supplemented congressional appropriations and significantly enhanced the Food and Drug Administration's ability to review product applications and a more predictable manner.

Based in large part on the success of the Prescription Drug User Fee Act, medical device user fees were authorized in 2002, followed by Generic Drug User Fee Amendments of 2012, and the Biosimilar User Fee Act of 2012, both of which are the focus of today's hearing. I look forward to learning more about their implementation to date, and ways to improve these important programs going forward.

Approval of additional biosimilars will undoubtedly increase competition in a complex and often costly biologic drug market. Small-molecule generics already account for billions of dollars in savings each year. Nonetheless, for a variety of reasons, generic competition is lacking for certain products despite the absence of patent protection. We will hear from the Food and Drug Administration and from industry about how improving

and reauthorizing the Generic Drug User Fee Amendments will help to close those gaps.

We will also hear from our colleagues, Kurt Schrader from Oregon and Gus Bilirakis from Florida, about H.R. 749, the Lower Drug Costs through Competition Act, a bill that they recently introduced along with a bipartisan number of cosponsors. H.R. 749 aims to encourage market entry by generic manufacturers in situations where it may not otherwise make sense from a business perspective.

I understand that introduction of this bill has led to a robust discussion about additional and alternative ways to spur such competition. That is a good thing. I appreciate the sponsors' willingness to hear from a variety of stakeholders and to work with bipartisan committee staff to improve the bill prior to proceeding to markup.

Again I want to welcome all of our witnesses here today. I apologize for the late start. Thank you for being with us, and look forward to your testimony. The chair now recognizes the ranking member of the subcommittee, Mr. Green from Texas, 5 minutes for an opening statement, please.

[The prepared statement of Mr. Burgess follows:]

**********COMMITTEE INSERT 1**********

Mr. Green. Thank you, Mr. Chairman, and thank Dr. Woodcock for being back with us and our distinguished panelists for the hearing this morning.

Today is the first hearing of the user fee agreement reauthorization cycle. We have learned a great deal since the first prescription drug user fee agreement authorization, and every 5 years have amended and expanded the user fee programs to build on past successes and further support timely review and approval of safe and effective medical products.

The affordability of therapies is an issue of great growing concern. Robust competition in the prescription drug market between innovative drugs and generic drugs and innovator biologics and biosimilars is crucial to providing patients with greater access to affordable therapies. Generic drugs are proven to be a safe and affordable alternative to brand name drugs.

It is estimated that generic drugs account for 89 percent of prescriptions dispensed in the U.S., but only 27 percent of the total drug cost. In 2015 alone, generic drugs saved American families $227 billion. Similar to generics, biosimilars hold great promise to make complex products available at lower cost to patients.

Due to growing concerns about the time it is taking FDA to review generic drug applications and the backlog of such applications, Congress passed the generic drug user fee

amendments in 2012. Interest in participation in the program has exceeded initial predictions, and the agency has struggled to get the new program off the ground and keep up with the oversize workload and undersized resources.

GDUFA II, like subsequent reauthorizations of the prescription drug and medical device user fee programs provides an opportunity to address lessons learned from the past 4 years and improve the program so that we have a strong market of safe and effective generic drugs. Following the enactment of the Biologics Price Competition and Innovation Act, the biosimilar act, BP act, BsUFA, was established. Welcome to the FDA acronyms.

BsUFA II provides an opportunity to build on progress made and enhance the program. Stakeholders and the FDA have agreed to review timelines, meeting structures, and new programs to increase the number of first-cycle approvals which will save resources for sponsors and the agency and, more importantly, make safe and effective therapies available to patients and introduce additional competition in the market.

I look forward to hearing more about the agreements between the stakeholders and the FDA on GDUFA II and BsUFA II. It is crucial that Congress authorize these programs in a timely manner to ensure the agency has the resources and tools needed to support generic and biosimilar competition. And I want to mention my concern about the impact of the administration's across-the-board

hiring freeze with the FDA. FDA must have an adept and capable and sufficiently sized workforce to make timely scientific decisions in the interest of patients and the public health. Currently, FDA has 1,000 vacancies at the agency and the majority of which are in the Center for Drug Evaluation and Research.

We worked to help the agency attract and hire highly qualified professionals at the 21st Century Act. The hiring freeze threatens the laudable work that could have a detrimental impact on the hiring goals all ready to negotiated performance goals of the user fee agreements. I hope the administration takes this into account when implementing this deeply flawed policy.

We are also here today on H.R. 749, Lower Drug Costs through Competition Act. Over the past few months we have had productive and bipartisan conversations about the proposal and ways to achieve the shared goal of enhanced generic competition. I have concerns as the legislation is written, however, including a concept of how a priority review voucher for generic drug manufacturers will impact with existing and newly negotiated provisions of GDUFA II.

I would like to continue to work with my colleagues to improve the legislation. There is a growing bipartisan support for the government to take action and lower prescription drug costs. Rising drug costs is not a simple problem and with a simple solution. While more competition for generics and biosimilars

is an important way to make medicines more affordable, it alone is not sufficient to address the problem of affordabilities.

Mr. Chairman, I would like before I yield the remainder of time to my colleague from Colorado, Congresswoman DeGette, just for the public do you have any knowledge that we are going to have a hearing next week on the markup of the Affordable Care Act?

Mr. Burgess. It is my understanding that the markup has not been noticed and it will be noticed in a timely fashion if it occurs.

Mr. Green. Well, thank you for that little bit of information. I will yield my time to my colleague.

[The prepared statement of Mr. Green follows:]

**********COMMITTEE INSERT 2**********

Ms. DeGette. Thank you. Well, just in the few seconds left I want to echo Mr. Green's concerns about this hiring freeze, particularly with the implementation of 21st Century Cures, but also with reauthorization of the UFAs, because I don't see how we can improve access if we have a hiring freeze.

The other executive order that we are deeply concerned about on both sides of the aisle is this order that you have to repeal two regulations before you can enact a new regulation, because as we are trying to implement the UFAs and also 21st Century Cures I don't see how we are going to be able to use those draconian, I think it is just draconian in this standpoint.

Mr. Chairman, I am going to have a series of questions that I am going to submit to Dr. Woodcock and our other witnesses about this, but I think this is something, a concern that we share on both sides of the aisle. And I appreciate your comity, and I yield back.

[The prepared statement of Ms. DeGette follows:]

**********COMMITTEE INSERT 3**********

Mr. Burgess. The chair thanks the gentlelady. Does the gentleman from Texas yield back? Apparently so. The chair then recognizes the gentleman from Florida, Mr. Bilirakis, 5 minutes for an opening statement, please.

Mr. Bilirakis. Thank you. Thank you, Mr. Chairman. Again thank you for including the Lower Drug Costs Through Competition Act as part of this hearing. I am proud to join my colleague, Congressman Kurt Schrader, to responsibly use the power of the free market to bring lower prices and more drug choices to the market.

This legislation would directly address some of the problems we have seen with bad actors in the drug space such as Turing Pharmaceuticals and Valeant Pharmaceuticals. Too often we have seen the price of lifesaving medications skyrocket due to bad actors taking advantage of monopolies in the market. We cannot allow this to continue. Our bill would incentivize drug companies to enter into these markets where no generic currently exists. My constituents in Florida and folks nationwide need relief. I hope that this committee will move this bill this month, and I yield back. Thank you, Mr. Chairman.

[The prepared statement of Mr. Bilirakis follows:]

**********COMMITTEE INSERT 4**********

Mr. Barton. Would the gentleman yield some of this time to me, Mr. Chairman?

Mr. Burgess. The gentleman from Texas is recognized if the gentleman from Florida yields back.

Mr. Bilirakis. Yes, I yield back.

Mr. Barton. I won't take any more than 3 minutes and 47 seconds. I want to thank you, Mr. Chairman, and I want to thank the ranking member, Mr. Green, for hosting this hearing today on the Biosimilar User Fee Act. Not everything in the Affordable Care Act was bad. I know that is a shock for my friends on the minority side to hear a Republican say that. But Congresswoman Anna Eshoo and myself put in a strong biosimilar section in this committee, in the Affordable Care Act markup when the Energy and Commerce Committee did that. It was one of the few bipartisan provisions, it created a new and distinct biosimilar industry sector. Success of that regulatory provision can only be measured now by how it is implemented. We have thousands of patients, Mr. Chairman, that are facing cancer, inflammatory disease, kidney disease, and other serious disorders. We expect that they will benefit from biosimilars over the next decade. Although this is a new industry, I do believe that Congress and the administration have an important role to play in the development and success of the biosimilar marketplace.

So while this is not the focus of the hearing today, I would

ask that we take a look at this CMS finalized payment methodology that they just finalized and, in my opinion, if that stands it will dramatically reduce the investment and availability of biosimilars.

So Mr. Chairman, thank you for the hearing. I look forward to hearing the witness. We are glad to have you again, you have been here before. And with that I yield back.

[The prepared statement of Mr. Barton follows:]

**********COMMITTEE INSERT 5**********

Mr. Burgess. The chair thanks the gentleman. The chair recognizes the gentleman from New Jersey, Mr. Pallone, the ranking member of the full committee, 5 minutes for an opening statement, please.

Mr. Pallone. Thank you, Mr. Chairman. Mr. Chairman, I must follow up on the little dialogue that you had with Ranking Member Green at the end of his statement with regard to the ACA bill. It seems like everyone knows that there is going to be a markup in full committee next Wednesday of the Affordable Care Act except for the Democrats who haven't been told anything. And I know you have long been an advocate for regular order, I just want to read this statement from the Speaker.

The Speaker on the Today Show on February 28th, he said that the majority's proposed ACA replacement legislation will be carefully considered and completed through the committee process with public engagement and transparency. We are going through the committee process step-by-step. We are having public hearings. We are having committees work on legislation. We are not hatching some bill in a back room and plopping it up on the American people's front door. Well, I have been told, not by the Republicans, not by The Chairman, not by you, but by, you know, K Street and everyone else around here that you guys can go down to H-157 right now as we speak and go in there to the basement, the secret basement that, you know, that the Speaker

says would never happen, and look at the bill that is going to be marked up next Wednesday. But I can't go down there. You know, maybe the lobbyists know where it is, they know what is in it. You know, I don't know what the media knows, but they certainly know there is a markup. Maybe the Russian ambassador is down there and he can tell us what is in the bill. Maybe they will let him in, but they won't let me in.

And, you know, you actually, you know, I want to commend you again, Mr. Burgess, Chairman, you were on MSNBC's Chris Hayes last night and you said that you don't agree with the decision to keep the House's GOP bill secret, warning that it could backfire. You suggested Republicans owed it to the public to share their plan. It is time. Put your pencils down and turn your papers in, he told MSNBC's Chris Hayes. So you seem to be an advocate for letting everyone see this. I mean, I would just remind you, you know, I know you always talk about transparency with the ACA, but when the Democrats considered the ACA, the House conducted 79 committee hearings and markups over a 2-year period. The House posted the original language of the bill online for 30 days, engaging in public deliberation before the first committee held the markup.

Now from what I can see, what is going to happen is you may put out a notice Monday of a markup in full committee Wednesday, we come back Tuesday night and we won't even have 12 hours before

the markup would happen. Now I don't know that that is for sure, but that is what everybody is hearing. So let me just ask you, can I go down right now myself, Mr. Green, Ms. Eshoo, can we go down to H-157 and see this bill? Would you just ask, I would like to know whether I can go down there and look at this bill.

Mr. Burgess. Were you asking Mr. Green or myself?

Mr. Pallone. No, I am asking you, Mr. Chairman. I mean, I like what you said on MSNBC, but can I go down and look at the bill?

Mr. Burgess. The chair does not have that information available, but I will find out for you and relay it to you as soon as it becomes available.

Mr. Pallone. Well, I would appreciate it because I really think that Democrats should be looking at the bill in addition to K Street, in addition to the media, and God knows what goes on with the Russian ambassador. But I want to yield the balance of my time to Mr. Schrader.

[The prepared statement of Mr. Pallone follows:]

**********COMMITTEE INSERT 6**********

Mr. Schrader. Thank you. I want to thank the ranking member and thank you, Mr. Chairman, for having the hearing.

On a more bipartisan note, I think it is pretty evident American patients, states, and taxpayers, we are paying exorbitant prices for many prescription drugs, and it is really time for Congress to act. Every few months we are seeing headlines about exorbitant price hikes from unscrupulous bad actors like my good friend Gus Bilirakis talked about.

Buying the rights to produce drugs that have been on the market for decades usually where there are no competitors, seemingly overnight these prices go through the roof. In the case of Daraprim, a drug used by some transplant patients, people living with AIDS, Turing Pharmaceuticals raised the price from $13.50 per pill to $750 -- come on, man. Last year, Valeant, another pharmaceutical company raised the price of their drug to treat lead poisoning, been around forever, by more than 2,700 percent. That is criminal.

For both these drugs and many others, the drugs have been off patent for years and ages. There is no generic competitor on the market. Unfortunately, generic manufacturers who want to bring a competitor face this long approval process we are going to be talking about. I think GDUFA I is going to help a bunch. But our bill, lowering drug costs through competition, makes a huge difference in getting these drugs to market that much faster.

It also looks at the risk mitigation strategies, potential abuse.

We have solicited feedback on our bill, look to learn more from stakeholders. This hearing hopefully provides another opportunity. It is important. I am glad we are able to come together in a bipartisan fashion to make this happen.

And I yield back, Mr. Chairman.

[The prepared statement of Mr. Schrader follows:]

**********COMMITTEE INSERT 7**********

Mr. Burgess. The gentleman yields back. The chair thanks the gentleman. We now conclude with member opening statements. The chair would like to remind members that pursuant to committee rules, all members' opening statements will be made part of the record.

For what purpose does the gentleman from Oregon seek recognition?

The Chairman. Just to make a brief opening statement, Mr. Chairman. And I want to commend my colleague from Oregon and my colleague from Florida for bringing this legislative concept forward. It is one we have talked about. I think it makes a lot of sense. It is a piece of the puzzle, it is not the whole puzzle. It doesn't solve all the problems, but that is how we are going to look at this, a piece at a time trying to get it right.

And so I commend Mr. Schrader. I commend Mr. Bilirakis and others, and I want to thank our witnesses for their participation today. And we look forward to bipartisan legislation when it comes to this and other issues before the committee. With that I yield back.

[The prepared statement of The Chairman follows:]

**********COMMITTEE INSERT 8**********

Mr. Burgess. The gentleman yields back. The chair thanks the gentleman. And again we want to thank all of our witnesses for being here today, for taking time to testify before the subcommittee. Each witness will have the opportunity to give an opening statement followed by questions from members.

We have two panels of witnesses today, and we will begin with Dr. Janet Woodcock, the director, Center for Drug Evaluation and Research at the Food and Drug Administration. We appreciate you being here this morning, Dr. Woodcock. You are recognized for 5 minutes for an opening statement, please.

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

Dr. Woodcock. Thank you. We are here today to discuss the proposed reauthorization of two user fee programs known by the acronyms of GDUFA and BsUFA that support review of generic drugs and biosimilar drugs, respectively. FDA approval of generic or biosimilar versions of brand drugs after patent and exclusivity protections have expired, introduces competition into the marketplace and results in more affordable medicines.

Indeed, generic drugs are estimated to have saved the American public $1.5 trillion over the last 10 years. Almost 90 percent now of all prescription drugs dispensed in the U.S. are generics. Before GDUFA I was enacted, Congress, the industry, and FDA all recognized that the program was a victim of its own success and it was not able to keep up with the flood of applications that were coming in.

Congress authorized GDUFA I, and I am happy to report it has been a success. FDA has met all the program goals of GDUFA I. In addition, virtually all of the piled up applications have been reviewed and either approved, they have been sent to the manufacturer for the deficiencies, or they are in a new review cycle. So they are all in process of the review process.

FDA approved or tentatively approved 835 generic drugs in

fiscal year 2016, which is a new record, and over the 4 years of this program so far we have approved 56 new generics, first generic drugs. Similarly, the biosimilar user fee program is on track to provide affordable alternatives to biologicals. So far, four biosimilars have been approved and we are working on 64 development programs with developers that would provide competition for 23 biologics. We have also issued six final and four draft guidances.

But these user fee programs are version 1.0. We and industry have learned a lot in the course of operating these over the last 4-plus years. So over the past year, we worked hard with industry to envision ways to improve the program that meets the industry's need for timeliness, transparency, predictability, but also meets the public's need for a steady flow of high quality affordable medicines.

We think the proposals for GDUFA and BsUFA II meet these twin objectives from both the public good and working well for industry and the agency. Additionally, across multiple drug user fee programs that are up for reauthorization, we have added new financial management provisions and modified fee structures in a way that will simplify and improve the infrastructure of all these user fee programs, so that is a part of these two new programs.

As in your work with 21st Century Cures, which we were happy

to work with you on, these user fee programs are intended to improve U.S. citizens' access to safe and effective medicines, and it is really important that they be reauthorized because they are providing that function now.

I will be happy to answer any questions.

[The prepared statement of Janet Woodcock, M.D. follows:]

**********INSERT 9**********

Mr. Burgess. The chair thanks Dr. Woodcock. Thank you for your testimony. We will move on to the question and answer portion of the hearing. I begin the questioning by recognizing myself for 5 minutes.

Dr. Woodcock, the FDA, Food and Drug Administration, often reviews and makes decisions on complex, novel drug applications for serious conditions within 6 months. Decisions on whether to approve such new drug applications are almost always made in the first review cycle. On the other hand, the median review times for generic drug applications have actually increased since the Generic Drug User Fee Amendments was authorized, and in 2015 reached 48 months with only nine percent of generic applications approved in the first review cycle.

So this doesn't seem like the right direction. In 5 years from now, what percentage of first-cycle approvals would you consider a success?

Dr. Woodcock. Well, I would consider a success to be a considerable increase over the rate we are seeing now. I think we are up about 10 percent maybe. It is hard to say with the recent submissions, but we can look at the class of 2014-2015 and see how many of those have gotten a first-cycle approval. And it is still I think under ten percent.

So if we could get up to 20, 25 percent it would be excellent, and then keep building that over time. Because right now, if,

next year if a company were to send in, if you were a company you would send in a generic drug and, say, it would be a first generic and it were a good application, it was complete, you could be on the market in 8 months.

Mr. Burgess. I beg your pardon?

Dr. Woodcock. You could be on the market in 8 months.

Mr. Burgess. 8 months. So I guess, you know, the issue is here is really how do we move the needle so that the overwhelming majority of generic applications are actually approved on the first cycle?

Dr. Woodcock. That is one of the goals of GDUFA II. So for complex generics we have put in and proposed a program where we would work with the companies before the application was submitted and work out a lot of the complex issues. These might be applications where there is an injector or other device used with them, or where there are very complicated molecules.

But also we plan to provide more training and interaction with industry up front in general so that they can get to a point where their applications can be approved on the first cycle.

Mr. Burgess. So that is, I mean, under anyone's definition that would be moving the needle. For priority submissions of noncomplex products, which according to the Food and Drug Administration itself constitute a relatively small portion of their overall workload but are especially important to public

health, should the agency have a similar program to ensure quality applications are submitted at the outset, reduce the opportunity for failure?

Dr. Woodcock. Well, we are proposing that at least for complex drugs that there be a very intensive program to make sure that they get it right the first time.

Mr. Burgess. Are there additional tools or authority that the Food and Drug Administration would need particularly in the space that deals with the development of complex generics under the 505(j) pathway?

Dr. Woodcock. What we are proposing in GDUFA II would give us new tools. We would actually meet with the companies in advance. There would be submissions during and interactions during the review process. This is actually somewhat similar to what we do for the new drugs that you mentioned earlier.

And I will point out that the PDUFA program over the 20 years of operating has brought the first-cycle drug approval up to what, well over 80 percent of drugs that are approved on the first cycle now in the new drug side. But it wasn't that way at the beginning.

Mr. Burgess. Dr. Woodcock, do you think the FDA needs additional authority in order to approve drugs faster on this pathway?

Dr. Woodcock. No. I think that we need more, the resources that we have negotiated under GDUFA II or other types of resources

provided, because this is a labor-intensive activity, all these additional interactions with the industry that help them get their submission in shape the first time.

Mr. Burgess. Well, I certainly thank you for being here today. Again as I mentioned to you before we started, it doesn't seem possible that this is the third reauthorization that I have lived through. I really do appreciate your testimony. I appreciate putting together the list of medications that actually have been approved that may not be generally known, so I appreciate you making that as part of the packet today of information that you shared with the subcommittee.

And I will yield back my time and recognize Mr. Green for 5 minutes for questions, please.

Mr. Green. Thank you, Mr. Chairman. Dr. Woodcock again, welcome. The review model instituted by PDUFA is a result of lessons learned over the years and a commitment from both the FDA and industry to work towards a first-cycle approval. PDUFA now enjoys an average 80 percent first-cycle approval. One common criticism we have heard of the FDA is the need to improve the quality of applications under GDUFA so it moves more toward approving the applications in the first cycle. In fact, you note in your testimony that prior GDUFA generic applications were approved in one review cycle less than one percent of the time. That rate has increased to nine percent under GDUFA I. Following

the chairman's question, follow up, can you elaborate more on how GDUFA II will improve that first-cycle approval?

Dr. Woodcock. Yes. Well, first of all, we are getting industry focused on the fact that the benefits of a first-cycle approval. In the past it was about a median of four cycles, and sometimes we would go up to 11 cycles, industry would go through in getting their application, and sometimes they had time because they were waiting for patents to expire or what have you.

So we are going to focus on that and then for the very complex ones we are going to put in place, we are proposing to put in place a special program where we work with the industry before they submit their application. So that is off the clock, all right. And we help them get it, meet with them and help them get it into place and we issue certain guidances early, and then we meet with them during the program to make sure the review is on track and that they have answered all the questions.

Mr. Green. Okay. Much attention has been given to the backlog of the generic applications. Can you help this committee understand the nature of these pending applications and what the agency has done to address them? I think you may have answered that, that you are actually working with them before filing, so I appreciate that.

On the BsUFA meeting, Dr. Woodcock, when you were here last February to testify about the implementation of BsUFA you

discussed the increasing number of meeting requests that the agency was receiving from sponsors. We have heard from industry that these meetings are valuable and providing clarity about the data and the information the agency will need for approval and to address any outstanding questions FDA will have early in the process. What improvements of these meetings with sponsors will be made under BsUFA II?

Dr. Woodcock. Yes. Well, those meetings are very valuable. We are all feeling our way in biosimilarity. It is a new concept. It is not safety and effectiveness, it is biosimilarity that provides the entry to the market, and how to prove that is a new concept. So we had not been meeting all of our meeting goals under BsUFA I because the industry appetite for them was very large and we were not able to meet with all the industry that wanted to meet with us.

So under BsUFA II we have changed some of the timelines. We are increasing the staffing so that we will be able to meet these meeting goals and meet with industry that needs to talk with us about how to craft their biosimilar program. Much of this is analytical work, in vitro work, sometimes though there would even be a clinical trial that would be done.

Mr. Green. In the short time I have left, let me just ask too about some of the concerns about the, as I said in my opening statement about the number of vacancies at the FDA and also a

freeze on hiring. Obviously that would hurt the process right now, and is there anything the FDA can do now with staff?

Dr. Woodcock. Well, as you know, our hiring problems have been persistent for the last 5 or 6 years and we have run deficits. We are working with the new administration and we hope that we will be able to address these issues, continue to address them as we have been trying to address them.

Mr. Green. Thank you, Mr. Chairman. I have one other question. Can you explain different considerations given under GDUFA II for small businesses, because that is one of the issues we have heard.

Dr. Woodcock. Yes, there is a different fee structure for a small business exemption so that that will help, and there are different levels of the program that -- small business exemption, yes. It is complicated how we are doing it so we can get back to you, but we have taken the issue of small business more into account in the fee structure in GDUFA II.

Mr. Green. Thank you, Mr. Chairman. I yield back.

Mr. Burgess. The chair thanks the gentleman. The gentleman yields back. The chair recognizes the gentleman from Kentucky, Mr. Guthrie, vice chairman of the committee, 5 minutes for your questions, please.

Mr. Guthrie. Thank you, Mr. Chairman. Thank you, Dr. Woodcock, for being here. We appreciate it very much. Do you

know the percentages of generic drug applications that go through more than three review cycles, or how about five review cycles?

Dr. Woodcock. Well, it depends on when you are talking about because that is in flux right now. Historically, the median was four, so about half were less than four or less, and obviously about half were more than four, okay.

Mr. Guthrie. Yes.

Dr. Woodcock. Okay, so now that is shifting a little bit. That curve is shifting to the left and we hope to see fewer and fewer total review cycles. The reason that is happening right now is because we are doing a lot of information requests and we are going back and forth with the company during the review cycle to try and get as much of this fixed as possible. And we hope that the vast majority of ones, all these ones that we have been reviewing, will be approved on the second or third cycle.

Mr. Guthrie. Okay.

Dr. Woodcock. But the older ones may still need considerable fixing up before they can get approved.

Mr. Guthrie. You almost got to my next question, but so how many total years in like the back, when you talk about back and forth between FDA and the company, if you are in three cycles, I mean, how many years is that typically? Or maybe even 5 years.

Dr. Woodcock. Historically that is very difficult to say, all right. Right now the first cycle is going to be 10 months,

right. And then you send it back to the company, say, if it doesn't get approved, and then it depends on when they send it back to us. Right now the industry due to our vigor in getting through all these, industry has 1,800 applications with them that they are trying to respond to and send back in. Well, that is a lot of applications and they aren't going to be able to send them all back in, in a month. So what we think is over the next few years, if GDUFA II is reauthorized we will get into a steady state. And you put an application in and you have a predictable path, you know when you are going to get it back. If it isn't approved, you will have time you can rapidly work on it, send it back in a couple months and it will be fixed. Now if, and if I may go on.

Mr. Guthrie. Go ahead, yes.

Dr. Woodcock. What if they have a plant somewhere that has been found to have problems, now that may take longer to remediate especially if very serious deficiencies were identified. So there are going to be some outliers where they can't really send it in again until the issues with their manufacturing or some other serious issue is remediated.

Mr. Guthrie. Are the multiple review applications, are they typically from smaller companies or newer companies or with less experience, or does experience and company size not matter?

Dr. Woodcock. We have found them from everybody.

Mr. Guthrie. Okay.

Dr. Woodcock. So there is a lot of educational work to be done.

Mr. Guthrie. Are there any particular characteristics of applications that come through on the first cycle that you say, well, these are characteristics that could be expanded throughout the rest of the, people having issues with that?

Dr. Woodcock. Yes, and we are making a great effort to try and identify that and have standardized tables and more standardized submissions and so forth so that industry knows, you know, have we filled everything out, is everything complete, is it all in here? We are doing more on the refusal to file so they get it back quickly, and it isn't filed so they can make sure it is complete before they get in the process and have to wait 8 months. So we agree with you. If we could identify those characteristics, we could help the applications be more complete.

Mr. Guthrie. Yes. Well, I wanted to help you and help everybody work better. That is why we are here. So does FDA currently expedite resolution of an inspection related issue when it is the only obstacle for generic approval particularly if the case is priority submission? So do you expedite inspection related issue?

Dr. Woodcock. We may expedite ones that are straightforward but, you know, we are dealing with fraud sometimes, we are dealing

with very serious deficiencies, say, with sterility of drugs and so forth, and those have to be remediated by the sponsor before we could responsibly approve the drug.

Mr. Guthrie. Absolutely. We don't disagree with that. Well, thank you, you answered my questions. I yield back almost a minute of my time.

Mr. Burgess. The gentleman yields back. The chair thanks the gentleman. The chair recognizes the gentleman from New Jersey, Mr. Pallone, the ranking member of the full committee, 5 minutes for your questions, please.

Mr. Pallone. Thank you, Mr. Chairman.

Dr. Woodcock, I wanted to ask you about the abuse of REMS. I believe with many of my colleagues on the committee that we should encourage and support robust generic competition in the marketplace, however, if we are to achieve this goal we must ensure that we are limiting barriers to generic entry wherever possible. Unfortunately, there is evidence that some brand drug manufacturers are using REMS programs to delay competition by preventing generic and biosimilar manufacturers access to samples of branded drug products and these samples are needed by generic and biosimilar manufacturers to conduct the bioequivalence studies needed for FDA approval.

So my question is, you note this problem of certain brand companies delaying or denying generic companies access to

reference products in your testimony, can you discuss further how REMS programs are being inappropriately used to delay generics' entries to the market and what steps the agency is taking to curb those abuses?

Dr. Woodcock. Well, the REMS programs and other restricted distribution programs restrict general access to the drugs in some cases. And so a generics company would have to get the drug in order to compare it in a bioequivalence study and also compare back, reverse engineer the product so they are making a copy. And in many cases they have been denied access to the drug and so they are not able to do those things.

The steps we have taken, we are willing to review the protocol of the generic and send a letter to the brand saying, you know, this is an appropriate use for the drug and, you know, it is under, you know we have looked at it, so that there isn't a reason that says, well, we are worried these people are irresponsible and they are going to take our drug and do something.

We have made it clear that drugs even under REMS can be used for bioequivalence studies and so forth, but we can't compel companies to give their drug away to a competitor, to a generic competitor. We have also talked to the FTC about this general issue and, you know, had shared conversations with them.

Mr. Pallone. Well, I mean are there other tools or authorities that you need or you suggest to address the abuse?

I mean you said that you can't compel, but should we be legislating something?

Dr. Woodcock. I don't know the answer to that. But I know it is a problem that we struggle with a lot and that the companies struggle with and it has delayed availability of generics.

Mr. Pallone. And I mean, I was going to ask you this, but I think you answered the question. But let me just say that you seem to think that there is, I mean the argument is made that REMS drugs have high risk profiles that make it unsafe for generic companies to be able to access them for purpose of development, but I think your answer to that is not really.

Dr. Woodcock. Yes. And we are willing to look at the protocols under which they are going to be tested and tell the brand company that we find these acceptable uses.

Mr. Pallone. Okay. All right, let me move to the priority review. Prescription drug costs in this country continue to soar, and the examples of Sovaldi, Daraprim and EpiPen have all highlighted the very real problems. I believe that we would all agree that expediting access of generic drugs is one way we can help to address high drug costs. On average the cost of a generic drug is 80 to 85 percent lower than the brand name.

So my question is prioritizing the review of first generics and sole-source generics is one way the agency can help ensure there is competition, can you please discuss how the agency

currently prioritizes the review of generic drugs and how the timeline for review of an application that is prioritized differs from a standard generic drug application?

Dr. Woodcock. We prioritize first generics, shortage drugs, drugs under PEPFAR, and certain other categories where, say, there is a sole-source drug, and we shorten the time that we expect to get done to 8 months. So we move them through more quickly kind of like the express lane at the supermarket, okay, so we do prioritize those.

Now it is quite possible that it might be difficult to shorten those timelines more, and the reason for that is the inspections that have to be done. We have to do inspections, and in fact the generics typically have many more establishments in their application than a brand application has and they might be all over the world. And if we haven't been there in a certain amount of time based on a risk based assessment we need to go do an inspection.

Mr. Pallone. And is this why under GDUFA II the FDA and industry have agreed on this 8-month priority review for certain applications? I mean, how do you get that 8-month review timeline?

Dr. Woodcock. Well, it is gotten by we need to have enough time in which to do inspections in different countries, if necessary. And why is that? Why would we want to make sure we

had done inspections? Well, recently, for example, we have had cases where testing labs actually switched the samples like this so that the results would come out similar, because you are supposed to be similar and it wasn't going to be similar. So they switched samples so that they would get the right results.

We have had other cases where people are going to release their drug based on their own specifications and they found it wasn't going to meet the specifications so they made up new test results. So our obligation is to if we approve a generic drug in the United States, the public needs to know it is going to work the same as the brand drug it replaces, and that is why we have to go and do inspections sometimes. Now if we have been in the facility recently then we might not have to do that. And so we only do it on a risk base, based on whether we have been in there and other considerations.

Mr. Pallone. All right, thank you. Thank you, Mr. Chairman.

Mr. Burgess. The chair thanks the gentleman and the gentleman yields back. The chair recognizes the gentleman from Florida, Mr. Bilirakis, 5 minutes for your questions, please.

Mr. Bilirakis. Thank you, Mr. Chairman. And I thank you, Dr. Woodcock, for being here, appreciate it so much.

A couple of years ago Turing Pharmaceuticals took an off-patent drug that treats HIV patients, Daraprim, and raised

it by a price of 5000 percent. Unfortunately, this was not a standalone situation. Since then we have seen other drug companies, Valeant and Mylan, take old drugs and raise the price because of a lack of competition in the marketplace.

I have heard there were about 150 off-patent drugs that exist where we could have a generic, but no generic company has chosen to enter those markets. Is 150 an accurate number? What are some of the reasons for that kind of situation?

Dr. Woodcock. Our understanding right now is there are a 182 drugs that are off-patent and have no generics competition and there may well be other generics that are sole-source where the innovator has withdrawn, because right now there are 546 drugs where the brand name has withdrawn from the market and some of those may only have one generic. So if you lump them all together we call them sole-source products, they only have one source. And the reasons for that we believe are mainly market reasons that companies don't think it is worth their return on investment, they don't think if they enter that market they would make money compared to other opportunities they might have to make money. And so many of them have small markets and so forth. For example, we recently, there was recently drugs that have, you know, you can file a generic now, and we had nine generics file for one and we had 16 file for another.

So where there is a big market there is a great interest,

right, in getting a generic, but these small market drugs maybe that are seen as, you know, not a good income stream or maybe they will be overtaken in a number of years, there isn't as much in trust.

Mr. Bilirakis. Thank you for that. Do you know the size of the generic filing backlog and how old are some of the filings?

Dr. Woodcock. There is no backlog in the filing.

Mr. Bilirakis. No backlog?

Dr. Woodcock. Correct. Yes, there hasn't been for some time, that is right. So they are filed within, we are given a certain time period to do the filing review and we have no backlog within that. Yes, there was at the beginning of GDUFA that we eliminated.

Mr. Bilirakis. Okay, thank you very much. In your testimony you talk about the approval process. You have 8 or 10 months to review an application and if they are deficient you issue a complete response letter. How long does it take for a company to respond?

Dr. Woodcock. That is highly variable. And right now, as I said earlier, I believe it is longer than it will be in the future because we did have that backlog of applications. We got a lot of them through our system. We sent them back to the companies. Right now there are 1,800 applications at the companies and, you know, that is a surge of responses. They are going to have to

prioritize those and get the ones they deem most important back to us first. So we don't control the time where they are back with the companies.

Mr. Bilirakis. But on the average how long would you say?

Dr. Woodcock. Well, because it is a moving target, it was different before GDUFA and it has changed during, I think it is really hard to say. Ideally, it would only be a few months unless there are facility problems where a facility must be remediated, or we have seen some major problem, say, with the data where they have to go back and reverify it or redo it and those would be much longer.

Mr. Bilirakis. A company that is into its fifth review cycle, how many years old could that application be assuming everyone used their full time allotted in each section what would you say?

Dr. Woodcock. It is really hard to say, but --

Mr. Bilirakis. Can you give me any specific examples?

Dr. Woodcock. Well, it might be 5 years, say, it could be 5 or 6 years --

Mr. Bilirakis. 5 or 6 years.

Dr. Woodcock. -- under review, yes.

Mr. Bilirakis. Thank you very much. Well, you know what, I will probably yield back, Mr. Chairman, because my next question is very long. Appreciate it. We will submit it for the record,

I appreciate it. I yield back.

Mr. Burgess. The chair thanks the gentleman and appreciates his consideration. The chair recognizes the gentleman from Oregon, Mr. Schrader, 5 minutes for questions, please.

Mr. Schrader. Thank you, Mr. Chairman, and I appreciate Dr. Woodcock being here, and thank you for FDA's attention on this and working with the committee. Nice to see a process in general working very well and everyone willing to make it work hopefully even better and I appreciate your participation.

Pretty impressive with the backlog being reduced 90 percent in a 5-year time span. Wish we could do that in a lot of other areas in government these days. But I am curious about, you know, the terminology acted on, you know, in terms of reducing that backlog. What percentage of, you know, that backlog constitutes new applications, maybe reapplications, people that didn't even have a good application to begin with, you know, that you couldn't even begin to make substantive comments on, do you have that breakdown for the committee?

Dr. Woodcock. Yes, it is a pretty substantial percentage. Keith, do you know the number? Okay, we can get back to you on that but there is a pretty substantial percentage of that, quote, backlog that couldn't be approved or tentatively approved the first time and required going back to the company and then resubmission.

Mr. Schrader. So most of it is just normal, you know, what you would call perhaps normal, didn't quite get it all right, please fill in the blank?

Dr. Woodcock. Correct. That is correct.

Mr. Schrader. All right. So what about just, have you given any thought -- you have done a lot of good work with preapplication processes and all that. How about just an education session, I mean, particularly for the small outfits that just don't have the team of lawyers or whatever to work through or read all these websites? They are just trying to do the Lord's work. Is there an opportunity for folks to tune in to an education session once or twice a year about here is what you need to do and here is some of the common problems we see?

Dr. Woodcock. Yes, and we do that routinely and a tremendous amount. And also we issue guidances on most new reference drugs that come out, the brand drugs, and so we will issue guidance well in advance on how to develop a generic for that.

Mr. Schrader. Well, I am not talking just guidance, I am talking about a real person, you know, sitting down.

Dr. Woodcock. Oh, we do. So we have webinars. We go to the technical meetings of the associations. We do gather up common deficiencies and we post lists of these and we are really trying. But we think it will take, we are seeing improvement. We are up to nine percent, right, of first-cycle approvals with

the new ones, but we think it will take time. We don't like cycles either because it increases our work. It slows time to access and it just clogs up the system. But we will, I agree, education is the key to get -- and also our refusal to file, we list all the reasons.

Mr. Schrader. So with all that again each of my colleague Congressman Bilirakis' point, if you are doing all this or there seems to be, I think, you know, a number of cycles that we should allow the reapplication for and then maybe cut it off.

I mean at some point, you know, if you are doing all the up-front work and everyone agrees you are doing the education, plus the guidance, plus the review, at some point so the backlog, you know, out of the 1,800 or whatever it is that are still in the backlog, you know, how many have been, it would be interesting for us to know how many have been through one cycle, two cycles, three cycles to get to the average or whatever, because there is some due diligence on a company's part, you know, to not waste your time or the taxpayers' dollars.

Dr. Woodcock. Yes. Well, we could certainly provide you with what statistics we had. As part of getting this whole program up and running we have put in a new IT system that tracks the process from soup to nuts so to speak. And we can get reports out of that and I am trying to get these reports by cohort, like the class of '13, the class of '14, the class of '15, what happened

to them, how many cycles.

Mr. Schrader. That would be really helpful.

Dr. Woodcock. Yes. So we are very interested in that too and we can provide you with what information we have on that.

Mr. Schrader. I guess then the last comment I make, Mr. Chairman, is that, you know, our bill, we are really trying to target those lifesaving medications. These are medications that aren't just a public health priority which you already prioritize, but these are, you know, immediate either acute or chronic health care lifesaving medications we are trying to accelerate to market.

And generally the ones we are talking about aren't very complex, you know, wouldn't take hopefully FDA's resources to an extreme, and many can be manufactured right here in the United States to decrease that global footprint you talk about that would really require a lot of time. And I think that is the rationale between our bill trying to make sure that that is the top priority because it is lifesaving and has to be done almost immediate.

And I appreciate your efforts on our behalf, and I yield back, Mr. Chairman.

Mr. Burgess. The gentleman yields back. The chair thanks the gentleman, and the chair recognizes the gentleman from Missouri, Mr. Long, 5 minutes for questions, please.

Mr. Long. Mr. Chairman, today we are discussing issues of competition and ways we can improve drug development to lower cost

in the private drug market. On that theme and before I forget, I would like to ask unanimous consent to enter into the record a letter from the FTC to CMS outlining ways in which we can best maintain a system of competition and transparency between providers and payers in this market.

Dr. Woodcock, to promote the goal of achieving first-cycle approvals and approvals on the earliest legally eligible date, the industry has placed a focus on increasing transparency and communication during the review process. Under the current agreement, how often and at what stages of the review and approval process does FDA communicate with the applicant?

Dr. Woodcock. Well, we usually don't communicate with a technical matter with the -- well, let me start again. There is a process called controlled correspondence. That was part of GDUFA I agreements and we had a backlog of that. Okay, we are totally caught up with that and we answer all these. These are inquiries from sponsors that are written that we can answer about their application and we send those back. And we get hundreds of those every year, so we are in written communication.

But right now we do not really have meetings and those type of communications with applicants prior to --

Mr. Long. So you are not getting any type of feedback or anything from the applicants?

Dr. Woodcock. Not currently. That is not how the process

was set up.

Mr. Long. Okay.

Dr. Woodcock. However, the proposed GDUFA II for the complex generics will set up more processes that we can talk to the applicants beforehand. For the more simple generics, which are many of them, the guidance that we put out before they start making their product should provide all the information they need on submitting an application and what they need to do. It is basically a cookbook.

Mr. Long. Okay. With that I yield back, Mr. Chairman, thank you.

Mr. Burgess. The gentleman yields back. The chair thanks the gentleman. The chair recognizes the gentlelady from California, Ms. Eshoo, 5 minutes for questions, please.

Ms. Eshoo. Thank you, Mr. Chairman. And Dr. Woodcock, it is nice to see you again. Even though he left awhile ago, I want to publicly acknowledge the kind and generous remarks of Congressman Joe Barton relative to the biosimilars legislation that became part of the ACA. It was a big vote in the full committee here, 47 to 11. It was Senator Kennedy's legislation in the Senate and his Republican sponsor was Senator Orrin Hatch.

So when I hear the steps being taken to fulfill what we set out to do, it was to bring biosimilars forward essentially in the form to create a generic biosimilar. And so that was awhile ago.

We passed the ACA several years ago, so this didn't -- the implementation is slow but each step is very important.

Dr. Woodcock, I read your, all 24 pages of your written statement last evening, and I think that what I drew from it is the following that progress is being made on several fronts. I think that when we talk about hiring freezes and words that are very familiar around the Congress, they start losing their meaning. They start losing their meaning, because if in fact, which you have the agreements that you have entered into with industry partners on user fees for both of these reauthorizations, if you don't have the staff, forget the timing of these applications or the timeliness of when these applications can really get to market.

So I don't know if, well, I hope that there will be advocates from the majority that will point this out to the administration, because I think every question and comment today with the exception of what Mr. Pallone said in the beginning about will there-won't there be a hearing next week, or a markup next week, they have all been tied to timeliness. And so I just want to underscore that.

I also want to add something else to this, and that is that these user fees are private sector dollars. And all of this business with sequester, I did legislation on it so that the FDA would be able to have access to those dollars and it made it all

the way up to the conference committee and someone pulled it out.

But I still think that it is a very important, it is something that is very important to appreciate. And so those private sector dollars should not be treated the way the public sector dollars are treated, and I think FDA is more than entitled to use those dollars as a result of the user fees in order to accomplish all the things that you wrote about in your 24-page written statement.

I want to turn to something that I have been pursuing, well, now it is more than a couple of years. We all know that the FDA plays a critical role in protecting the health of all Americans, but all the members of this committee may not be aware that there is an FDA's Office of Women's Health. And it was established by an act of Congress in 1994, and I think it demonstrates the impact, the importance that the FDA and Congress placed on ensuring that the FDA adequately considers the impact of its decisions on women, which leads me to sodium oxybate.

This is an important drug but it is also a dangerous drug. It is also a dangerous drug if it gets into the wrong hands. We know that -- well, I think that we all feel that we read too many stories today about sexual violence against women and there are, it is just the list goes on and on. But what I want to pursue with you -- and I have a stack of letters. I mean it is like we are pen pals. I am not satisfied on the following front and that is that as the drug moves to a generic version that the word safety

with a big red stamp can honestly be placed on the generic. And you know that I have had misgivings about it.

What I would like to ask you today, because there is not a lot of time -- I have a minute and, oh, I think I have gone over -- is to ask you to make a commitment today to me to meet with me and the women advocates that care so much about this. Would you be willing to do that?

Dr. Woodcock. I am happy to do that.

Ms. Eshoo. All right, that would be great.

Thank you, Mr. Chairman, for your indulgence.

Mr. Burgess. The gentlelady yields back. The chair thanks the gentlelady and recognizes the gentleman from North Carolina, Mr. Butterfield, 5 minutes for questions, please.

Mr. Butterfield. Thank you very much, Chairman Burgess. Thank you for holding this very important hearing today. These agreements that we are talking about, Mr. Chairman, are so important to improving public health and they represent good faith negotiations between the prior administration and industry. They show the way that the FDA should work and it is my hope that the current administration does not stand in the way of progress.

The advances in biologics and generics have been quite significant and generics have saved our healthcare system nearly $1.5 trillion over the last 10 years. Biologics have helped develop treatments for serious diseases like rheumatoid

arthritis. It is important that we continue to build on this progress by supporting the FDA's agreement with industry.

However, it is highly concerning that this administration seems to not understand the challenges facing FDA in ensuring safety while working with industry to approve treatments. The administration believes that the process at the FDA is, quote, slow and burdensome, end of quote, despite a record year of generic drug approvals or tentative approvals in 2016. It is critical therefore that the administration respect these agreements and ensure that the FDA has all of the resources that it needs to review these important treatments.

If the administration truly wants FDA to protect public health and fulfill its mission, it should not implement a hiring freeze that could prevent the replacement of key personnel. Now is the time to staff up at the FDA and other agencies as well whose mission it is to work for the betterment of public health. It should also follow through on Congress' promise to provide additional resources to the FDA as this committee did through the 21st Century Cures Act. Lastly, the administration should nominate an FDA administrator committed to the agreements reached with industry and not someone who wants to simply accelerate drug approval without concern for safety and efficacy.

Dr. Woodcock, thank you for your testimony. Thank you for the FDA's efforts to reach these agreements with industry, and

I appreciate your explanation of how additional resources were important in implementing the first act. Do you agree or disagree that the additional 1,000 new employees hired during the first agreement helped increase the FDA's responsiveness to these applications?

Dr. Woodcock. Absolutely, they were essential. And that is part of, first, our agreement and then our track record that we have succeeded with this program.

Mr. Butterfield. At the end of January, Democratic leaders on this committee sent a letter to the administration asking for clarification about the January 23rd executive order implementing the freeze. In that letter they asked whether federal hiring for programs supported by user fees at the FDA would be subject to the freeze or if those programs might be eligible for an exemption from the executive order. I am concerned that this executive order could in fact make it more difficult to implement these agreements and respond to the applications.

Can you please describe the potential impact of the executive order on the generic and biosimilar user fee agreements?

Dr. Woodcock. Well, as I said earlier, we are working with the administration and we hope we can move forward on all these programs. But we are working closely with the administration now.

Mr. Butterfield. All right. Well, I wish you the best of

luck on that. Dr. Woodcock, you described significant challenges in hiring staff who can address the complexity of biologics. How can the additional hiring authority in the 21st Century Cures Act help with that? Does the executive order compromise any of those hiring authorities?

Dr. Woodcock. Well, I want to thank the committee for their work on 21st Century Cures. I think it is a good step forward. We are working on planning the implementation of the various provisions within 21st Century Cures and we hope to continue to move ahead on that.

Mr. Butterfield. All right. All right, like Mr. Bilirakis said a few minutes ago, my last question would consume the time and so I am going to yield back. All right, thank you, Mr. Chairman.

Mr. Burgess. The chair thanks the gentleman. The chair recognizes the gentleman from Oklahoma, Mr. Markwayne Mullin, 5 minutes for your questions, please.

Mr. Mullin. Thank you, Mr. Chairman. And Dr. Woodcock, thank you so much for being here. I know you are doing the best you can underneath the circumstances and I really appreciate your focus on industry. I mean that is where it starts.

A big focus I have is obviously watching over small businesses too, and one of the concerns I have, or the primary concerns, really, I have is over the GDUFA -- am I pronouncing

that right, by the way? These acronyms we have up here sometimes might be easier to explain them rather than to say them -- was it didn't provide any relief for small businesses. Do we believe on the second GDUFA it is being addressed?

Dr. Woodcock. It is being addressed in two ways. One, for the first filing people will not have to pay fees if they are not on the market for their manufacturing facility. Those were the people who were the hardest hit, those who hadn't a contract for manufacturing. And then the fees are going to be tiered. There is a different fee depending on the volume in the various company programs, so there is various tiers.

So we were very conscious of the small business and also the different size of the businesses. And we tried to craft with industry the fee structure in a way it would be fair to everyone.

Mr. Mullin. Thank you. And another concern we have been hearing is the inconsistency on the FDA inspections. Some businesses we have heard have been put on hold. Are we addressing that?

Dr. Woodcock. The FDA is going through a huge reorganization of our field force, which is not the Center for Drugs, it is the Office of Regulatory Affairs which houses all our inspectors or our field inspectors, and they expect in May to go into a reorganization at which time they will have a pharmaceutical inspectorate. In other words, a group of

individuals who will solely inspect drug manufacturing facilities instead of, you know, inspecting foods maybe and the devices and so forth.

And so we hope to have a very close relationship with them. We have worked out a new process by which these facility evaluations will be done between us and we hope that one of the big payoffs is going to be a great deal more consistency in how we approach these facilities.

Mr. Mullin. With these field inspectors do they have SOPs, standard operating procedures?

Dr. Woodcock. They do. They have compliance policy guides they call them which guide how you do an inspection and so forth, but we are also working on what we call the new inspection protocol which will be much more of a checklist type of thing. We are piloting that now.

Mr. Mullin. One of the most frustrating things and the reason why I am really focused on this, especially with those businesses that have been put on clinical holds, as a small business owner myself it is imperative that I deliver the same product over and over and over again. And I am in the service industry and we have, you know, well over 150 individuals that work with us and we are constantly trying to improve our operating procedures.

But when you have people that had the authority that the

inspectors do and they are inconsistent in delivering that, just standard operating procedures seems like that that would clarify so much that we have in bringing clarity to and surety to those that they are going in and inspecting. And I get, you know, that you have a new field staff, but surely there is ways that we can help, we can work together with bringing consistency to the industry, because the last thing we need is inconsistency on something that is so important with the Food and Drug Administration.

Dr. Woodcock. Well, I agree with you. And actually yesterday marked a landmark where we signed a mutual reliance agreement with Europe over working to rely upon their inspections in Europe and they would rely on ours in the U.S. And to do this internationally, which will really help on speed that we have been talking about today and help leverage other inspectorates, we need to move toward common procedures so that --

Mr. Mullin. Agreed.

Dr. Woodcock. -- we can understand what each other has done and feel comfortable relying on it. So we are working in that international area too. But I completely agree with you, and we are actually working on, underneath our concept of operations we have put forward for the new structure we are working on SOPs. That is the next step.

Mr. Mullin. Thank you. And if I can be of any assistance

to you in it, please let me know.

Mr. Chairman, I yield back.

Mr. Burgess. The gentleman yields back. The chair thanks the gentleman and the chair recognizes the gentleman from Georgia for 5 minutes for questions, please.

Mr. Carter. Thank you, Mr. Chairman. Dr. Woodcock, good to see you. Thank you for being here. We appreciate your participation in this. As I understand it, the generic drug user fee act was designed to speed up access and that you were going to get help from the companies, from the manufacturers, the generic manufacturers in order to speed up that process and it was somewhat of a trade-off. And I think the original idea was good and certainly to a certain extent it has worked.

But let me ask you, of the 6,000 outstanding abbreviated new drug applications what percentage of those would you say have begun the process of being reviewed by the FDA?

Dr. Woodcock. All.

Mr. Carter. All of them have begun?

Dr. Woodcock. Right. Well, first of all, I am not sure where the 6,000 comes from. There was 2,800 and some right before the program started and then we have gotten a certain number each year, up to a thousand each year since the program started. But meanwhile we are approving some, you know, all during that period as well.

Mr. Carter. Okay. What can we do to help you? What can Congress do? Tell me what we can do in --

Dr. Woodcock. You can probably pass GDUFA II, okay.

Mr. Carter. Okay.

Dr. Woodcock. Because what you are maybe hearing, all right, is that the old applications, the ones that were sitting there well before this program started, when they come out they are going to be 5 years old because they were sitting around all that time.

Mr. Carter. Sure.

Dr. Woodcock. But the ones, say, next October, if you pass this legislation or something near it, the agreement is in 10 months, you send in a good application, in 10 months you are on the market. And we hope as many as possible will get that first-cycle approval, either tentative approval or full approval, depending on the patent status so that they are off our plate, okay, they are done. And we hope to continuously improve that over the next 5 years so that by the end of that time most of the applications would go through and be out on the market.

Mr. Carter. Okay. I trust you and I hope you are right and I hope that is the scenario that plays out.

Hang with me for just a second. As you know, I am the only pharmacist currently serving in Congress and I am under a lot of pressure trying to answer what is going on with prescription drug

pricing, why are these drugs going up? We have had instances over the past 2 years that I have been a member of this August body where we have had bad actors in the marketplace, where we had Turing Pharmaceuticals, where we had Valeant, where we had Mylan.

And now we have, just recently we had this drug come out, deflazacort, that is going to be marketed as Emflaza by Marathon Pharmaceuticals. Interestingly enough, I just recently found out that that CEO was also involved in the Valeant case. So, you know, this is not something new with him.

My question is this. I have had compounding pharmacies come into my office and tell me we could have helped in that situation particularly with the situation with the Daraprim in Turing, that they could have marketed that but they needed FDA to give them that authority to do that and they couldn't get it. FDA can help us in these situations where these rogue companies, if you will, have us by the short hairs and we cannot do anything about it. We have the ability out there.

And I know the safety part of it is extremely important. I respect that and I am very sensitive to it, but at the same time, I think it is irresponsible of us -- and I say us being government and the FDA. I put us in the same bucket there. I think it is irresponsible of us not to at least attempt to do something about that.

Dr. Woodcock. Well, we are happy to work with Congress.

There is a range of options that people brought up and we are willing to work with Congress.

Mr. Carter. Okay. Well, see, that is what I am telling you. That is what the people coming in my office are telling me is that they had an alternative to the Daraprim, but they couldn't get it approved through you to get it marketed.

Dr. Woodcock. Well, yes, we don't approve compounded drugs. That is mainly under state as you know, but there are a number issues probably too complicated for a 5-minute conversation.

Mr. Carter. Exactly.

Dr. Woodcock. But we are certainly, the issue sole-source or only a few source drugs where then they are vulnerable to market, you can rise up the prices easily --

Mr. Carter. Exactly.

Dr. Woodcock. -- is a problem that many people are trying to address. As I said there are 182 drugs that we know of that are off-patent and have no generic competition right now.

Mr. Carter. And let me, we need to address that because that is not the way the system was set up and that is not the way the free market ought to be working. Those drugs ought to have generics as soon as they come -- what is causing that, do you know?

Dr. Woodcock. We believe that there are market forces. It is not attractive enough to be a competitor. It is a small market or has some other characteristics where the generics are not

interested. I mean, this has been going on for years, so the people had plenty of opportunity to submit generic applications but they haven't.

Mr. Carter. And that seems to be what we are headed toward that what the Emflaza is doing, I mean, this is for Duchenne muscular dystrophy. I mean, you know, they have a limited market that they are catering to and we need to make sure those patients, and they need it now. They can't wait.

Dr. Woodcock. Well, that drug is newly approved in the United States so it is protected by various exclusivities.

Mr. Carter. But that drug has been being used in Europe for years.

Dr. Woodcock. I know.

Mr. Carter. And it is just much, much less than what they are going to be charging for it in America. Now that is outrageous. I don't like the federal government being involved in anything, but we need to step in there. That is wrong.

Dr. Woodcock. So that is the situation. So there are some brand drugs that have pricing issues in people's minds and then there are generic drugs or brand drugs that actually could have generic competition that don't have them.

Mr. Carter. You know, I can accept it to a certain extent if it is innovative, but that is not innovation. That is just bringing something over here and playing the market.

Dr. Woodcock. Sure.

Mr. Carter. Mr. Chairman, I apologize. I know I went over my time and I yield back.

Mr. Burgess. The gentleman yields back. The chair thanks the gentleman.

Dr. Woodcock. Mr. Chairman.

Mr. Burgess. Yes.

Dr. Woodcock. I misspoke earlier in my oral. Could I just give you a very brief correction?

Mr. Burgess. Great, sure.

Dr. Woodcock. Thank you. I said we have approved 56 first generics. What I meant is in the backlog cohort only there were 56 that we have approved, all right. We have approved 405 first generics overall during GDUFA I. So it is in my testimony but I just wanted to correct the record here. Thank you.

Mr. Burgess. Very well, and we appreciate you being here with us, Dr. Woodcock. We are not going to recess, but immediately transition into our second panel of witnesses who we thank for being here today and taking the time to testify before the subcommittee. Again Dr. Woodcock, thank you for your testimony. As a reminder, each witness will have the opportunity to give an opening statement followed by questions from members.

So the committee will come back to order. Again I want to thank our second panel of witnesses for being with us today and

appreciate their indulgence.

Our second panel of witnesses today includes Mr. Allan Coukell, senior director of the Health Programs at Pew Charitable Trusts; Mr. David Gaugh, senior vice president of Science and Regulatory Affairs, Association for Accessible Medicines; Mr. Bruce Leicher, senior vice president and general counsel of Momenta Pharmaceuticals and chair of the Biosimilars Council for the division of the Association of Accessible Medicines; Ms. Juliana Reed, vice president of Government Affairs, Coherus Biosciences, and immediate past president of the Biosimilars Forum; and Ms. Kay Holcombe, senior vice president of Science Policy, Biotechnology Innovation Organization. We appreciate all of you being with us today. We will begin our panel with you, Mr. Coukell, and you are now recognized for 5 minutes for an opening statement. Thank you.

STATEMENTS OF ALLAN COUKELL, SENIOR DIRECTOR OF HEALTH PROGRAMS, THE PEW CHARITABLE TRUSTS; DAVID R. GAUGH, R.PH., SENIOR VICE PRESIDENT FOR SCIENCES AND REGULATORY AFFAIRS, ASSOCIATION FOR ACCESSIBLE MEDICINES; JULIANA REED, VICE PRESIDENT OF GOVERNMENT AFFAIRS, COHERUS BIOSCIENCES, IMMEDIATE PAST PRESIDENT OF THE BIOSIMILARS FORUM; BRUCE A. LEICHER, SENIOR VICE PRESIDENT AND GENERAL COUNSEL, MOMENTA PHARMACEUTICALS AND CHAIR OF BIOSIMILARS COUNCIL, ASSOCIATION FOR ACCESSIBLE MEDICINES; AND, KAY HOLCOMBE, SENIOR VICE PRESIDENT, SCIENCE POLICY, BIOTECHNOLOGY INNOVATION ORGANIZATION

STATEMENT OF ALLAN COUKELL

Mr. Coukell. Thank you, Mr. Chairman, Ranking Member Green, and members of the subcommittee. I appreciate the opportunity to present testimony. Pew is a nonprofit, nonpartisan research and policy organization with programs that touch on many areas of American life. I was asked today to focus on the challenge of rising pharmaceutical costs within the user fee context and beyond it.

As you know, drug spending in the United States topped $300 billion in 2015. That is up nine percent just in that year alone. That is faster growth than the rest of health care and it is a trend that strains budgets and helps drive up insurance premiums and the cost of Medicare and other taxpayer-funded programs. It

also hits consumers in the pocketbook, and three-quarters of Americans say that prices are unreasonable.

The evidence suggests this is not a short-term fluctuation but a long-term trend, a trend that is driven largely by the rising cost of new medicines especially high cost specialty drugs that are used by only one or two percent of the population but account for about a third of drug spending. Some of these products are exciting therapeutic advances, true breakthroughs, some are not, but they are reaching market at ever higher launch prices, and year-on-year increases in price after launch are another major contributor to rising drug spending. A number of generic drugs have also undergone steep price hikes, but in general generic prices as a category remain flat or falling.

So what can be done in response? Well, changes to FDA's approval process may offer some potential to address drug spending, many key opportunities lie elsewhere. Generic competition has long been the main tool to manage drug prices in the United States, and the first GDUFA agreement has helped to reduce the backlog of pending applications.

Other potential areas for efficiency include policies to ensure that generic companies have access to brand name products for bioequivalence testing, policies to limit so-called pay-for-delay settlements that in some cases cause anticompetitive delays in market entry. The Lower Drug Costs

Through Competition Act would award a generic priority review voucher to manufacturers who bring drugs to market in cases of limited competition or a drug shortage and would establish a 6-month timeline for FDA review of priority applications compared with the 8-month priority review goal in GDUFA II.

It is important to note that FDA does already prioritize generic applications when there is only one competing product, so the net benefits and practical feasibility of a 6-month review are a little bit unclear. Perhaps more important than shortening the duration of review is reducing the number of review cycles. And I commend the FDA and the industry for their shared commitment in GDUFA II to improving first-cycle success rates.

When focusing on measures to increase competition, we should note that the biologic drugs which are a big driver of increased spending won't be affected by changes in the generic approval process. However, anything that hastens biosimilar development including better aligning the exclusivity for biologics and small molecules would help to reduce spending. There are also potential ways to increase competition among drugs that are already on the market. There are well established tools in the commercial insurance market, tools like formulary placement and prior authorization that are absent or limited in parts of the Medicare program and consideration could be given to policies that would increase competition within Medicare Part D and Part B and

potentially shift some drugs from one program to the other. More broadly, factoring value into coverage decisions including the choice not to cover a drug whose cost isn't justified will help reduce overpayment for marginal clinical gains, and Congress could take steps to help advance this alignment.

Finally, there are opportunities to improve transparency in purchasing. Pharmacy benefits managers negotiate deep discounts from drug companies on behalf of their employer and insurance clients, but these contracts can be extremely complex making it difficult for even the sophisticated clients to determine whether they have achieved an optimal share of savings. Congress could consider requiring greater transparency of contract terminology and definitions between payers and PBMs as well as mandating the ability to audit these arrangements.

The balance between access to innovative medicines and constraining cost growth is a long-term challenge with no single solution. In striking the right balance, Congress should look both within and beyond the user fee agreements. I thank you for holding this hearing and welcome your questions.

[The prepared statement of Allan Coukell follows:]

**********INSERT 10**********

Mr. Burgess. The gentleman yields back. The chair thanks the gentleman. At this point the chair would like to recognize the chairman of the full committee.

The Chairman. I thank the subcommittee chairman. I appreciate the indulgence of the committee and our witnesses. We need to deal with a slightly different matter that involves us all and I just want to clarify, because I know there have been questions that have been raised.

Reports that the Energy and Commerce Committee is doing anything other than a regular process of keeping its members up to speed on the latest developments in its jurisdiction are false. We are continuing to work on drafting and refining legislative language to provide relief from a failing law, and by that I mean Obamacare. Part of that process is giving committee members and staff the opportunity to work closely together to draft a bill that reflects the concerns of our constituents and reflects our mandate from voters to repeal and replace Obamacare. Simply put, Energy and Commerce majority members and staff are continuing to discuss and refine draft legislative language on issues under our committee's jurisdiction.

And with that I yield back to the chairman.

Mr. Burgess. The chair thanks the gentleman.

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

STATEMENT OF DAVID R. GAUGH, R.PH.

Mr. Gaugh. Thank you, Chairman Burgess, Ranking Member Green, and members of the Subcommittee on Health. And first, let me thank you for asking me to participate in this very important and timely hearing. I am David Gaugh, senior vice president for Sciences and Regulatory Affairs at the Association for Accessible Medicines, AAM, formerly GPHA, and I am a licensed pharmacist.

AAM represents key stakeholders to the generic industry and generics represent 89 percent of all prescriptions dispensed in the U.S., but only 27 percent of the expenditures on prescription drugs. As such, generic drugs play an ever-important role in bringing down artificially high prices of drugs, thereby keeping medicines within the reach of the American public.

I would like to begin today by commending the committee for your continued focus on these important issues as we examine them here today. The generic industry's remarkable growth plays a vital role in the lives of Americans every day. This growth in the generic industry has also served to underscore the critically important role of the FDA and, as I will highlight, the level of cooperation between industry and the FDA has never been greater. However, the agency remains underfunded and the responsibility of ensuring access to safe, effective, and affordable medicines is a shared one and that is why the generic industry has agreed

to provide FDA with additional resources to address these ongoing challenges.

I am here to discuss AAM's conviction that the best way of achieving the goal of providing patients access to generic alternatives is through the development of policies that promote robust, competitive markets. Generic manufacturers make complex analyses when selecting which products to pursue. This analysis can include assessing the complexity in reverse engineering, the state of intellectual property of the product, the size of the market, the likely number of competitors, the product development and manufacturing capabilities, and all cost associated. Because of these complexities, AAM believes that the best way to control drug costs generally is through the policies that incentivize competition, and GDUFA II does just that.

The priority of the generic industry in GDUFA II was to achieve a more effective and transparent generic review program. We believe that accomplishing this will improve the rate of first-cycle approvals on the earliest legally eligible date through greater transparency and communications between the agency and the industry. Thus, both FDA and the generic industry benefit by sharing knowledge and experiences throughout the review process. Our goal is not merely a faster review timeline, but a more effective review process. The fewer review cycles required to get to approval, the sooner patients and payers can

experience the benefits of generic competition. We strongly believe that GDUFA II is well positioned to achieve this goal.

A few of the key areas to focus on: Application Metrics. So the FDA will act on 90 percent of all ANDAs within 10 months for standard application and all those indicated as priority within 8 months and this includes the inspection component of the review process. Bridging, or we called it no ANDA left behind -- prior to the completion of GDUFA I, all applications and supplements that did not have an official GDUFA I goal date and were subsequently given target action dates will be assigned a GDUFA II goal date on or near October 1 of 2017.

Complex products -- GDUFA II creates a pre-ANDA submission communication pathway for complex products. This early engagement between industry and the FDA will significantly contribute to the applicant's ability to improve the overall submission quality of ANDA's which in turn will contribute to first-cycle approvals.

Transparency and communications -- this agreement includes transparency and communications between FDA and the ANDA applicant through the liberal use of information requests, division review letters, and the complete response letter. These enhancement are intended to decrease the number of review cycles and move them for first-cycle approval.

Reporting and accountability is also included with several

new performance and financial reporting requirements to enhance transparency and efficiently maintain them. These new reporting requirements will allow Congress, industry, and FDA to better assess FDA's resource management, planning, and processes.

Small business consideration -- the proposal supports small businesses by exempting them from a facility fee until the first ANDA is approved in that facility, and the proposal also provides for the tiering of the annual ANDA program fee based on small, medium, and large companies and this tiering is based on the number of approved ANDAs those companies hold.

In conclusion, Mr. Chairman, the GDUFA II user fee proposal is culmination of months of negotiations between FDA and industry, and the final product as transmitted to Congress represents a careful balance among all stakeholders involved. We respectfully urge the committee to approve GDUFA II as negotiated and agreed to by the FDA and industry without changes to this agreement. Thank you.

[The prepared statement of David R. Gaugh, R.Ph. follows:]

**********INSERT 11**********

Mr. Burgess. The gentleman yields back. The chair thanks the gentleman. Ms. Reed, you are recognized for 5 minutes for an opening statement, please.

STATEMENT OF JULIANA REED

Ms. Reed. Thank you, Mr. Chairman and members of the committee for the opportunity to be here today. I am Juliana Reed, vice president of Government Affairs for Coherus BioSciences and the immediate past president of the Biosimilars Forum. I was a member of the Forum's biosimilars user fee negotiating team last year.

The Biosimilars Forum appreciates the opportunity to testify today regarding its participation in the negotiations for the BsUFA program for fiscal years 2018 to 2022, or BsUFA II, and to provide our perspective on the reauthorization of the user fee legislation. We urge Congress to support the outcome of BsUFA II and to reauthorize the program prior to September 30th, 2017.

The Biosimilars Forum is a nonprofit trade association representing biosimilars manufacturers who are dedicated to the development of a new and sustainable biosimilars market in the U.S. with the goal of expanding access to these important medicines while lowering costs for patients and the overall U.S. healthcare system. The members of the Biosimilars Forum represent the majority of the U.S. biosimilars program and development at the FDA and are subject to the user fees we are discussing today.

The Biosimilars Forum is solely focused on biosimilars and

the associated policies necessary to foster a vibrant U.S. biosimilars market that delivers high quality, safe, and effective biosimilar medicines over the long term. This singular focus on biosimilars is important. It is a recognition that biosimilars are unique, they are not generic drugs, and they are not branded biologics.

Biosimilars are a new and distinctive industry sector, created by Congress via the Biologics Price Competition and Innovation Act, or BPCIA, and governed by new and individualized policies and regulations solely devoted to this sector of the biosimilar pharmaceutical industry. In fact, FDA's regulatory treatment of biosimilars reinforces the uniqueness of each product through the agency's approval pathway, naming policy, and pharmacovigilance efforts. This distinction is important to the members of the Forum and something on which we continuously work to educate our partners.

As we work together to build this new industry, we all need to look at biosimilars with a different lens that acknowledges this distinction. The Biosimilars Forum is proud to have participated in industry negotiations with the FDA regarding the reauthorization of BsUFA and greatly appreciates the cooperation of the agency and the other industry groups represented during the negotiations.

The Forum entered into BsUFA II negotiation process with four

primary goals: ensuring solid financial support for the program; improving communication between the FDA and biosimilars products sponsors; increasing transparency during the approval process and regarding the spending of user fees; and preventing the expenditure of BsUFA funds on extraneous policy issues or activities that are not exclusive to biosimilars.

Within BsUFA II there are significant enhancements to the biosimilar user fee program that support the review and approval of biosimilar medicines in the U.S. These agreed-to enhancements include a revised review process meant to increase the transparency and communication that will facilitate an increase in the likelihood of first-cycle approval; agency commitments to complete and publish several draft and final guidance documents that will provide industry with additional clarity and certainty regarding the biosimilar development and review process; agency commitments to augment and strengthen staffing of the biosimilars program including hiring product reviewers; and enhancements to the user fee structure and management that will allow greater transparency, predictability, and long-term stability of the program in the U.S. Again, we encourage Congress to support the BsUFA reauthorization and provide the FDA with the necessary resources it needs to continue to build its program.

Mr. Chairman, reauthorization of the BsUFA is key to successful implementation of the BPCIA. But I would be remiss

if I didn't also mention that it is critical for all federal agencies to be consistent in their treatment and support of biosimilars and to recognize that this new industry has additional needs in order to further ensure that biosimilars will increase access and lower costs for patients who need these medicines.

As noted, FDA has a responsibility for making clinical distinctions among products and the agency's policies support the notion that each biosimilar is unique. Unfortunately, CMS did not share this view. Congress should require CMS to review its current reimbursement policy for biosimilars and make it consistent with FDA biosimilar policies. Specifically, FDA policy on biosimilars acknowledges the unique nature of each biosimilar and CMS should align its policy by assigning unique, individualized billing codes to each biosimilar.

FDA guidance to industry makes it clear that each biosimilar is approved in a distinct fashion with variances in approved clinical indications and interchangeability, if possible. FDA's guidance for industry on nonproprietary naming of biologic products further distinguishes individual biosimilars and brand biologics by setting out a naming system whereby different suffixes will be assigned to the name of the biosimilar and its reference products. CMS policy should likewise recognize this distinction for payment and reimbursement purposes.

In addition, as the Biosimilars Forum works closely with

patients and the providers who will prescribe biosimilars it is critical that they understand the science behind biosimilars and the FDA's rigorous review process so they have confidence when using and prescribing them. We call on all stakeholders including Congress to support collaboration and education efforts to advance biosimilars.

Thank you for the opportunity to be here. I apologize I went over my time, and I am happy to answer any questions.

[The prepared statement of Juliana Reed follows:]

**********INSERT 12**********

Mr. Burgess. The chair thanks the gentlelady.

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

STATEMENT OF BRUCE A. LEICHER

Mr. Leicher. Good morning, Chairman Burgess, Ranking Member Green, and members of the Subcommittee on Health. Thank you for the opportunity to participate in this important hearing. I am Bruce Leicher, senior vice president and general counsel of Momenta Pharmaceuticals and the chair of the Biosimilars Council Board. I had the opportunity to participate in the BsUFA I as well as the BsUFA II negotiations in those capacities.

The Biosimilars Council is a division of Association for Accessible Medicines. It works to ensure a positive regulatory and policy environment for biosimilar products and educates the public and patients about the safety and effectiveness of biosimilars. We are deeply committed to accessible, affordable, and high quality medicine, and we strongly support the BsUFA III package.

I would like to start with a personal story as someone who has worked in the biotechnology industry for over 25 years and in the biosimilars industry since its inception. About 8 years ago I appeared before the House Judiciary Subcommittee on Courts and Competition Policy to support the BPCIA. Many of the witnesses testified about their fears of biosimilars, how biosimilars were more complicated than generics, and how we should be very careful about proceeding with biosimilars legislation.

I testified about how significant scientific innovation would address these concerns and make biosimilar competition possible. I emphasized that American ingenuity would make us global leaders by enacting legislation that did not put a ceiling on biosimilar innovation.

Congress listened and acted with courage. It passed the BPCIA. American innovation was unleashed. Many prior opponents of biosimilar competition entered the business and today we have a growing and thriving biosimilars industry creating good jobs and leading the world with our innovative science, particularly in the science of more fully understanding our biologic products.

Today, Dr. Woodcock reported that over 64 biosimilar programs were under review of development of 23 different biologic products. Momenta alone has seven biosimilar development programs. This was made possible by the BPCIA and by BsUFA I user fee funding. We learned in BsUFA I, however, that the innovation involved in biosimilar development, that is, the science of understanding what is in a biologic for comparison purposes, is complicated and involves many new skills that the industry and the FDA need to understand. This requires new staff and training to assure high quality and efficient review. Historic FDA staffing cannot meet these needs, reviews which depend far less on clinical data and far more on new, innovative scientific techniques that demonstrate that a biosimilar is highly similar

to the reference product and has no clinically meaningful differences.

In addition, even more innovation is underway to allow for approval of interchangeable biologics which can be shown to perform the same in any given patient, and, when approved, substituted at the pharmacy like generic drugs. This innovation is what makes biosimilars competitive, affordable, safe, and effective for patients, but these innovations squarely depend on having the critical additional FDA resources to be funded by BsUFA II.

Innovation was used to craft the BsUFA II commitment letter. We took a hard look at the first 5 years. Not only are new FDA resources needed, more efficient regulatory approaches that use funding more wisely are necessary to accelerate FDA review. Together we included innovations from BsUFA I and PDUFA to enhance the review process and to ensure regulatory clarity. The BsUFA II user fees are now tied to the level of resources needed and adjust with resource demand. It is also important to emphasize that the funding provided by user fees is in addition to, not a substitute for, congressional appropriations, and expenditure is contingent as in the past on an appropriate spending trigger.

Specific improvements include enhanced communication and meeting opportunities that eliminate unnecessary delays; using resource capacity planning to set budgets, staffing levels, and

fees; adopting the highly effective program review model to increase first-cycle application approvals; commitments to dedicate staffing and to issue regulatory guidance to promote best practices and predictability; and expanding biosimilar education activities. Each improvement accelerates high quality development and review to help assure that patients have more timely access to lifesaving, affordable, safe, and effective biosimilars.

So in conclusion, BsUFA II is the culmination of months of hard work and negotiations between the FDA and industry. It represents a careful balance among the stakeholders. We respectfully urge the committee to approve a clean draft of BsUFA II without changes to the underlying agreement. Timely passage is important to ensure patients have access to lifesaving biosimilar medications that they require. This historic agreement provides a critical step toward accomplishing this goal.

Thank you, and I would be happy to answer any questions.

[The prepared statement of Bruce A. Leicher follows:]

**********INSERT 13**********

Mr. Burgess. The chair thanks the gentleman. Ms. Holcombe, you are recognized 5 minutes for an opening statement, please.

STATEMENT OF KAY HOLCOMBE

Ms. Holcombe. Mr. Chairman, what an honor it is to speak with you today. In 1992, this committee planted the seed that has grown into user fee programs that provide FDA with a significant portion of the resources it needs to ensure that patients have timely access to safe and effective medicines. This committee also successfully produced with an overwhelming bipartisan House vote, the BPCIA, legislation that established an FDA pathway for the approval of biosimilars.

BIO was an early and strong supporter of this legislation to create a balanced pathway for greater competition in the biologics marketplace and of the user fees to make that work. BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. Our membership includes most of the large biopharmaceutical companies, but the vast majority of our members are small biotechnology companies working on the most cutting-edge R&D. BIO is proud of the innovative spirit and dedication of these small companies.

I want to focus my comments today principally on the reauthorization of the biosimilars user fee program. We believe the BsUFA reauthorization proposal you are considering meets all

of our overarching goals and supports and enhances the biosimilars user fee program. We strongly support timely reauthorization of BsUFA.

During the course of BsUFA I, FDA issued guidance documents to assist sponsors and other stakeholders to understand the agency's expectations and how this new process would work. They also issued final guidance on naming for biosimilar and innovative biological products to establish a way to provide clarity for prescribers and patients and to assist pharmacovigilance. In addition, FDA issued five guidance documents that remain in draft, including the most recent draft guidance on the agency's views on determining interchangeability.

BIO continues to urge that the agency finalize this draft guidance as quickly as possible as interchangeability is an important component of promoting the biosimilars marketplace. Because of both the complexity of the products and the novelty of this category of highly similar or interchangeable products, we recognize that these early years necessarily have been a time of learning and building. And although four new biosimilars products approved since enactment of BPCIA and initiation of BsUFA may seem like a small number, we are confident that the program and the availability of biosimilars to patients will grow as the agency builds expertise and capacity.

With this as background, BIO worked with FDA, other industry

organizations, and other stakeholders to develop proposals for continued progress and enhancements during BsUFA II. Some of the key commitments have already been mentioned here and I am not going to mention them again. The hope is that these new programs under BsUFA II will enhance the ability of sponsors and patients to work together to get biosimilars to the marketplace.

I want to mention in particular the BsUFA commitments that relate to financial enhancements of the program to provide sustainability for the BsUFA program and to provide commitments to hiring goals and moving forward with FDA's hiring of the skilled staff that it needs to do its job. BIO has longstanding views about the negative potential consequences of the sequester of user funds or hiring freezes that can result in FDA's inability to fill vacancies and make the new hires that are necessary for meeting its commitments under these user fee programs.

User fees support a significant number of FDA personnel including those needed to carry out the BsUFA commitments. If FDA is unable to make these hires, user fees cannot be spent. This is a situation that is unacceptable to fee payers and is not good for FDA or for the patients who are waiting for the approval of biosimilar therapies.

Finally, Mr. Chairman, I want to address very briefly your request to comment on the Lower Cost Drugs Through Competition Act. BIO supports competition in the prescription drug

marketplace. We believe a robust, competitive market exists today, but we also recognize that there can be more done to promote generic entry particularly where an older, off-patent drug has lost regulatory exclusivity yet lacks meaningful generic competition.

We all want to see FDA approve generic drugs as efficiently as possible. Competition and greater choice are good for patients, and whatever reasonable steps can be taken to help FDA enhance its generic drug processes should be considered seriously. On behalf of BIO, I want to thank you for the opportunity to present our views today, and I am happy to take any questions you may have.

[The prepared statement of Kay Holcombe follows:]

**********INSERT 14**********

Mr. Burgess. The chair thanks you. That concludes our witness testimony. We will move into the question portion of the hearing for our second panel. I recognize myself 5 minutes for questions.

Mr. Gaugh, if I could start and ask you, you were here, I think, when Dr. Woodcock gave her testimony. And I think, if I understood her correctly, she said that there is no backlog in the approval of generic drugs, and I would just ask you if you agree with that statement.

Mr. Gaugh. So there is a bit of a discrepancy between the industry and the FDA on that statement, whether or not there is a backlog, but it doesn't really matter what word you use. I do agree with Dr. Woodcock that all applications are currently under review. But if you look back at the original statutory backlog of GDUFA I, there were 2,866 products in that category. There are now 1,500 in that category that are still not approved. So they are going back and forth under active review between the FDA and industry, but those are still sitting there so they have been there for 4 years or longer. Add in year 1 and year 2 applications and there is another 2,000, roughly, and those have been under review for at least 2 years.

Mr. Burgess. Mr. Gaugh, staying with you, I guess the question is has the FDA met all of its goals under the first generic drug user fee agreement?

Mr. Gaugh. Yes, they have.

Mr. Burgess. But then we continue to hear significant concern about review times and the number of cycles it takes to approve applications, the lack of communication between review division staff and applicants, so are you confident that the new agreements will address those concerns?

Mr. Gaugh. Yes. So in the first agreement, in GDUFA I, there were no solid metrics -- I will use that phraseology -- for the pre-GDUFA and years 1 and years 2. In years 3, 4, and 5 there were solid metrics. So we have seen some significant advances in those years and that is why we are asking the FDA to divide out the metrics, or the report-out metrics if you would that they are giving us, in cohort years, so we can know how things are happening per year. When we look at a first-cycle review of only nine percent that is looking over the entire cohort. We would like to see what that looks like per cohort.

Mr. Burgess. I guess what I would like to get from you is a sense as what the FDA can do to substantially improve the review process and what steps can industry then take to improve the quality of submissions on a more consistent basis?

Mr. Gaugh. So the steps we have taken in GDUFA II are a couple. One, Dr. Woodcock talked about the complex products, and so we have preapplication meetings that help us understand that. That happens with every one of the products under the ANDA, understanding there is only about 150 to 175 products there, but

they have that opportunity to have those conversations before the application is even submitted, so both industry and the FDA knows what is coming in the door. Under GDUFA II we have done that in the complex products and so we think that will take large steps in getting to that first-cycle review for complex. It doesn't fall for the noncomplex products. But remember, there is over a thousand applications that are entered into the FDA every year for review and approval. That would be a huge resource drain to try to have those pre-meetings. We are working in that direction, but again this is GDUFA II, not GDUFA VI.

Mr. Burgess. And thank you. I thank you for your responses.

Ms. Holcombe, if I could ask you, I mean, you referenced in your testimony the learning and building that has been going on during the Biosimilar User Fee Agreement course. If I understand correctly there have been four approvals with biosimilars; is that accurate?

Ms. Holcombe. Yes, that is accurate.

Mr. Burgess. It seems like a low number.

Ms. Holcombe. It does.

Mr. Burgess. So would you care to expound upon that?

Ms. Holcombe. We have hope.

Mr. Burgess. We all have hope.

Ms. Holcombe. I know hope is not a strategy.

Mr. Burgess. This is a very hopeful subcommittee.

Ms. Holcombe. As Dr. Woodcock mentioned, FDA is working with sponsors, biosimilar sponsors, now through the course of the biosimilar product development meetings on 64 development programs to 23 reference biological products. So we can't obviously predict that all 64 of these are going to turn out to have marketed products, but certainly some high percentage of them will. So we could move over the next few years, certainly over the next 5 years, from four products to 56, let's say, or even 46, which would be terrific.

Mr. Burgess. Agreed. That would be terrific.

I yield back my time and recognize Mr. Green for 5 minutes for questions, please.

Mr. Green. Thank you, Mr. Chairman.

And Mr. Leicher, in the first panel Dr. Woodcock discussed the increasing number of meeting requests that the agency received from sponsors. You mentioned in your testimony that one of the improvements under BsUFA II is enhanced communication and meeting opportunities that are hopefully help to eliminating delays in development and review of biosimilars.

My first question, what improvements to these meetings with sponsors would be made under BsUFA II and why are these improvements helpful from your perspective?

Mr. Leicher. So yes, there are several improvements that

have been made. One was a discussion that we had with the agency about including specific reference to biosimilars in the preapplication IND best practice guidance document as well as in the meeting guidance documents which provide for specific responses, commitments to time frames for responses, and that can really enhance sort of correcting things in advance before an application is filed.

The other piece is the adoption of the program review model which was developed in PDUFA, so that when an application is filed there are specific goals set within the agency for timelines. There is a preapplication meeting with the sponsor to work out complicated issues and make sure that what is filed is approvable. And there is a series of communications and responses to the applicants so that you can actually strive for a first-cycle review the first time and do it right the first time.

Mr. Green. BsUFA II also moves from a 10-month timeline for review to a 12-month. Can you explain why this change was made and how will this impact the biosimilars?

Mr. Leicher. The ultimate goal of the change was to get to first-cycle approvals. What we believe was learned in PDUFA was that additional time was important to enable the communication that I was just discussing to occur so that we can actually respond to information requests and to communications in that time frame and actually finish it the first time, rather than have it coming

back and then waiting another 6 months beyond the 10-month period.

Mr. Green. And our goal again is to move with the process to make sure they do their job but also move it quickly. Mr. Coukell, the FDA approval process ensures drugs are safe and effective. Some have proposed policies to address pricing that circumvents that process. Do you have a position on whether we should look for solutions to pricing concerns that go outside the FDA approval process?

Mr. Coukell. Thank you for that question. You know, Dr. Woodcock in her testimony talked about the FDA's process for going out to a manufacturing facility and being on the floor and really seeing what happens there, and then talked about looking at data on bioequivalence to make sure that the copy of the innovative product performs in exactly the same way. If we are getting drugs that haven't gone through that process we don't have those same guarantees.

Mr. Green. Thank you. This is a question for both of you and Mr. Gaugh. I think we all agree that generic drugs are saving money and making medicines more affordable to patients. In fact, the Association for Accessible Medicines estimates that the generics are saving American families over $4 billion a week. And while generics account for 89 percent of the prescriptions expenses in America, it is only 27 percent of the total drug cost. That is why I think it is important to do what we can to reduce

the barriers to the generic competition and lower the often burdensome cost of prescription drugs.

Mr. Schrader and Mr. Bilirakis have proposed one way to address this important issue, and I am interested to hear what else could be done to increase generic competition in the market. Mr. Gaugh, what other policy proposal do you believe should increase generic competition and access to generic drugs, and also to Mr. Coukell and Mr. Gaugh.

Mr. Gaugh. Thank you. Dr. Woodcock also spoke earlier today about the REMS situation that we have. And so I know that in that bill that Representative Bilirakis and Schrader put forward that was to have a study on REMS, but we don't need another study on REMS. We have been looking at REMS since I was at the GDUFA table in 2012 and working on solutions for that. And we have had solutions that have been presented even in the last 6 months that never quite make it into the bill.

So REMS is one of the main indicators that prevents generic products from coming to market because we can't get the product to be able to develop it and develop the generic of the innovator.

Mr. Green. Mr. Coukell, do you want to use my last 19 seconds?

Mr. Coukell. Well, you know, there aren't that many drugs with that type of REMS, but there are some big drugs in there. One of them in that category is the seventh-most costly drug in

the Medicare program. It is $2 billion a year. So making sure that there is a pathway to market for generic versions of those drugs and non-REMS drugs that have restricted distribution could be meaningful.

Mr. Green. Okay. Thank you, Mr. Chairman. I yield back.

Mr. Lance. [Presiding.] Thank you very much. The chair recognizes Dr. Carter of Georgia.

Mr. Carter. Thank you, Mr. Chairman, and thank all of you for being here. Mr. Coukell, Mr. Gaugh, I understand both of you are pharmacists; is that correct?

Mr. Coukell. Yes, sir.

Mr. Gaugh. Yes, sir.

Mr. Carter. Good, good. I want to talk about something. I want to talk about PBMs, pharmacy benefit managers, okay, one of my favorite topics. Mr. Coukell, you say in your written testimony here, pharmacy benefit managers, the middlemen, that insurers and employers pay to both administer prescription drug benefits and negotiate discounts from drug companies play a crucial role, using their large sales volumes and their ability to create formularies to force drug companies to offer deep price concessions. However, a share of the savings accrues to the pharmacy benefit managers themselves, and their contracts can be extremely complex, making it difficult even for sophisticated benefits administrators to determine whether they have achieved

optimal savings.

Let me ask you, when you have three companies that control almost 80 percent of the market, as we have here in this country where we have three PBMs that control 80 percent of the market, wouldn't you agree that that is not much competition there? If you look at the pharmacy benefit managers and you look at their profits over the years, you see that they have exploded, that they have profits that have increased over 600 percent. Obviously they are not doing what they were supposed to have done.

Now you go on to say that Congress could consider requiring greater transparency of contract terms and definitions between payers and pharmacy benefit managers. Such a bill has been introduced by Representative Doug Collins of Georgia, the MAC Transparency bill that will call for more sunlight to be shed, for more transparency in our drug pricing system. I would like to just get your comments on that if you would about how that could help us in bringing down drug prices.

Mr. Coukell. Thank you for that question. PBMs with their negotiating power play an important role in bringing down drug prices, and then the important question is, is the ultimate payer, the self-insured employer or the insurance plan, getting adequate benefit? And of course the PBMs have to make some money in that deal too. That is their business model.

In my testimony in calling for transparency that was not

calling for public transparency on the price, but because these contracts are so complex and they have so many fees, the question is are there standards around contract definitions as well as audit mechanisms and standards around lack of conflict of interest in the people who advise on PBM contracts that could be beneficial to the ultimate payer.

Mr. Carter. And listen, I don't have any trouble with anybody making money, you know, more power to them, and that is not what I am getting at. But what I am getting at is that this is a shell game. They are ripping off the public, I am telling you, and that is what is happening with the PBMs. They are not achieving what they set out to achieve and what we think they are achieving by bringing down drug prices, because they are not passing them on.

Yet they avoid transparency, and this is what this legislation is trying to do. There has to be transparency within the marketplace. I will give you an example. We had the problem as you are well aware of, of the EpiPen that went up to like $600 for a two-pack. And when I was on the Oversight Committee we had the CEO of EpiPen of Mylan Pharmaceuticals, the manufacturer of that product, testify before us and she is at the beginning, I as a pharmacist, I was at the end.

So she says, okay, when it leaves us this is what the price is -- and I am going to just make up a number, $150 -- when it

gets to me it is $600. What happens in between? That is what we are trying to figure out. In between is that man behind the curtain. In between is the PBM. They are the ones who are marking that drug up and not passing it on. This is causing a problem in the market, in the generic drug market. This is one of the reasons why prescription drug prices are so high.

And this is why Representative Collins' bill, I think, is so essential and that we should pass it here in Congress, the MAC Transparency bill. Again I am not opposed to anybody making money, but I am opposed when they are causing the public the distress that they are causing them by increasing drug prices the way that they are.

Now there are others who need to be held responsible, including pharmacists, including pharmaceutical manufacturers, all of us have a part in this. But the transparency needs to happen. It needs to happen not only so we can bring down drug prices, but the things that is going to bring down healthcare costs all together in our healthcare market is going to be more competition. That is why this hearing is so important.

How can we bring about more competition within the generic drug market within health care itself? That is what we are working on right now in Congress when we are talking about health care and we are talking about all the things that we are talking about here. How do we increase competition so that we can bring

down costs? One way we do that is through encouraging more competition within the generic drug marketplace. That is what we have got to do. That is going to bring the prices down.

Just one quick example of how it does that in my own life. When I was still practicing I had this little company down the road who decided they wanted to get involved and wanted to become a player in the pharmacy market. I think the name of the company was Walmart. They came up with this. We are going to give you a 30-day prescription, a 30-day supply of generics for $4. I thought they were crazy. I said man, there is no way. I can't even buy it that cheap. I bowed my back and I said there is no way I am going to do that.

Well, guess what. A week later I was doing it. A week later I called my suppliers and I said you have got to do something. I have people walking down to that store and I am not going to have that. That is the way you drive down drug prices, through more competition, through more manufacturers, generic drug manufacturers on the market. That is the answer.

Thank you. I am sorry, I didn't mean to go on, but thank you very much.

Mr. Burgess. The gentleman yields back. The chair thanks the gentleman and recognizes the gentleman from Oregon, Dr. Schrader, 5 minutes for your questions, please.

Mr. Schrader. Thank you very much, Mr. Chairman. Dr.

Gaugh, just to confirm, in the previous session, previous panel, Dr. Woodcock indicated there might be in the neighborhood of 183 sole-source drugs where there is no generic competition. Would you agree with that number, roughly?

Mr. Gaugh. Roughly, yes.

Mr. Schrader. All right. Could you talk briefly about the pre-ANDA meetings and the increased communication and GDUFA and how you see this new process working out to make it even better?

Mr. Gaugh. Yes, in the pre-ANDA meetings it gives the industry the opportunity to meet with the FDA prior to actually filing the application with the FDA. It could be one or more meetings. Those meetings allow that conversation back and forth between the agency and the industry so that they can determine if they are taking the right path, or maybe they need to make a slight move in that path forward so when they do file their application the application is usually substantially complete and we would anticipate a first-cycle review of that.

Mr. Schrader. Good, very good.

Ms. Holcombe, one portion of our bill, Lower Drug Costs Through Competition Act, trying to close a loophole in the tropical disease priority review process. Some bad actors have announced plans to access brand name priority review vouchers by buying the rights to manufacture a drug from overseas and then bring it back to the U.S. for approval without having to do any

additional research or development. Would you agree that this program was intended to act as an incentive for new research, new drugs in the U.S. market, not just merely to adopt something from overseas?

Ms. Holcombe. I would agree that this program was intended to ensure that U.S. patients affected by these tropical diseases would be able to access safe and effective drugs to treat them. Our concern about the provision as it currently is written is worrying about taking away from FDA the ability to decide on an application-by-application basis what data are needed to provide an approval for a drug.

So there may be cases where a company has perfectly legitimately marketed a drug and had it approved first in a country where these diseases are endemic, and then brings this application to the U.S. because U.S. patients are now being affected from, because they travel out of the country, for example.

But if there have been legitimate, good, solid clinical studies that already have been done that are applicable to the U.S. patients who are affected by this condition, FDA will decide that maybe we don't need additional studies. If FDA has a different view, then of course they should be able to say to the company you need to do new studies. And sometimes that is going to happen for various reasons.

Mr. Schrader. And that is what our bill, I think, is trying

to get at, give FDA the final say --

Ms. Holcombe. Yes.

Mr. Schrader. -- using whatever appropriate studies are out there. Dr. Gaugh, a question on the risk management strategies and studies that we are trying to put in our legislation. Do you have any idea about the number of companies that may be restricted from accessing the market because of the REMS current provisions?

Mr. Gaugh. There is somewhere in the realm of 80 to 95 companies that have the restricted REMS.

Mr. Schrader. Oh, so a substantial number.

Mr. Gaugh. And then there is another probably 40 to 45 companies that have a restricted distribution set up, but it is not part of the REMS system.

Mr. Schrader. Very good. And with that I yield back, Mr. Chair, thank you. Thank you, all.

Mr. Burgess. The gentleman yields back. The chair thanks the gentleman. The chair recognizes the gentleman from New Jersey, Mr. Lance, 5 minutes for questions, please.

Mr. Lance. Thank you, Mr. Chairman. Good afternoon to the panel. Mr. Gaugh, following up on the chairman's questioning, do you believe it will be helpful for the FDA to have more presubmission meetings for noncomplex priority submissions?

Mr. Gaugh. I think the answer to that is it would always

be more helpful, yes. I think it is a more complex process than that. As we talked earlier, there is around a thousand applications that are filed every year, and with a thousand applications and having one or two or three meetings with the FDA on a thousand different products, probably so resource restrictive it couldn't happen.

So in GDUFA II we agreed to start this process in complex products, explore it and then we will move forward from there.

Mr. Lance. Thank you. Is there anyone else on the panel who would care to comment? Thank you. Again Mr. Gaugh, in your opening statement you mentioned a more effective generic drug review program as a goal of your organization. Touching on GDUFA II pre-ANDA submission communications pathway and information requests and division review letters, do you think these initiatives will reduce review cycles and what are the additional ways your organization believes the FDA sponsored dialogue could be enhanced?

Mr. Gaugh. So the potential does exist for that increased review and decreased cycle review time. In GDUFA I those information requests and division review letters were not part of the process, but we did negotiate with the FDA early on in GDUFA I to have them begin doing that which they did. So we have now codified that in GDUFA II, so that does give us the opportunity during a review cycle, whether it is chemistry, microbio

equivalence, for the reviewer to give an information request, for example, to a company who would then have roughly 15 days to respond and that could then move it right on in that still first-cycle review process.

Mr. Lance. Thank you.

Ms. Holcombe, good afternoon. It is always a pleasure to be with you. In your testimony you note that BsUFA II addresses the hiring issue which should result in improved processes and faster review times. Given that the reviewers are the same as PDUFA reviewers, do you believe the goals set out need to have any potential bandwidth issues for reviewers, or can we work together in that regard?

Ms. Holcombe. So BsUFA will benefit from the hiring goals that are included in the PDUFA agreement that this committee is going to consider at a subsequent hearing because of the fact that the reviewers are the same.

Mr. Schrader. Are the same, yes.

Ms. Holcombe. One of the issues with getting biosimilar products has been that these, when FDA was not sufficiently staffed in CDER and CBER in general, these reviewers who were reviewing two categories of products now just were simply overwhelmed. So we need to have changes in the hiring processes, we need to have some of the changes in 21st Century Cures, and we need to be sure that FDA is going to be able to meet those annual

commitments for hiring.

Mr. Schrader. Thank you. And I am so pleased that we don't have acronyms here in this --

Ms. Holcombe. We don't use acronyms.

Mr. Schrader. Acronyms, no. Thank you very much, Mr. Chairman, and I yield back the balance of my time.

Mr. Burgess. The chair thanks the gentleman. The gentleman yields back. The chair recognizes the gentlelady from California, Ms. Eshoo, 5 minutes for questions, please.

Ms. Eshoo. Thank you, Mr. Chairman. First, thank you to each witness. You did a terrific job. And I want to point out something that maybe some of you don't know, maybe everybody does. But even if everybody does, it is still worth saying it for the record, and that is that Kay Holcombe said when she began her testimony it is such an honor to be here. Here was her home. Kay Holcombe is one of the most distinguished individuals to have served on the staff of the Energy and Commerce Committee.

And I remember so well the farewell reception for Kay, boo-hoo, we were all boo-hooing. But that reception was filled with Republican senators, Democratic senators, Republican House members, Democratic House members. I mean, the breadth and the depth of her knowledge, her professionalism, and that recognition on a bipartisan basis is something that I will never forget. And I don't think there are that many people that could bring that

kind of a crowd together. So she is a superb professional and you know what, Kay, it is in honor to see you. And I waited so I could say this. I waited so I could say this because I have got to get out to Dulles, and wheels up and westward bound.

There is something in listening to the testimony of everyone here today, and members almost to a person have spoken about how the generic industry has grown, what it offers the American people. That generic drugs now account for 89 percent of prescriptions that are dispensed in the United States and that it saved the United States healthcare system almost, just rounding it off when you are talking about trillions, right, $1.5 trillion. That is not just walking-around money. That is not just loose change. And that is a period of a decade, over a decade.

So my question to you is, if this is -- that is a huge number and the savings are huge. Why do we have such a problem with the pricing of drugs in the country? They should be coming down not going up, according to these statistics. Can any of you speak to that?

Mr. Leicher. I could speak to it from a biologics perspective.

Ms. Eshoo. Short, because I have another question too.

Mr. Leicher. We don't yet have the biosimilars pathway up and running at the full tilt, essentially, as Kay spoke to earlier.

Ms. Eshoo. I know that one very well, believe me. I have

shot more bullets across the bow on it.

Mr. Leicher. And with the change in mix in products heavily to the biologics end of the spectrum, without this we had savings from generics.

Ms. Eshoo. Well, how much of the generic industry would you say that biologics is?

Mr. Leicher. How much of the generics industry is biologics? I am not sure I understand the question.

Ms. Eshoo. Well, you are saying that biosimilars have really not arrived yet and I agree with you.

Mr. Leicher. In the market --

Ms. Eshoo. The Obama administration dragged their heels. I don't know what this administration is going to do. We don't have interchangeability. The pricing is what CMS has done and I think they screwed it up. So, you know, it is not good, I don't think. I would give it a C- so far.

Mr. Leicher. What I would say is the majority of the highest selling products today are shifted over to the biologics end of the spectrum, so the opportunity to capture savings from generic substitution has declined as the biologics have taken the lead.

Ms. Eshoo. I appreciate what you have said. I am not so sure that I, in terms of the numbers that are stated and where we are in terms of drug prices I don't know. Is there a fact gap in this, Kay? Do you want to take a stab at it?

Mr. Gaugh. I think it is key to point out the --

Ms. Eshoo. Is your name Kay?

Mr. Gaugh. Sorry. No, it isn't.

Ms. Eshoo. Kay.

Ms. Holcombe. I don't know whether, there are some fact gaps which are much longer than a 5-minute conversation, but I do think that increased competition in the marketplace is going to drive down prices. And as Bruce pointed out, the biologics marketplace is at the chic end of the spectrum and as we have more biosimilars entering that marketplace I think we are going to see a difference. With the number of programs in development now, my speculation is that these programs represent the top used and the top selling biological products. These are the ones that are going to have biosimilars first. And I think we will, by the end of this next 5-year period we will be able to predict much more accurately what is going to happen in terms of the overall marketplace as we get more of these products on the market.

Ms. Eshoo. Thank you very much. My time is up. Thank you, everyone. Have a great weekend.

Mr. Burgess. The gentlelady yields back. The chair thanks the gentlelady. Before I yield to the gentleman from New Jersey, Mr. Gaugh, did you have something you wanted to offer us?

Mr. Gaugh. I was just going to point out the facts that you are talking about. So 11 percent of the products on the market

account for the opposite of 27, so 11 percent of the products on the market, the brand products, account for 63 percent of the dollars that are being spent. And those prices you see going up all the time, whereas in generics that is where the savings report comes. You see the savings from the generics and the prices typically going down and competition is what drives that. Thank you.

Mr. Burgess. The chair thanks the gentleman, and the chair recognizes the gentleman from New Jersey for 5 minutes for questions, please.

Mr. Pallone. Thank you, Mr. Chairman. As I mentioned earlier with the first panel, I believe as this committee looks at policies to encourage and support robust generic competition that we must also examine the barriers that are currently preventing generic access.

And so if I could start with Mr. Gaugh -- I hope I am pronouncing it right. In her testimony, Dr. Woodcock noted that certain brand companies are using REMS programs to delay or deny generic manufacturers access to reference product. Can you please discuss further ways, or the ways in which certain brand companies directly or indirectly refuse access to the reference product for generic drug development?

Mr. Gaugh. Yes, thank you. In the REMS program they are set up under -- and not all REMS. There are multiple different

levels of REMS. But in the REMS ETASU programs they are set up where they are restricted distribution programs. It is much like an early drug investigational review product where you keep tight controls so that you know exactly where each tablet, capsule, injectable vial went to from a patient standpoint.

They have done the same thing in the REMS, and so when you try to buy or try to purchase that since you are not a qualified patient, if you will, you don't get access to those drugs. And even though the REMS was not set up for that and there is a process currently where you contact the FDA, the FDA writes a letter to the company, that is really the only thing that happens. There is no stick to that, if you will.

Mr. Pallone. Thank you. I didn't realize that Dr. Woodcock was here. I really love the fact you stay for the second panel. You are one of the few people that does that. Mr. Leicher, I also understand -- well, I want to ask you something about utilizing restricted distribution programs also, but that was a tactic that Turing was utilizing to block competition to Daraprim. Can you discuss how certain brand companies are using the restricted distribution practices also to block access to reference product and the types of product that these practices are being used for?

Mr. Leicher. Well, thank you for the question, and what I would like to add to is this is not just a REMS problem, and it

is actually a much bigger problem, actually, in many respects, in the biosimilars business, because when we are developing generic drugs we need a smaller quantity to do analytical testing.

When we are developing biosimilars we have to do clinical trials with blinded vials and purchase very large quantities to do the adequate studies. And when you call a wholesaler to purchase a drug with an adequate medical license or pharmacist license, what you are finding increasingly today is wholesalers saying we can't sell it to you because you are doing biosimilar testing. And when we ask why, it is because they have to provide our name to the manufacturer and the manufacturer says you can't supply it. And that is the reason why we are very, we strongly support the FAST Generics Act or the CREATES Act as a solution to make that practice unlawful, because, you know, it ought to be a condition of approval that products are made available to licensed regulated companies by the FDA to develop biosimilars.

Mr. Pallone. Okay, thanks. One more question of Mr. Coukell. In your testimony you discussed a landscape with a number of different drug pricing challenges including launch prices and year-over-year increases. You have also talked about the need to increase generic competition, specifically policies to ensure generic companies have access to samples of the reference product for bioequivalence testing. Could you describe how that policy could be implemented in a way that yields

the most savings?

Mr. Coukell. Yes, sir. So first of all, REMS are there to protect patients and we have to make sure that those protections remain in place, but that is completely doable. And then there is sort of two pieces to it. One is, can the generic company get access to the product for purposes of testing, and there is a number of mechanisms and a couple have just been mentioned in the pieces of legislation that were mentioned. And then the second piece is can the company marketing the product that is under a REMS have access to the REMS program itself which is another barrier.

So they have to be able to get the product for testing and then they either have to be able to negotiate their way into a shared REMS program or stand up their own independent REMS program, and the FDA needs discretion to help them find the right solution on that latter part.

Mr. Pallone. Okay. Well, you know, I want to thank you all and thank the chairman also, because it is my hope that the committee continues to discuss legislation to promote generic competition and that we also consider policies that will address the use of REMS as a barrier for generic entry.

You know, one of the concerns I have, Mr. Chairman, is I am starting to hear from different people who will say, well, generics aren't really a factor in trying, you know, to keep drug

prices down, and I continue to believe that they are. I am kind of shocked by the fact that, you know, even some of my colleagues will say that they are not. So I think it is important, you know, the things that we are discussing today and in the future. Thanks again.

Mr. Burgess. The gentleman yields back. The chair thanks the gentleman. And seeing that there no further members wishing to ask questions, I do want to thank our witnesses for being here today. It was a long hearing and I appreciate your indulgence.

Two unanimous consent requests, or three unanimous consent requests from Mr. Schrader to enter into the record a letter from Premier, an alliance of 3,700 hospitals; the American Academy of Ophthalmology; and a letter from the American Academy of Dermatology. And then further, Mr. Long of Missouri had asked that we include a letter from the Federal Trade Commission in the record. So, without objection, so ordered.

[The information follows:]

**********COMMITTEE INSERT 15**********

Mr. Burgess. Pursuant to committee rules, I remind members they have 10 business days to submit additional questions for the record. I ask the witnesses to submit their response within 10 business days upon receipt of the questions. And without objection, the subcommittee stands adjourned.

[Whereupon, at 2:03 p.m., the subcommittee was adjourned.]