

Capital Reporting Company
FDA Public Meeting on Biosimilars User Fee Act (BSUFA) 12-18-2015

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U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
PUBLIC MEETING
ON BIOSMILAR USER FEE ACT
(BsUFA)

Friday, December 18, 2015

FDA White Oak Campus,
10903 New Hampshire Ave.,
Bldg. 31 Conference Center
Silver Spring, MD

Reported by: Christine Allen,
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1 P R O C E E D I N G S

2 (9:03 a.m.)

3 DR. TOIGO: Good morning, everybody, and
4 welcome to this public meeting on the
5 reauthorization of the Biosimilar User Fee Act.
6 My name is Terry Toigo and I'm the Associate
7 Director for Drug Safety Operations in the Center
8 for Drug Evaluation and Research. My job is to be
9 your moderator today.

10 Today's meeting is an important step to
11 begin to gather input from stakeholders on
12 features of the BSUFA program in advance of the
13 discussions that will occur with the regulated
14 industry.

15 We have a full agenda for today's
16 meeting. We will start with Dr. Janet Woodcock,
17 Director of the Center for Drug Evaluation and
18 Research, and she will get us started with opening
19 remarks. You don't have to come up yet, Janet.
20 I'm going to go through the logistics.

21 That will be followed by Leah Christl,
22 who is the Associate Director for Therapeutic

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1 Biologics in the Office of New Drugs in CDER, and
2 she will provide a presentation on the BsUFA
3 background and the reauthorization process.

4 Then we will have panels. The panels
5 will provide perspectives from the following types
6 of groups. We will have consumer and patient
7 advocates, health care professionals, the
8 regulated industry, and then our last panel will
9 be scientific and academic experts.

10 After the panel presentations, Theresa
11 Mullin, Director of the Office of Strategic
12 Programs in CDER, will then provide some remarks.

13 At the end of that, there will be an
14 opportunity for public comment. If you wish to
15 speak during the public comment session, you need
16 to sign up at the registration desk, and I ask
17 that you do that before we have the break, then we
18 can figure out how we want to set up the last
19 session. If you want to speak, if something comes
20 up in the first part of the meeting and you decide
21 then you want to speak, as long as you can sign in
22 with the folks at the registration desk, we can

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1 take care of that.

2 Each of our panelists will have 10
3 minutes to present the perspective from their
4 organizations, and we are going to ask you to
5 adhere to that time frame. It will be my job to
6 let you know when you approach your time limit,
7 and your microphone will not cut off, but I will
8 politely ask you to move on if you get to your 10
9 minute time frame.

10 FDA provided two questions in the
11 Federal Register Notice to help
12 panelists in the preparation of their comments.
13 The two questions: What is your assessment of the
14 overall performance of the BsUFA program to date,
15 and what aspects of the BsUFA performance goals
16 should be retained, changed, or discontinued to
17 further strengthen and improve the program.

18 BsUFA reauthorization deals with process
19 enhancements and funding issues. Policy issues are
20 beyond the scope of the reauthorization process.
21 There is also a public docket that will be open
22 until January 19 to which you can submit public

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1 comments, and speakers, if you have additional
2 comments after your presentations and you want to
3 submit something in writing, we ask that you do
4 that to the docket.

5 Brief logistics, housekeeping items. We
6 will have a 20 minute break at 10:30. Food and
7 beverages are in the lobby. I'm sure most of you
8 are familiar with that process, since you have
9 been here before. The restrooms are down the hall
10 and to the right.

11 That is our opening and logistics. I'm
12 going to turn it over to Dr. Woodcock, and she's
13 going to get us started for today. Thank you all
14 for coming. We appreciate your participation in
15 this process.

16 DR. WOODCOCK: Thanks, Terry. Good
17 morning, everyone. Here we are, bright and early,
18 talking about the user fee program. I'd like to
19 thank everyone for coming today to this meeting.
20 It's really important to us to have public input
21 as we go through this renegotiation process.

22 The purpose of the public meeting really

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1 is to hear the stakeholder views from the wide
2 variety of stakeholders as we consider whether to
3 retain, to change, or discontinue the current
4 BsUFA performance goals in any next BsUFA that
5 there might be. That is really the purpose of the
6 meeting. We really want to hear input from
7 everyone about that.

8 The first Biosimilar User Fee Act or
9 BsUFA was over three years ago and allowed FDA to
10 begin development of the infrastructure it needed
11 to support this new program. We started out with
12 nothing, and we didn't really have an
13 appropriation for this program, so it was foreseen
14 that we would develop a user fee program to
15 support these activities. We had to get started
16 before we had appropriation or before we had any
17 money for the program.

18 We created for the industry when we
19 started the BsUFA program -- we had the statute
20 first, then we got BsUFA, is what I was trying to
21 say. BsUFA really allowed us to begin this
22 infrastructure and to figure out how to do funding

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1 of the program when in fact we didn't have any
2 marketed products.

3 We created the biosimilar product
4 development program, and that provided a mechanism
5 and structure for collection of development phased
6 fees, which is quite different than our other user
7 fee programs that are related strictly to
8 applications and marketed products.

9 We did this because the development
10 phase for this was unknown, developing a
11 biosimilar was viewed to be intense, and since the
12 biosimilars by definition are supposed to have
13 less in the clinical development phase, it was
14 felt there would be much more in the product
15 development and comparison phase, and that would
16 be during the IND process.

17 This allowed the agency to work toward
18 devoting additional resources to meeting with
19 companies regarding products they were developing
20 to help streamline that development process, so
21 that companies as they were developing the new
22 biosimilars could do the right things and could

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1 get good advice from the agency about what we were
2 looking for.

3 Hopefully, this whole pipeline, once it
4 became mature, would lead to safe, effective, and
5 possibly more accessible biosimilar products for
6 patients.

7 The accomplishments of this program --
8 first of all, we did approve the first biosimilar
9 in the United States in March of 2015. That was
10 RCO, everyone knows, or Filgrastim-sndz, which is
11 a biosimilar to Neupogen or Filgrastim, which is a
12 reference product that is licensed by the FDA, and
13 the indication is to stimulate white blood cell
14 growth in patients with cancer and help them fight
15 infection. It has a number of other uses. We
16 published three final guidance's in 2015, and we
17 have published five draft guidance's since 2012.

18 We are aware that development of
19 biosimilars is really a global activity, that
20 there has been a program going on in Europe for
21 longer than we have had legislation for
22 biosimilars, so we work with the international

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1 regulators and others, like the World Health
2 Organization and so forth, on all the different
3 matters that have to do with biosimilars in all
4 these different regions.

5 We hope to make sure we do have
6 regulatory convergence so there is more or less an
7 uniform global structure around biosimilars and
8 how they are developed and how they are regulated.

9 We have begun and we want to continue
10 outreach efforts toward the public and clinicians
11 about biosimilars. I think I've concluded that
12 really targeted outreach, when you approve a
13 Filgrastim, the hematologic community, the
14 oncologists, they are going to be the most
15 interested in that. Your dermatologists aren't
16 going to be interested.

17 We're not going to try to educate the
18 world on these. We're going to try to educate the
19 relevant specialties that use the reference
20 molecules about the biosimilars in a timely
21 manner, when a biosimilar is coming available, so
22 they can understand.

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1 I can say for my community, the
2 rheumatologic community, there has been ongoing
3 discussion. I've been at their annual meetings
4 for years talking to them about this. Leah Christl
5 has come with me sometimes and talked about it.

6 I can say there is still considerable
7 concern by the clinical community about the use of
8 biosimilar products and what's going to happen.
9 It's the unknown. Going forward in the next
10 program, as more biosimilars become available,
11 this part of the activity is going to become more
12 important.

13 We certainly saw that years ago with the
14 generics program. There was a considerable amount
15 of resistance in the clinical community with the
16 use of generics, that they were inferior. There
17 is still some residual of that but not very much
18 since 88 percent of dispensed drugs in the United
19 States are generic drugs. At the beginning of the
20 program, we forget, because it was a long time
21 ago, there was clinical resistance.

22 That is going to be an increasingly

1 important part of the program. First, we built
2 the infrastructure, the conceptual framework for
3 how biosimilar would be evaluated and how its
4 biosimilarity would be evaluated. We need to
5 build and publish the conceptual framework for the
6 inter- changeability part, and we are working on
7 that.

8 Then we had to develop the
9 infrastructure of the machine to get the reviews
10 done, and how we would structure the review
11 process for biosimilars and all that would work,
12 and we have done that, and then anticipating
13 approval of a number of biosimilars over the next
14 several years, we're going to have to figure out
15 how to work with the clinical community and help
16 educate them about this.

17 There are challenges as this program is
18 dynamically evolving. There is a large number of
19 industry biosimilar development programs underway,
20 and that is terrific. That is really good news, I
21 think, for consumers. It means we are going to
22 have a robust program.

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1 As of November 2015, there were 59
2 programs in the biosimilar product development
3 program. That doesn't mean that is every single
4 biosimilar program there is in the world. That
5 means that's the people who have signed up for our
6 program and are paying user fees, and are getting
7 advice from us. That is a lot of entities.

8 As I said, when we started out, when the
9 statute was enacted, we didn't get additional
10 resources for this program. We have carved those
11 resources out ourselves out of our appropriation
12 that was existing and we have some increment from
13 the biosimilar development program from the fees
14 that we charge under that, which is the current
15 user fee program, and then there is the
16 application fee.

17 We really need to figure out going
18 forward, if we get a significant proportion of
19 these 59 products come forward and turn into
20 applications for marketing, how we are going to
21 get this work done, and how the biosimilar program
22 in the future would be funded to support getting

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1 this work done.

2 We do have challenges at FDA. We
3 continue at CEDR to have challenges in recruiting
4 and retaining critical staff for review of the
5 biosimilar development programs and the
6 application submissions. This is very complicated
7 science. I think it's very fun, but the people
8 that have to do it every day are also highly
9 sought after in the outside, for much more
10 competitive salary positions outside.

11 We need to be able to offer a desirable
12 program here that we can get those scientists and
13 clinicians in-house and build our biosimilar
14 development program.

15 With those challenges, that's what we
16 need to think about as we think about the future
17 of the program. That is what we think about. We
18 also need to know from our stakeholders, many of
19 whom are represented here in this room, what do
20 you think about as what needs to be considered as
21 we consider a second user fee program.

22 I know it's hard for everyone because

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1 although we have approved one biosimilar, it's not
2 as if it's like the new drug program, the generic
3 program, we're approving hundreds of applications
4 every year, or in the case of generic, maybe
5 approaching 1,000 products.

6 How do we structure a user fee program,
7 what are the needs, what aspects should be
8 considered from each one of the stakeholders.

9 To reiterate, the purpose of this
10 meeting is to hear stakeholder views as we
11 consider whether to retain, to change, or
12 discontinue the current BsUFA performance goals in
13 the next BsUFA program. We'd like to know from
14 those of you here, what is your assessment of the
15 overall performance of the BsUFA program to date,
16 what is your experience, if you have experience
17 with it, and what aspects of the BsUFA performance
18 goals should be retained, changed, or discontinued
19 to further strengthen and improve the program.

20 I would also ask what do you envision,
21 if you could fast forward three to four years,
22 think about those 59 development programs, what do

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1 you envision the biosimilar review program looking
2 like and needing to look like five years from now,
3 and then if so, how we would be able to build that
4 program to meet the needs.

5 We look forward to hearing all your
6 views on the reauthorization of this critical
7 program, and this is truly the kick-off of
8 starting to think about the future for this
9 program. Thanks very much. Thank you, Terry.

10 DR. TOIGO: Thank you, Janet.

11 (Applause.)

12 DR. TOIGO: Our next speaker is Dr. Leah
13 Christl, the Associate Director for Therapeutic
14 Biologics in OND and CDER.

15 DR. CHRISTL: Good morning, everyone.
16 I'm going to take just a little bit of your time
17 and go through the BsUFA program and the
18 reauthorization process.

19 What I'll do is give a little bit of
20 background about BsUFA and the fee structure,
21 speak very briefly about the workload and
22 performance, talk about some additional

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1 accomplishments under BsUFA, speak very briefly
2 about the reauthorization process, just to orient
3 folks who might not be as familiar with this
4 process as others, and then touch on FDA's goals
5 for BsUFA 2.

6 The Act directed that FDA develop
7 recommendations for a new user fee program for
8 351(k) applications. When the Act was passed, it
9 amended the Federal Food, Drug and Cosmetic Act to
10 include 351(k) applications and the definition of
11 "human drug application," enabling FDA to collect
12 the same fees for 351(k) and 351(a) BLAs through
13 September of 2012.

14 At the time, the Act had directed FDA to
15 think about a user fee program for the biosimilar
16 products, whether those would be their own user
17 fee program or whether they would get rolled and
18 under PDUFA, how they would do that. FDA did
19 develop recommendations to Congress for a separate
20 user fee program for 351(k) applications through
21 fiscal years 2013 to 2017. Again, we could have
22 kept them under PDUFA or created a new user fee

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1 program.

2 What we did was create this new user fee
3 program or BsUFA. On July 9, 2012, the President
4 signed FDASIA, which included the authorization of
5 BsUFA. With that passage, BsUFA then allows FDA
6 to collect user fees from the biosimilar
7 biological product industry to supplement the non-
8 user fee appropriations that the agency spends on
9 the process for review of these products. Again,
10 this was October 2012 through September 2017.

11 The basic BsUFA construct is the same
12 construct as any user fee program. These fee
13 funds are added to appropriated non-user fee funds
14 and are intended to increase staffing and other
15 resources to ensure a predictable review process.
16 The user fees are intended to pay for services
17 that benefit those who are paying the fees.

18 The fee discussions with industry,
19 again, this was mentioned previously, they focused
20 on desired enhancements in terms of specific
21 aspects of activities and the process for the
22 review of biosimilar biological product

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1 applications.

2 Part of those discussions and
3 negotiations look at what new or enhanced
4 processes FDA or industry would want to seek
5 during that period of the user fee program,
6 discussions about what's technically feasible,
7 what resources are required to implement and
8 sustain those enhancements, and again, the user
9 fee negotiations, and the construct of user fee
10 negotiations does not include a discussion of
11 policy.

12 Our experience with this user fee
13 program and every user fee program, I think, is
14 the devil is in the details. What are the
15 details? The BsUFA user fees are intended to
16 support FDA staff work against an increasing
17 performance level. The way BsUFA 1 was set up is
18 there are a number of goals, many of them are
19 listed here in this chart. We did note that not
20 all the commitments are listed there.

21 As you can see, for some of them they
22 had an increasing goal over the five years of the

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1 user fee program, some of them starting at a 70
2 percent goal to whatever activity it was within a
3 certain time frame, and then increasing up to 90
4 percent performance for certain goals by the end
5 of the user fee program in 2017.

6 The goals that are listed here include
7 application reviews, supplement review, including
8 manufacturing supplements, looking at special
9 protocol assessments, clinical hold responses, and
10 then there were a number of goals around
11 scheduling and holding meetings. Again, not all
12 the commitments are listed here. We do have some
13 additional commitments about conveying filing
14 issues or review issues and reviewing non-
15 proprietary names.

16 The current fee structure, there were a
17 number of principles that guided the BSUFA
18 program. We wanted to ensure sufficient review
19 capacity to support the biosimilar review, to
20 prevent unnecessary delays in development and
21 approval of the 351(k) products.

22 There was an assumption made that the

1 351(k) fees should be comparable to the 351(a)
2 fees for a standard review because of comparable
3 complexities of the review process and the
4 products.

5 We wanted to create a fee structure to
6 ensure that funds were available to support
7 critical development fees for review activities.
8 Again, as Dr. Woodcock had mentioned, there wasn't
9 an existing industry, so we looked very much at
10 the development phase review activities as a part
11 of BsUFA, and really tried to build the program
12 around focusing very heavily on the development
13 phase activities.

14 Also, we were very cognizant of avoiding
15 redirection of resources from 351(a) application
16 review under PDUFA to 351(k) activities.

17 The current fee structure that was
18 enacted as part of BsUFA 1, there are a number of
19 fees that are here, one of the unique aspects of
20 the BsUFA program is this concept of a biosimilar
21 product development fee, and there is an initial
22 or an annual fee, and this is per product, so it

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1 is for each product in the BPD phase, and that was
2 set at 10 percent of the human drug application
3 fee for that given fiscal year.

4 When a sponsor joins, they pay the
5 initial fee, and then as long as they are in the
6 program, it's an annual fee. It's not a fee for
7 service type of system. There's an annual fee
8 that covers the interactions with the FDA, be it
9 meetings, exchanges through written
10 correspondence, so on and so forth.

11 If a sponsor does withdraw from the
12 program for a certain period of time and wants to
13 rejoin and get engaged with FDA about the
14 development of that product, they would pay a
15 reactivation fee, which was set at twice the
16 initial BPDC, and then after that, as long as they
17 are in the program, they would then pay the annual
18 fee.

19 Like the other user fee program, under
20 PDUFA, there is also an application fee, and
21 again, that is for each biosimilar product that
22 will be submitted in the individual application,

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1 and that was set equal to the human drug
2 application fee under PDUFA less the sum of the
3 initial and annual and reactivation fee that had
4 already been paid for that product.

5 There is also an establishment and
6 product fee that would be for approved products,
7 and these are annual fees that you can see here.

8 Very briefly about performance and
9 workload that we have seen so far under BsUFA 1, I
10 will just very quickly touch on last year, so
11 fiscal year 2014, BsUFA review meeting on
12 performance. All of the goals are listed up here.
13 It's a busy slide.

14 The first section of the blue bars deals
15 with where current performance is for each of
16 those different metrics. The red line in both
17 cases is the goal for that existing year. Again,
18 some of these had increasing goals over time, so
19 you can see on that top portion, the goal for that
20 fiscal year for all of those performance elements
21 was 70 percent, and on the bottom portion of the
22 slide, for those elements, it was 90 percent goal

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1 for performance.

2 You can see based on that red line there
3 are blue bars that are one side and blue bars that
4 are on the other. There are some things we are
5 meeting the goals on as of last year, and there
6 are some things that the agency has not met the
7 goals, particularly around meeting scheduling, so
8 that would be when meetings were held within the
9 certain time frames that were agreed to in the
10 BsUFA negotiations.

11 You can see, for example, the third line
12 down would be the BPD Type 2 meetings, and the
13 performance was under 70 percent. For the BPD
14 Type 3 meetings, it was above the 70 percent goal.

15 The other portion of the slide, you can
16 see the number of submissions that would have been
17 subject to that particular goal in that given
18 fiscal year. This gives you an idea of the amount
19 of workload that would be against those particular
20 goals in addition to FDA's performance for fiscal
21 year 2014 on these goals. This is combined CDER
22 and CBER performance for fiscal year 2014.

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1 In addition to the BsUFA performance
2 goals that I just touched on, there were a number
3 of different accomplishments that we wanted to
4 note that were occurring under BsUFA 1. Again,
5 this is a new program, so there had to be an
6 establishment of the actual program and the review
7 process and how it is that FDA was going to
8 interact with sponsors in terms of development of
9 these products.

10 FDA established three committees to
11 ensure consistency in the regulatory approach and
12 guidance to sponsors for proposed biosimilar
13 product development programs, intended for
14 submission under 351(k), the PHS Act, and then
15 related issues.

16 The committees that were charged with
17 discussing and coordinating issues were the
18 CDER/CBER biosimilar implementation committee,
19 BIC, and then each of the centers has their own
20 biosimilar review committee. The biosimilar
21 implementation committee was focused on policy
22 issues, guidance developments, looking at

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1 developing policy around the development and
2 approval of the biosimilar products.

3 The biosimilar review committees were
4 charged with more scientific aspects of
5 implementation of BsUFA, so looking at the policy,
6 if it was scientific policy, ensuring
7 implementation, and all these committees were also
8 intended to provide an aspect of central oversight
9 to help promote consistency in the agency's
10 approach as we developed this program.

11 CEDR also developed the OND therapeutic
12 biologics and biosimilars staff, of which I am the
13 lead. This is housed in the Office of New Drugs,
14 and the staff was created again to ensure
15 consistency in the approach and advice provided to
16 sponsors. TBBT is one of the few organizations
17 within CEDR that actually sees every development
18 program. We also manage the BRCs, so we are the
19 ones that are bringing issues before the BRC and
20 helping to manage that.

21 Again, this is all around providing
22 consistency in the advice and making sure that the

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1 agency is being consistent in their scientific
2 advice and the application of policy to the
3 development and review of these products.

4 We also provide a central point of
5 contact for OND and other staff in addition to
6 industry, so there is a communication portal
7 inside and outside of FDA for this particular
8 review program.

9 The agency also held two public
10 meetings. One was in November of 2010. This
11 meeting was held to obtain input on specific
12 issues and challenges. The comments and
13 discussion that came out of that meeting helped to
14 inform the development of the first three draft
15 guidance's FDA published in February of 2012.

16 There was another public meeting that
17 was held in May of 2012, and this was to obtain
18 input on recently issued draft guidance's, so
19 those draft guidance's that we issued in February,
20 we then had a public meeting in order to receive
21 feedback and make sure as we moved forward in
22 finalizing those guidance's that we weren't just

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1 taking into account the public comments that were
2 received in the docket for these guidance's, but
3 we provided an opportunity for stakeholder input
4 and discussion and exchange of ideas.

5 To date, FDA has issued a total of eight
6 guidance documents related to the implementation
7 of the BPCI Act. I won't go through each of
8 these. I will note they are separated into the
9 guidance's that have been issued in final form.
10 In addition, the lower portion are the draft
11 guidance's that have been issued to date.

12 FDA has noted in the guidance agenda
13 that they intend to publish additional guidance on
14 these topics that are listed up here, and we know
15 these are eagerly awaited by both FDA and
16 industry.

17 In terms of the reauthorization process,
18 there are some mandated things that need to occur,
19 including a consultation phase, a public review of
20 the recommendations, and then the transmittal of
21 those recommendations.

22 This is our first step in looking at

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1 renegotiating BsUFA and moving into the BsUFA 2
2 negotiations. This is an opportunity for public
3 input, stakeholder input, as we move into the
4 negotiation phase that will start next year.

5 As a part of BsUFA 2, there is going to
6 need to be a discussion of some of the assumptions
7 that went into BsUFA 1 that helped to form not
8 just the performance goals but the conversation
9 around resourcing.

10 There were a number of assumptions that
11 were made including predictable workload with
12 consistent numbers of BPD programs and meetings,
13 along with applications that were going to be
14 coming in.

15 The assumptions included that there
16 would be eight BPD products on average, with no
17 more than 11 at one time. You heard what Dr.
18 Woodcock said, as of November 30, 2015, there were
19 59 programs in the BPD program. That is quite an
20 increase over the 11 that was anticipated to be in
21 the program at any one time.

22 There was also an assumption that there

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1 would be one to two BPD meetings per year, per
2 sponsor, with a total of 16 on average based on
3 that average, eight products in the BPD program at
4 any given time, and if you look back at the
5 performance slide, you can see the number of
6 meeting submissions that occurred during fiscal
7 year 2014, so you can see it's definitely over 16.

8 There was also an expectation there
9 would be 13 351(k) applications through the end of
10 fiscal year 2015. Those companies who have
11 submitted 351(k) BLAs have publicly disclosed -- I
12 think folks are fairly familiar with the
13 applications that have been publicly disclosed.
14 Clearly, one of those applications was approved by
15 FDA.

16 Again, there were assumptions that were
17 made, if you remember, on the fee structure around
18 not just the application fees but also product and
19 establishment fees that would be coming in for
20 approved products, so with an expectation there
21 would have been 13 351(k) BLAs that would come in,
22 there was a certain revenue stream that was

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1 anticipated during the course of BsUFA 1 based on
2 these assumptions.

3 There were also assumptions that were
4 made regarding the resources required for
5 reviewing the 351(k) development programs and
6 applications. Again, this was thought to be
7 similar to the PDUFA resource requirements for
8 standard applications, so there being a need to
9 discuss some of those assumptions as well
10 regarding not just incoming submissions and that
11 aspect of workload, but actually the work that the
12 agency puts in.

13 Also, assumptions that were made around
14 the ability to recruit and hire qualified staff
15 for the BsUFA program. As Dr. Woodcock indicated,
16 there are challenges that the agency has around
17 hiring and recruiting staff with the essential
18 expertise to be reviewing these applications.

19 The agency's priorities for BsUFA 2
20 include to review the existing BsUFA program to
21 further increase the quality and predictability of
22 product development and review for these products.

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1 Again, to revisit the workload assumptions from
2 BsUFA 1 to ensure there is adequate resourcing and
3 accurate resourcing so we can make sure the
4 program is functioning as soundly as it can, and
5 we are being responsive to industry needs.

6 Also wanting to ensure financial
7 soundness through fair and efficient fee structure
8 enhancements, including financial management and
9 reporting system enhancements. Also, there will be
10 a focus on recruiting and retaining critical staff
11 for the review of the biosimilar product
12 development stage and then also the application
13 review.

14 With that, I thank you very much.

15 DR. TOIGO: Thank you, Leah, for that
16 background. I am now going to ask our consumer
17 and patient panel to join us. We have
18 representatives from AARP, the Colon Cancer
19 Alliance, and from the Digestive Disease National
20 Coalition.

21 Our first speaker for this panel is
22 Leigh Purvis from AARP.

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1 MS. PURVIS: Hi. Thank you for having
2 me here today. My name is Leigh Purvis. I'm
3 Director of Health Services Research in AARP's
4 Public Policy Institute, and I am responsible for
5 developing and helping to guide all of AARP's work
6 around prescription drug issues, which I like to
7 sum up as "I Do Drugs."

8 I feel like I'd be remiss in my role as
9 a representative from a consumer organization if I
10 did not stop and kind of level set as we're
11 talking about these issues and kind of give you a
12 better idea of what consumers are experiencing on
13 the ground and why AARP finds this issue so
14 important.

15 I don't think this is going to be a
16 surprise to anyone in this room, but we have
17 certainly caught on to the fact that biologics
18 really represent the future of the drug industry.
19 They represent a growing amount of the drugs that
20 are in the pipeline. It's obvious that more and
21 more of them are going to be coming into the
22 market. They also represent a lot of the top

1 selling drugs, so we are spending a lot of money
2 on these products.

3 Something else that is important to note
4 is that the number of indications for these
5 products is expanding, so the way we like to sum
6 it up is that there are a lot more of them coming
7 and a lot more people are using the ones that are
8 already here.

9 Again, no surprise to anyone in this
10 room, part of the reason that AARP has really
11 focused on this issue is the fact that the prices
12 associated with these products are so incredibly
13 high. We're looking at tens of thousands of
14 dollars at this point, which is considered a low
15 price, so they can obviously reach hundreds of
16 thousands of dollars.

17 They are also are being used again by
18 more people. One example that we like to point to
19 is the new PCSK9 inhibitors, the new cholesterol
20 drugs. That is a proposed patient population of
21 anywhere between 10 and 15 million people with an
22 annual cost of around \$14,000 per year. The

1 numbers associated with that are just incredible,
2 and it really speaks to perhaps the sustainability
3 of the system and perhaps not being able to
4 sustain those types of spending.

5 Our population is particularly
6 vulnerable to the costs associated with biologics.
7 We use more prescription drugs than any other
8 segment of the population, and we also use them on
9 a chronic basis. The majority of older adults
10 have two or more chronic conditions. When we are
11 talking about prescription drugs, we are talking
12 about costs that they are facing for the rest of
13 their lives. This is not one bad year. Again,
14 something you will face for the rest of your life.

15 Biologics are commonly used to treat
16 conditions that are commonly found in older
17 populations. This is not a population that really
18 can absorb the costs associated with these
19 products. The median income for Medicare
20 beneficiaries is around \$23,000, and more than one
21 in four have less than \$10,000 in savings.

22 If you are prescribed a very expensive

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1 product for the rest of your life, you really do
2 not have the means to absorb the costs associated
3 with it.

4 We are kind of unique as a consumer
5 organization in the fact that we represent
6 consumers and we also try to keep an eye on the
7 programs they rely on. Being cognizant of time,
8 I'm just going to talk about Medicare Part B
9 today, which is the part of Medicare related to
10 physician services.

11 Under Medicare Part B, beneficiaries are
12 responsible for 20 percent of their prescription
13 drug costs. There is no out of pocket cap. If
14 you're prescribed an incredibly expensive drug,
15 you are looking at potentially in some cases as
16 much as \$100,000 in cost sharing every year for
17 the rest of your life.

18 There is no one in this room who can
19 absorb those kinds of costs. That is a huge
20 concern for us. Yes, there are a lot of Medicare
21 beneficiaries that have supplemental coverage, but
22 the fact of the matter is the costs associated

1 with expensive drugs don't just disappear into the
2 ether. They will be rolled back into the
3 supplemental coverage cost sharing and premiums,
4 which will eventually make that type of coverage
5 completely financially prohibitive, which again,
6 kind of defeats the purpose.

7 The Medicare program itself is spending
8 a lot of money on biologics. In 2013, eight out
9 of the top 10 drugs with the highest Medicare Part
10 B expenditures were biologics. That is
11 incredible, that is an incredible amount of money.
12 Part B spent around \$21 billion total, and again,
13 biologics are representing a growing share of
14 those types of costs.

15 All that is a very long way of saying
16 biosimilar competition cannot come soon enough for
17 our members and for the programs they rely on.

18 I have seen projections that until
19 biosimilars become available, spending on
20 biologics is projected to grow by more than 10
21 percent annually. This is not something that our
22 health care system can absorb.

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1 On the other hand, good news, there are
2 a lot of biologics with patents that will be
3 expiring in the near future, so the opportunities
4 for competition are here. We just need to be able
5 to take advantage of them.

6 There are many things that AARP does. We
7 do not manufacture biosimilars, so there is only
8 so much that we can say about this process, and
9 most of it really speaks to an overarching theme
10 that we have about biosimilars, which generally is
11 that we want to make sure there are no unnecessary
12 barriers to competition and to the savings that
13 were intended by the creation of the approval
14 pathway.

15 We can have some level of specificity in
16 terms of what we think, and the two ideas that we
17 really fall into are kind of competing but there
18 is a balance that can be achieved here. One is we
19 want to be sure that FDA has the resources it
20 needs to be able to approve safe and effective
21 biosimilars. We think that is incredibly
22 important. Again, our members rely on these

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1 products. We want to make sure they are reaching
2 them, we want to make sure they are safe, we want
3 to make sure they are effective.

4 However, we are a little concerned in
5 the sense that some of these fees might be high
6 enough that they may disincentivize manufacturers
7 from producing these products.

8 In our eyes, we think it would be
9 helpful if FDA were willing to kind of revisit
10 these fees as they develop more real world
11 experience with approving them, perhaps reducing
12 them, phasing some out, or perhaps even
13 considering similar to what we see under PDUFA,
14 perhaps returning some of the fees if a product
15 doesn't not actually get approved at the end of
16 the process.

17 I always like to close, and this is kind
18 of the theme of the entire presentation, close
19 with a little bit of a recap of what this means to
20 our members.

21 The costs associated with these products
22 really are not sustainable for patients or for

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1 payers. The health care system simply cannot take
2 the costs associated with biologics. We need the
3 competition.

4 More importantly, patients are reaching
5 the point where they cannot access the products
6 they need to get and stay healthy, and to us, that
7 is just unconscionable. We have to be able to
8 treat patients.

9 The final thought that we find ourselves
10 saying about biosimilars, biologics, and really
11 any prescription drug these days is the fact that
12 medical advancements are meaningless unless
13 everyone can afford access to them.

14 Thank you.

15 DR. TOGIO: Thank you, Leah. Next, we
16 will hear from Eric Hargis, who is the CEO of the
17 Colon Cancer Alliance.

18 MR. HARGIS: Thank you. I want to thank
19 Dr. Woodcock and the FDA for the opportunity to
20 share the patient advocacy perspective on the
21 reauthorization of the Biosimilar User Fee Act.

22 The FDA is being proactive in engaging

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1 patients in all areas of drug development and the
2 approval process, and we appreciate that the voice
3 of those who rely on this agency for both
4 innovation and safety is both heard and valued.

5 Biologics are integral to the treatment
6 of colorectal cancer. Thanks to innovative
7 medicines, we are seeing an improvement in both
8 survival and quality of life. While we recognize
9 the value these medicines have for patients and
10 the huge financial investment necessary to create
11 them, their costs has a dramatic impact on
12 patients and their families.

13 The cancer diagnosis doubles the rate of
14 bankruptcy, and in almost half of the 100,000
15 patients who contact our organization every month
16 are in desperate need of financial assistance.
17 Biosimilars have the potential to lessen the
18 financial impact on both patients and payers.

19 While we will not see the type of price
20 drop common with generics, given the high cost of
21 biologics for colorectal cancer, even a 20 percent
22 reduction in price translates to significant

1 dollar savings.

2 The Colon Cancer Alliance would welcome

3 biosimilars for colorectal cancer as the lower

4 cost treatment for our community provided first

5 the FDA approves the biosimilar based on evidence

6 it is the therapeutic equivalence of the

7 innovative biologic. Second, that appropriate

8 systems are in place to track adverse events.

9 Third, distinguishable names are used to avoid

10 inadvertent switching, and finally, that switching

11 from innovators to biosimilar or between

12 biosimilars is a decision of the clinician and the

13 patient and not the pharmacy.

14 To accomplish this goal, the FDA must

15 have the financial and human resources to answer

16 the question of how similar must the biologic be

17 so that patients are assured that it will provide

18 the same therapeutic benefit as the innovator

19 biologic.

20 While the public may think of

21 biosimilars in the same way as generics,

22 demonstrating equivalence presents an entirely

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1 different set of challenges, and we can't expect
2 the FDA to continue this as just another task
3 added to their already shrinking appropriations
4 budget.

5 In addition, the FDA must have the
6 necessary resources to ensure that the facilities
7 producing biosimilars meet the same quality and
8 safety standards as those making the innovator
9 biologic. There is and will continue to be
10 political pressure for the FDA to act swiftly in
11 approving biosimilars, and the agency must
12 withstand a rush to judgment and provide patients
13 the assurance that a reduction in price does not
14 come with a reduction in either efficacy or
15 safety.

16 User fees have become the major source
17 of funding for the FDA to carry out its important
18 work, now representing more than half of the FDA
19 budget. In the current environment, it is highly
20 unlikely Congress will provide the funding
21 necessary to address biosimilars, and the Colon
22 Cancer Alliance strongly supports the

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1 reauthorization of the Biosimilar User Fee Act of
2 2012 to ensure that the FDA can continue its work
3 to make biosimilars widely available.

4 In addition, we believe that this or
5 other legislation must address the unique needs
6 the FDA has to recruit highly specialized staff.
7 FDA must be able to go outside of HHS pay scale
8 for a limited number of staff positions. We're
9 not suggesting that the FDA staff generally make
10 more money than their HHS colleagues, but the
11 agency needs individuals with specific skills that
12 are in high demand in both the private and public
13 sector.

14 How can we justify asking users to pay a
15 fee for timely review if the agency cannot spend
16 some of that money to get the necessary staff
17 talent to conduct the work.

18 While FDA will not be able to offer
19 industry like salaries, going beyond HHS scale
20 will help recruit individuals with these skills
21 who share a passion for public service.

22 Again, we appreciate the opportunity to

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1 share the patient advocacy perspective on the
2 reauthorization of the Biosimilar User Fee Act,
3 and we encourage all appropriate steps to ensure
4 the FDA can make biosimilars widely available and
5 in a timely fashion.

6 Thank you.

7 DR. TOGIO: Thank you, Eric. Our last
8 speaker on this panel is Andrew Spiegel from the
9 Digestive Disease National Coalition.

10 MR. SPIEGEL: Good morning, and thank
11 you for the opportunity to comment on this
12 important legislation.

13 While I hold a number of relevant hats
14 in my role as a patient advocate, today as current
15 chair, I'm honored to represent the Digestive
16 Disease National Coalition. Founded in 1978, the
17 DDNC is an advocacy organization comprised of more
18 than 50 national patient and professional
19 organizations who are concerned with ensuring that
20 digestive diseases are on the radar of all health
21 care policy makers.

22 The DDNC focuses on improving public

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1 policies related to digestive diseases and
2 increasing public awareness with respect to the
3 many diseases of the digestive system.

4 In addition to my work with the DDNC, I
5 am currently the Executive Director of the Global
6 Colon Cancer Association, an advocacy organization
7 representing the millions of patients worldwide
8 who suffer from colorectal cancer.

9 Finally, I am the founding member and
10 sit on the steering committee of the Alliance for
11 Safe Biologic Medicines, an organization formed in
12 2010 to help support the FDA as they address the
13 unique challenges biosimilars present to
14 regulators.

15 For the last five years, we have worked
16 not only with the FDA, but regulators worldwide
17 and the World Health Organization to ensure that
18 these unique policy and regulatory challenges are
19 resolved in a way that places a premium on science
20 and safety.

21 We commend the FDA for its commitment to
22 bulletproof science and recognize that a long term

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1 sustainable biosimilars program requires such an
2 approach. The arrival of biosimilars to the U.S.
3 promises to offer new treatment options to
4 patients suffering from cancers, as well as other
5 serious conditions, such as rheumatoid arthritis,
6 psoriasis, and Crohn's Disease, as well as
7 colitis.

8 The patient community is excited about
9 the potential of biosimilars to reduce treatment
10 costs which would increase access, but we are
11 mindful that we cannot value speed at the expense
12 of safety or the quantity of biosimilars over
13 their quality.

14 Simply put, we recognize that in order
15 for patients to enjoy the benefits of biosimilars,
16 the FDA must always have the resources it needs to
17 measure both the timely yet thorough review
18 process.

19 The BsUFA was designed to do just that.
20 It was modeled with long-standing and successful
21 funding mechanisms for medical devices, MDUFA, and
22 prescription drugs, PDUFA, which have both been

1 repeatedly reauthorized as we recommend BsUFA
2 should be as well.

3 As patient advocates, we are extremely
4 encouraged by the success of BsUFA in promoting
5 both safe and timely introduction of biosimilars.
6 This past March, we saw the first biosimilar,
7 Zarxio, also called Filgrastim-sndz, approved.
8 Numerous other products are in the various stages
9 of the pipeline.

10 We can see the FDA's cautious science
11 based approach to biosimilar approval is working.
12 Take, for example, its use of distinguishable
13 naming, both in the Zarxio approval and in
14 subsequent guidance on biologic naming. It is
15 critical for patients and providers to always be
16 able to clearly identify which biologic product is
17 being used throughout treatment.

18 Accurate attribution of adverse events
19 to the correct biologic is also necessary for long
20 term tracking and safety and efficacy.

21 While we see the FDA's long-standing
22 commitment to transparency reflected in Zarxio's

1 clear naming, we feel a major obstacle to
2 biosimilar adoption overall could be insufficient
3 transparency on biosimilar labeling.

4 For example, the label of Zarxio neither
5 identifies itself as a biosimilar, does not state
6 whether or not it was interchangeable with its
7 reference product, nor does it provide any
8 analytical or clinical data demonstrating its
9 biosimilarity. It does not tell our physicians
10 whether its approval is based on its indication.

11 Say, for example, ulcerative colitis was
12 based on trials in ulcerative colitis or Crohn's
13 patients, where only on extrapolation from trials
14 in rheumatoid arthritis or psoriasis patients.

15 Together, these omissions could impact
16 the ability of patients and physicians to make
17 informed treatment decisions and could potentially
18 undermine physician confidence in biosimilars
19 generally.

20 Similarly, while we are encouraged by
21 BsUFA's progress since its introduction, we would
22 like to see further progress and more biosimilar

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1 approvals. The FDA has several years to assess
2 whether the funding mechanisms provided adequate
3 resources to thoroughly evaluate the ever-
4 increasing number of biosimilar applications. If
5 the FDA were to find more resources when required
6 to get safe, effective biosimilars approved and to
7 patients to a timely manner, we as patients would
8 be supportive of expanding the BsUFA program as a
9 funding mechanism.

10 Additionally, it is not only important
11 that these funds are sufficient to improve review
12 times, but that the allocated funds remain
13 dedicated to their intended purpose, so that the
14 FDA has the tools to perform this role.

15 It is important to all of us who want
16 safe and effective biosimilars to be successfully
17 introduced that the FDA get this right.

18 In closing, let me commend the FDA for
19 its continued work in bringing biosimilars safely
20 to the American patients. BsUFA is a critical
21 component of the U.S. biosimilars pathway, and
22 without reservation, we recommend it be

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1 reauthorized.

2 Thank you again for the opportunity to
3 comment on this important subject.

4 DR. TOGIO: Thank you, Andrew. That
5 concludes our consumer/patient panel, and thank
6 you for your thoughtful comments and the time you
7 took to prepare them.

8 Our next panel will be the health care
9 professionals' perspectives, and we have three
10 organizations represented, the Academy of Managed
11 Care Pharmacy, the American College of
12 Rheumatology, and the American Society of Health-
13 Systems Pharmacists.

14 Mary Jo, you can go right to the podium,
15 and we will go on down.

16 MS. CARDEN: Thank you. Good morning.
17 My name is Mary Jo Carden, and I serve as the Vice
18 President of Government and Pharmacy Affairs at
19 the Academy of Managed Care Pharmacy.

20 AMCP's more than 7,000 members that
21 include pharmacists, physicians, nurses, and other
22 health care providers and stakeholders, develop

1 and manage pharmacy benefits for more than 200
2 million Americans.

3 AMCP is committed to ensuring that
4 individuals in the United States receive access to
5 high quality, affordable, and safe medications.
6 AMCP applauds the Food and Drug Administration for
7 approving the first biosimilar in the United
8 States and its consideration of others.

9 AMCP understands that the approval of a
10 biosimilar is a major milestone, but more work is
11 necessary to provide clarity about the biosimilars
12 pathway and to encourage a robust market for
13 biosimilars. Today, AMCP offers our perspective
14 on the biosimilars pathway and also provides
15 recommendations for FDA to direct user fees in the
16 areas of post- marketing surveillance and
17 educational efforts.

18 First, let me begin by talking about
19 AMCP's position on biosimilars. AMCP supports an
20 abbreviated pathway for approval of biosimilars in
21 the United States. These medications play an
22 increasingly important role for the treatment of

1 chronic conditions, and offer hope for many
2 patients who had not had any access to
3 medications.

4 In many cases, biological products are
5 very costly to both patients and the health care
6 system, and the introduction of biosimilars will
7 help increase the competitive marketplace and
8 offer more choices for patients that will result
9 in increased access and lower costs.

10 However, to date, there are still legal
11 and regulatory challenges to the introduction of
12 more biosimilars to the market. FDA has issued
13 guidance on the pathway but has not finalized its
14 thinking in certain areas, including the issue of
15 naming.

16 AMCP supports a naming convention that
17 uses the same Government approved international
18 non-proprietary name as the reference product.
19 The naming convention has proved successful in the
20 generic small molecule market and should be
21 continued.

22 As proposed by the FDA, the naming

1 convention that affixes a four letter suffix to
2 the INN would result in confusion to both
3 patients, health care providers, and others. To
4 achieve the stated purpose of achieving a robust
5 pharmacovigilance process, AMCP supports the use
6 of the NDC that is readily available and provides
7 a system to identify the medication, package size,
8 and manufacturer.

9 The addition of more information does
10 not improve safety but rather adds another data
11 element that may result in additional confusion
12 and medication errors.

13 Next, AMCP supports interchangeability
14 that recognizes products may be substituted by
15 pharmacists and other dispensers without
16 additional notification to prescribers. AMCP
17 believes this reflects the spirit and the intent
18 of BPCIA and that interchangeability is similar to
19 the AB rating on generic products, which share
20 highly similar characteristics.

21 AMCP also supports the approval of
22 different indications for special populations

1 related to biosimilars.

2 In regard to active post-marketing
3 surveillance, AMCP supports the use of active NDC
4 based pharmacovigilance systems. To that end,
5 AMCP has launched the biologics and biosimilars
6 collective intelligence consortium, a public
7 service initiative that will draw on large sets of
8 identified pharmacy and medical data to provide
9 unbiased scientific information on the safety and
10 effectiveness of marketed biosimilars and their
11 novel corresponding biologics.

12 AMCP recommends that the next steps that
13 the FDA should take is first it should reconsider
14 its naming guidance that would implement a
15 hyphenated-random four letter suffix. AMCP has
16 stated before its concern that current proposals
17 will result in confusion to both the public and
18 health care providers. Other identifiers,
19 including the NDC, are already available to
20 distinguish products.

21 FDA should also seek public comment on
22 interchangeability through written comments and a

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1 public hearing. AMCP also recommends that FDA
2 hold a public hearing on the naming issue.

3 Finally, AMCP supports the use of user
4 fees to engage in a broad stakeholder educational
5 campaign to provide unbiased information about
6 biosimilars. This campaign should focus on health
7 care providers, payers, and consumers.

8 As the agency responsible for the public
9 health and safety of the medication supply chain,
10 FDA is a logical choice in providing this
11 education. AMCP is also committed to providing
12 education in this area and believes that a
13 public/private partnership would be effective in
14 ensuring that consumers understand biosimilars.

15 FDA's educational campaign should focus
16 on the needs of the various stakeholders and
17 should provide basic as well as higher level
18 information about biosimilars to health care
19 providers, payers, and decision makers. FDA should
20 also assess the needs of stakeholders before
21 releasing its information. It must also consider a
22 variety of means to communicate this information

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1 to accommodate people's differing levels of access
2 to information and understanding, including
3 websites, social media, print, apps, and video.

4 Again, thank you very much, and AMCP
5 supports the FDA's process to approve biosimilars,
6 and thank you for holding this meeting.

7 DR. TOGIO: Thank you, Mary Jo. Our
8 next speaker is Augus Worthing from the American
9 College of Rheumatology.

10 DR. WORTHING: Thanks very much. I'm
11 Angus Worthing, and I'm grateful for the
12 opportunity to be here and comment today on behalf
13 of ACR, the American College of Rheumatology, in
14 support of the reauthorization of BsUFA through
15 the fiscal years 2018 through 2022.

16 On a personal note, it's exciting to be
17 engaging with Government, patient groups,
18 industry, and my colleagues in the provider arena.

19 I'm a practicing rheumatologist in the
20 Metro D.C. area, and a member of the ACR
21 Government Affairs Committee. ACR represents the
22 vast majority of rheumatologists in the United

1 States. Rheumatologists, as we all know,
2 specialize in caring for Americans with
3 potentially disabling conditions, like rheumatoid
4 arthritis, lupus, psoriatic arthritis, ankylosing
5 spondylitis, gout, osteoporosis.

6 The FDA's approval of biologic medicines
7 has been a miracle treatment for our patients with
8 these and many other chronic and more rare
9 inflammatory conditions, cancers, and other rare
10 serious illnesses.

11 Not only have biologic medications
12 reduced the burdens of joint pain and organ
13 damage, disability and mortality from
14 rheumatologic diseases, they have improved the
15 quality and quantity of life for thousands of
16 Americans. They are changing the face and course
17 of many diseases in ways unimaginable a few years
18 ago.

19 Rheumatologists utilize and work with
20 biologics in many ways, as basic science and
21 clinical researchers, clinician prescribers, like
22 myself, and as monitors of on-site medication

1 administration in the clinic.

2 Rheumatologists' experience with
3 biologics is different from other pharmaceuticals
4 in three ways that are pertinent to our discussion
5 today. They are highly complex, highly
6 efficacious, and very expensive.

7 The ACR supports reauthorization of
8 BsUFA because it allows the FDA to continue its
9 vital and important work to evaluate emerging
10 complex biopharmaceuticals, whose approval as
11 biosimilars could reduce treatment costs.

12 The ACR's current position statement
13 regarding biosimilars strongly endorses that safe
14 and effective treatments should be available to
15 our patients at the lowest possible cost. It also
16 states that any decisions regarding approval of
17 biosimilars must be driven by sound science that
18 takes into account several observations and
19 guiding principles, including the following two:

20 number one, the size and complexity and
21 heterogeneity of biologics, and thus, biosimilars,
22 necessitate a greater degree of scrutiny in their

1 analytical evaluation than what is typically
2 required for small molecule generics.

3 Two, rigorous analysis of clinical
4 trials in humans is necessary to ensure safety and
5 efficacy of biosimilars, and provide the necessary
6 level of confidence in their use by patients and
7 providers.

8 We believe that BsUFA is a critically
9 important means to ensure that the FDA can perform
10 its important work and we offer the following
11 three analyses.

12 Number one, about cost and access, that
13 has been touched on before in this presentation
14 today. The price of biologics has increased
15 faster than other components of the health care
16 system, and is predicted to increase further.

17 This has led to reduced access to these valuable
18 therapies, mainly via insurance payers' use of
19 restrictive formularies, creation of various
20 tiering schemes, and co-insurance.

21 We know that at least one in six people
22 with rheumatoid arthritis already reduce their

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1 medication due to cost, potentially resulting in
2 long-term joint damage.

3 We physicians are extremely frustrated
4 when we see our patients suffer because they can't
5 obtain or use the medicines we have prescribed as
6 recommended by the FDA.

7 We hope the anticipated decrease in
8 costs resulting from the introduction of safe and
9 effective biosimilars will increase access to
10 agents and improve the health of all those who use
11 them.

12 Number two, a brief review of BsUFA to
13 date. As was stated at the public meeting here in
14 December 2011, the funding from fees paid by
15 sponsors of biosimilar products would "Provide FDA
16 with needed resources and provide prospective
17 manufacturers of these products with a clear and
18 more predictable review pathway in the new product
19 arena." The ACR supports these provisions.

20 As for fee amounts, it is appropriate
21 that the fees are structured based on FDA analysis
22 of the complexity of review required for innovator

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1 biologics, and are sufficient for the FDA to
2 perform the critical tasks required to ensure the
3 safety of our patients.

4 Thirdly and finally, review of the BsUFA
5 performance goals, ACR supports the performance
6 goals of FDA to promptly and carefully review what
7 look alike and sound alike proprietary names and
8 specifically package labeling. The increased
9 transparency will not only reduce medication
10 errors but also increase prescriber confidence in
11 biosimilar safety and efficacy data, and allow for
12 more extensive pharmacovigilance programs.

13 I think it would be appropriate to add
14 four things to product labeling or make sure four
15 things are there, the distinct name, compared to
16 the innovator biologic, the manufacturer, analytic
17 data, and clinical trial data.

18 In summary, ACR supports reauthorization
19 of BsUFA as one of the means for the FDA to
20 adequately and appropriately evaluate important
21 biopharmaceuticals that will ultimately increase
22 our patients' access to these highly effective

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1 treatments, as well as reduce their morbidity and
2 mortality, and improve their quality of life.

3 Thank you very much.

4 DR. TOGIO: Thank you, Angus. Our last
5 speaker is from ASHP, Christopher Topoleski.

6 MR. TOPOLESKI: Good morning. My name
7 is Chris Topoleski. I serve as ASHP's Director of
8 Federal Legislative Affairs. Two weeks ago, I was
9 the Director of Regulatory Affairs, so I am
10 holding two jobs at the moment, which as you all
11 know is the easiest thing. I'll be doing
12 interviews at the break if anyone wants to do reg
13 work.

14 AHSP represents pharmacists who serve as
15 patient care providers in acute and ambulatory
16 settings. The organization's more than 43,000
17 members include pharmacists, student pharmacists,
18 and pharmacy technicians.

19 For over 70 years, AHSP has been on the
20 forefront of efforts to improve medication use and
21 enhance patient safety.

22 I appreciate the opportunity to present

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1 the views of AHSP on the performance of the
2 biosimilar user fee program.

3 FDA's public health mission is to ensure
4 the safety and effectiveness of drugs, biologics,
5 and medical devices. No other agency or private
6 sector entity serves this vital public health
7 purpose in our society.

8 AHSP believes that the allocation of
9 sufficient Federal resources to the FDA to meet
10 its mission is a necessity, and those funds should
11 be achieved primarily through Federal
12 appropriations. AHSP strongly supports increased
13 appropriations for the agency and is working to
14 achieve that through our work with the Alliance
15 for a Stronger FDA. We're pleased to see the
16 increases for the FDA proposed in the recent
17 omnibus package.

18 AHSP has a long-standing professional
19 policy that supports legislation and regulations
20 that promote greater patient access to less
21 expensive biologic products. AHSP's policy
22 emphasizes that safety comes first and a desire to

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1 rush drugs to market should never surpass the need
2 to ensure that products are safe and effective.

3 Drug user fees do not replace the need
4 for increased appropriations from Congress.

5 However, AHSP does recognize that with the
6 agency's increasing applications for biological
7 products with the passage of the BPCIA, biosimilar
8 user fees represent an important and viable means
9 to help bring safe and effective biological
10 products to market.

11 My comments today will focus on the
12 current state of post-marketing surveillance, one
13 of the activities for which the FDA may spend the
14 user fees collected on.

15 The AHSP policy shown on this slide
16 supports a biological product naming convention as
17 consistent with international naming standards
18 developed by recognized authorities such as the
19 WHO, USAN, and the United States Pharmacopeia. In
20 addition, this naming convention is also supported
21 by other national organizations, including the
22 NCPDP.

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1 These organizations have developed a
2 harmonized biosimilar naming approach based on a
3 shared non-proprietary name for originator
4 biological products, related biological products,
5 and biosimilars. Under their authority, these
6 products essentially share the same non-
7 proprietary name but can be individually
8 identified through their unique NDC or other
9 unique codified identifiers, and trade names.

10 FDA has proposed a non-proprietary
11 naming process that deviates from existing
12 standardized approaches that have been applied by
13 international authorities such as INN and
14 USAN.

15 Under FDA's proposal, a unique randomly
16 generated suffix composed of four lower case
17 numbers will or suffixes related to the licensed
18 holder of the product, which could change over
19 time, would be applied to the originator
20 biological products, related biological products,
21 and biosimilars.

22 AHSP is concerned that this approach

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1 varies from the naming processes that are already
2 in practice in other developed countries such as
3 those in Europe.

4 Furthermore, using randomly generated
5 suffixes would be unlikely to achieve FDA's goals
6 of product recognition and recall by prescribers,
7 patients, and others. Non- meaningful,
8 unpronounceable suffixes are unlikely to be
9 readily recalled or accurately associated with
10 specific products.

11 Consistent with other standard setting
12 groups, national pharmacy organizations and the
13 WHO, AHSP does not believe there is a need to
14 develop a naming convention that differs from the
15 current standard. Without well designed testing,
16 it is unclear whether FDA's proposal for a naming
17 convention would achieve the high level
18 pharmacovigilance or would cause confusion among
19 clinicians and patients who rely principally on
20 proprietary names for self reporting about branded
21 products.

22 FDA is also planning to change the

1 official names for biologics with globally adopted
2 INNs and USANs. Initially, this would apply to a
3 small number of products but eventually would
4 retrospectively change the names of a broad group
5 of existing products to include unique randomly
6 generated four letter suffixes. Such a naming
7 change would require extensive education and
8 potentially require reprogramming of health
9 information technology systems. This could result
10 in significant risk for medication errors.

11 AHSP supports a biosimilar naming
12 approach that relies on the ability to track
13 medications by NDC or by other standard product
14 identifiers. While all hospitals and health
15 systems may not currently have the ability to
16 fully track drug products by the NDC, they will be
17 required to have that capability pursuant to the
18 Drug Supply Chain Safety Act, which requires
19 package level NDC tracking by 2022.

20 In addition, there are at least two
21 other options available to health care
22 organizations that could be implemented until more

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1 permanent solutions are developed. The first is
2 to apply the current vaccine adverse event
3 reporting system model to the biologic and
4 biosimilar products.

5 This regulatory framework already exists
6 for vaccines in all clinical settings and could be
7 applied by the FDA to ensure that
8 pharmacovigilance regardless of where a patient
9 receives the biologic.

10 The second option is to manually enter
11 an NDC into the patient's electronic health
12 record. Given that the current universe of
13 biologic and biosimilar products proposed by the
14 FDA is small, this could serve as an initial
15 solution while a more permanent one is developed.
16 The AHSP is prepared to work closely with the FDA
17 to develop such a solution.

18 AHSP believes there is a great deal more
19 to be discussed regarding the appropriate non-
20 propriety naming policy that should be employed by
21 the FDA. We believe it is premature to implement
22 the draft guidance until the agency has engaged in

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1 a robust stakeholder discussion.

2 Therefore, we believe it to be in the
3 best interest of public health for the FDA to
4 delay finalization of the guidance and proposed
5 rule pending a meeting in accordance with 21 CFR
6 Part 15 to hear the opinions and concerns of all
7 related parties that would be impacted by a non-
8 proprietary naming policy that deviates from the
9 current conventions.

10 AHSP appreciates the opportunity to
11 comment at this meeting today. We look forward to
12 working with the agency over the coming months as
13 they prepare for BsUFA reauthorization. Thank
14 you.

15 DR. TOGIO: Thank you, Chris. That
16 concludes our health professional panel. Thank you
17 for taking the time to prepare the comments and
18 come and present them. We appreciate your input.

19 We will now take a break. We are ahead
20 of schedule. According to the agenda, we are
21 supposed to be back at 10:50, but how about we are
22 all back at 10:45, and we will start at 10:45.

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1 Thank you.

2 (Recess.)

3 DR. TOGIO: This is last call for public
4 speakers. I have two people who have signed up
5 already. If you want to speak during the open
6 public hearing, you need to come see me now.

7 If Kay, Juliana, David, and Michael can
8 join me at the front, we will be ready to get
9 started.

10 This is our second to last panel, and
11 these are perspectives from the regulated
12 industry, and we will hear from BIO, Coherus
13 Biosciences, GPhA, and PhRMA. Kay Holcombe is
14 going to get us started. I did not put the name
15 tags in the right order, but that is okay, Kay,
16 you are listed on the agenda first, so you can go
17 first. I know you like to go first.

18 MS. HOLCOMBE: I just think this is an
19 example, Terry, of the last shall be first.

20 The Biotechnology Industry Organization
21 greatly appreciates the opportunity to speak with
22 you today regarding the Biosimilar User Fee Act.

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1 BIO is the world's largest trade
2 association representing biotechnology companies,
3 academic institutions, state biotechnology
4 centers, and related organizations across the
5 United States and in more than 30 other countries.

6 BIO supports the timely reauthorization
7 of BsUFA, and may I just say that when we started
8 user fees, we created the monster acronym, UFA,
9 and BsUFA has almost taken us over the edge,
10 acronym-wise.

11 We believe that this reauthorization
12 should strive to clarify and enhance the processes
13 and tools FDA uses to regulate biosimilars and
14 improve the transparency, sustainability, and
15 financial accountability of the BsUFA program.

16 When BsUFA was enacted, it established a
17 program of user fees associated with a category of
18 products new to the U.S. market and the U.S.
19 regulatory system. Therefore, unlike when the
20 grandfather of user fee programs, PDUFA, began,
21 there was no market, and neither the FDA nor other
22 stakeholders had a good idea of what the volume of

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1 applications, products, or facilities would be,
2 and how long it would take for an application
3 volume and a market to grow to the point where a
4 user fee program constructed like PDUFA could be
5 viable.

6 In discussing this reauthorization,
7 stakeholders will have more information, although
8 certainly not the level of understanding that
9 existed when the other user fee programs were
10 established. It, therefore, will be extremely
11 important for us to learn from FDA how the program
12 is proceeding.

13 While we have seen the reports of the
14 extent to which the agency is currently meeting
15 performance goals, it will be more important to
16 know how the agency is allocating resources in
17 this program, how many FTEs are required to
18 conduct the anticipated meetings, and to evaluate
19 applications, and the extent to which and how the
20 agency predicts this workload will change as the
21 number of sponsors interested in entering this
22 market and the number of applications increase.

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1 As PDUFA evolved over its nearly 25
2 years, to include multiple activities related to
3 the review of human drug applications, we
4 anticipate this program will evolve as well.
5 Biosimilar user fees already are designed to
6 support a wide range of FDA activities, including
7 meeting with sponsors during development, BLA
8 review, and post-market safety.

9 With this new to the U.S. category of
10 products, this latter is especially important. Not
11 because these new highly similar products are
12 inherently higher risk, but because they are
13 biological products that have the potential to
14 cause unexpected immunogenic responses, because
15 they are highly similar but not identical risks,
16 the reference products in lieu of which they may
17 be prescribed and used, and because they are new.

18 Both prescribers and patients need to be
19 educated and well informed throughout the course
20 of biosimilar development and use, so that this
21 new category of products will result in a robust
22 market.

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1 As interest in the U.S. biosimilars
2 market grows, the structure of this program will
3 undoubtedly need to change. We welcome the
4 opportunity to discuss with FDA and other
5 stakeholders what changes make sense and how fee
6 changes or fee structure modifications can be
7 phased in effectively and judiciously as the
8 numbers of applications and products increase.

9 Beyond fee adjustments are questions of
10 what additional activities need to be undertaken
11 to ensure a robust and patient- centered
12 biosimilars marketplace in the U.S., and to what
13 extent such activities are appropriate for
14 discussion in the context of BsUFA.

15 For example, there is significant
16 interest in increasing the number of final
17 guidance documents that will provide sponsors with
18 greater understanding about FDA's expectations
19 regarding data needed in biosimilar applications,
20 both in general and in specific product
21 categories.

22 While FDA has issued several final

1 guidance's, there are also important documents
2 still in draft which need to move forward.
3 Additional guidance also is needed and planned by
4 FDA.

5 For example, we need guidance regarding
6 how FDA will make determinations of
7 interchangeability, and regarding labeling of
8 biosimilar products. Regulatory guidance as we
9 all know plays a critical role in the development
10 of any new class of products, and is in the best
11 interest of all stakeholders, whether they are
12 companies trying to decide if this is a
13 marketplace they can and wish to enter, or
14 providers and patients who may want to and will
15 use these products. Timely and appropriate
16 regulatory guidance can help the development of a
17 robust biosimilars market.

18 We understand that specific policy
19 outcomes or change are not appropriate user fee
20 discussions. However, the development of guidance
21 and the time frames around such development are
22 clearly in bounds. It will be helpful to

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1 understand as well the extent to which existing
2 BsUFA resources have been used for policy and
3 guidance development, and how FDA sees this
4 playing out in the future.

5 As to BsUFA performance goals, it is
6 hard to estimate whether and how agency
7 performance can or should improve, because of the
8 relatively small numbers to date. We have little
9 visibility into the length of time or the FTE
10 effort needed to review an application, and we
11 have similarly limited understanding of the
12 resource needs for the other aspects of the
13 biosimilars program that would help us determine
14 whether the current BsUFA structure is appropriate
15 for long term program sustainability.

16 The BsUFA program must continue to
17 evolve to the benefit of patients and to support
18 FDA's ongoing implementation of a well-constructed
19 science based pathway for the approval of
20 biosimilar products. To this end, for BsUFA 2,
21 BIO will work with PhRMA to advance and support
22 policies to achieve the goals I mentioned at the

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1 beginning, to clarify and enhance the processes
2 and tools FDA uses to regulate biosimilars, and to
3 assure transparency and financial sustainability
4 of the BsUFA program.

5 BIO looks forward to engaging with FDA,
6 other stakeholders, and Congress to consider the
7 best pathway forward to timely BsUFA
8 reauthorization. Thank you for the opportunity to
9 talk with you today.

10 DR. TOGIO: Thank you, Kay. Next, we
11 will hear from Juliana Reed, who is speaking on
12 behalf of The Biosimilars Forum.

13 MS. REED: Thank you. A special thanks
14 to the FDA for holding the workshop today and for
15 the invitation to speak. As mentioned, I am
16 Juliana Reed. I am the current President of the
17 new organization this year, The Biosimilars Forum.

18 A little bit about The Biosimilars
19 Forum. We are a non-profit organization working
20 to advance biosimilars in the United States. We
21 are the first non-profit organization solely
22 dedicated to biosimilars and expanding access to

1 biosimilars.

2 Right now, our member companies are
3 developing at least 70 percent of the current
4 proposed biosimilar products that are currently
5 advancing at the FDA.

6 The members of The Biosimilars Forum and
7 one of the reasons why we came together was
8 because as you can see, we represent a very
9 diverse and in some cases, especially in this
10 town, an unlikely group of bed fellows. We came
11 together as folks know with the biosimilars
12 industry being a new industry. We also felt that
13 we needed a place, and why we have the name the
14 "forum," we needed a forum to work on this new
15 industry and the policies that will govern this
16 new industry.

17 We were able to come together, as you
18 see, we have innovators, we have start-up's like
19 Coherus and EPIRUS, and we have traditional
20 generic manufacturers like Teva, altogether to
21 support again the new biosimilars industry and to
22 work together to advance it.

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1 As I mentioned, the Forum represents the
2 majority of the current programs under
3 consideration at the FDA in biosimilars. We also
4 are very honored to have Sandoz as a member,
5 having the first U.S. approved biosimilar to date,
6 but also the members represent the majority of
7 biosimilars approved outside the U.S.

8 The Biosimilars Forum supports the
9 reauthorization of the user fees. We're very glad
10 to hear several of the things today that support
11 the user fees, support biosimilars, but also we
12 believe we share several of the positions and
13 things that the FDA is seeing as well, so we look
14 forward to working with the FDA team on the user
15 negotiations as we go forward.

16 It's vital to all of our members and the
17 biosimilar sponsors in the U.S. that we have a
18 productive dialogue that will lead to the timely
19 product approvals. It's important for us to
20 continue to lower the cost of biologic drugs in
21 the U.S.

22 Some considerations we would like to

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1 move forward with as we continue this dialogue
2 with the FDA. It is crucial that we continue to
3 maintain our current momentum and build on our
4 experience, but here are some key things.

5 One, we would like to continue with
6 aggressive but also realistic time frames for
7 review and approval. We would like to work with
8 the FDA to ensure that there are adequate and
9 skilled resources for the review of these
10 products. Meaningful and frequent communications
11 between biosimilar application sponsors and the
12 agency are important to our members.

13 Also, as you noticed in our membership,
14 leveraging the scientific knowledge of the
15 experienced manufacturers and scientific experts
16 in the industry is important to the FDA, and we
17 look forward to supporting you on that.

18 Education of stakeholders including
19 industry, providers, and patients, is a key
20 principle and foundational goal of the Forum, and
21 we again would like to support the FDA in that as
22 well.

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1 Using lessons learned to improve our
2 outcomes and meeting expectations. This is a new
3 industry. It is a new user fee program. We are
4 coming with open minds and changing the lens and
5 the paradigm of how user fees in the industry can
6 succeed.

7 This is a tremendous opportunity for
8 both the industry but also the agency and the
9 patients, and we are all in the same place with
10 the goal to advance a high quality and robust
11 biosimilars market. We look forward to continuing
12 to work with the agency and with our other
13 stakeholders here on shaping the market and
14 renewing the user fees.

15 Thank you.

16 DR. TOGIO: Thank you, Juliana. Our
17 next speaker is representing the generic drug
18 industry from GPhA and the Biosimilars Council,
19 David Gaugh.

20 DR. GAUGH: Thank you. Good morning,
21 everyone, and thank you for allowing us to speak
22 in front of you on this very important program,

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1 the reauthorization of BsUFA.

2 I'm David Gaugh, Senior Vice President
3 for Sciences and Regulatory Affairs, representing
4 the Generic Pharmaceutical Association, and more
5 importantly, the Biosimilars Council, which is a
6 division of GPhA.

7 The Biosimilars Council works to ensure
8 a positive environment for patient access to
9 biosimilar medicines. The Biosimilars Council is
10 a leading source of information about the safety
11 and efficacy of these affordable alternatives to
12 the costly brand biologic products.

13 Areas of focus include public health,
14 expert education, strategic partnership,
15 government affairs, legal affairs, and regulatory
16 policy. Of course, for those of you who would
17 like more information about the Biosimilars
18 Council, we have put our website on here so you
19 can check it out.

20 The Biosimilars Council is currently a
21 13 member organization, so these companies
22 represent the Council, and as my esteemed

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1 colleague just before me stated, a couple of the
2 companies, Sandoz and Teva, for example, are the
3 lead outside the United States for biosimilars and
4 also some of the leads on the biosimilar
5 applications that have been filed with the agency
6 thus far.

7 The impact of biosimilars on patients.
8 Biosimilars as interchangeable biologic products
9 holds promise not just for consumers and the
10 pharmaceutical industry, but for sustaining a
11 health care system with very finite resources. By
12 2016, it is predicted that 8 out of the top 10
13 most dispensed pharmaceuticals in the United
14 States will be biologics.

15 In a recent study by Express Scripts, it
16 was estimated that the potential savings of \$250
17 billion in the next decade will occur with the
18 approval of just 11 biosimilar products.

19 Where things with implementing BSUFA 1.
20 FDA has expanded a considerable effort in drafting
21 guidance's, some of which are now final. FDA has
22 met with multiple sponsors to date. There are

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1 estimated to be well over 50 products under
2 development in the United States under the BsUFA
3 pathway.

4 Although it may be too soon to judge the
5 agency's performance on applications given the
6 number of submissions, the BsUFA program can be
7 elevated for the biosimilar related work that
8 consumes the greatest amount of FDA resources -
9 development phase support. To date, eight BLAs
10 have been announced as submitted to the FDA, and
11 the actions to date for five of these submissions
12 has passed.

13 We only know of the review outcomes and
14 timing of two of those five, and for the two, FDA
15 has completed their review within the 10 month
16 goal, Sandoz's Filgrastim, for example, with an
17 approval, and Pfizer's epoetin alfa with a
18 complete response letter.

19 Of the remaining three, we do not have
20 public information available to us concerning
21 their status. Overall, there are fewer biosimilar
22 approvals at this point than what either the

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1 industry or FDA predicted several years ago.

2 Where things stand, continued.

3 Development phase support and meeting management
4 is a predominant activity where improvement is
5 needed. For 2013, the BsUFA performance report
6 found that all three goals not met were related to
7 meeting management. For 2014, which is a
8 preliminary report, found that seven goals where
9 there is potential to miss, six relating to
10 meeting management.

11 According to the Eastern Research Group,
12 BsUFA workload study meetings and policy
13 development consumed a majority of the CEDR staff
14 activities, 45 percent for meeting activities, 19
15 percent for policy activities, and 7 percent for
16 BLA review.

17 An assessment of the current BsUFA
18 processes. We have found interactions with FDA
19 under BsUFA to be very constructive. We believe
20 that a 10 month review clock for biosimilars,
21 which is two months less than that of the standard
22 PDUFA drug review, is justified because FDA is

1 granting multiple development meetings prior to
2 the BLA submission, allowing for extensive
3 feedback and aligning prior to the submission in
4 order to improve the completeness of the quality
5 of the BLAs.

6 These multiple meetings permitted under
7 BsUFA enable industry to obtain extensive feedback
8 which in turn led to improved dossiers.

9 At present, FDA is expanding a very
10 significant portion of biosimilar resources on
11 regulatory policy issues. We are hopeful that
12 these issues will be resolved in the very near
13 future, which will free up significant resources
14 to provide timely and detailed feedback to the
15 sponsors on the product reviews.

16 To date, FDA has issued four final and
17 eight draft biosimilar guidance's plus a proposed
18 rule on non-proprietary naming. It is critical
19 that FDA continues to provide guidance's to
20 industry and proceed with the outstanding
21 guidance's the agency has said they would be
22 introducing this year, which includes

1 interchangeability, labeling, and statistical
2 considerations for demonstrating analytical
3 similarities.

4 Additionally, FDA should prepare a
5 guidance to address life cycle management or post-
6 approval requirements, covering topics such as
7 requirements for biosimilars and interchangeable
8 biosimilars as well as supporting manufacturing
9 changes, such as the need to establish similarity
10 to the originator or comparability to approved
11 biosimilars.

12 From a future state standpoint, increase
13 and strengthen FDA resources and capabilities to
14 improve the review and approval of these critical
15 products. Staffing goals should be met at the FDA
16 commitment levels. Advisory committees that
17 increase the number of scientific experts from
18 outside the agency, more analytical and functional
19 experts with a strong understanding of the science
20 of comparison, and the assessment of biosimilarity
21 should be added.

22 These are imperative since the risk

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1 based considerations for biosimilars are highly
2 driven by analytical and functional data.

3 Maximizing the efficiencies of FDA
4 meetings and improving the outcomes, a clear
5 process where time lines should be established for
6 follow up clarification to any BsUFA meeting.
7 Application orientation meetings permitted under
8 PDUFA and very beneficial to FDA reviewers should
9 be encouraged under BsUFA. Additional touch
10 points during the review of the 351(k) is very
11 important.

12 Finally, Type 2 meetings should be
13 specifically authorized to provide written advice
14 on whether the achievement of certain pre-defined
15 product quality attributes would enable the use of
16 targeted clinical programs and allow for the
17 determination of interchangeability.

18 FDA and the industry need to work
19 collaboratively to create a public education
20 campaign around biosimilars. These collaborative
21 educational efforts will provide a key and
22 independent source of information regarding

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1 biosimilar products, their safety, and the
2 scientific development.

3 Additionally, other key stakeholders,
4 payers, patients, and clinicians would contribute
5 to an extensive educational campaign.

6 With that, I want to thank the agency
7 for this time and allowing us to present our
8 position and some of our thoughts for a future
9 under the reauthorization negotiations that will
10 soon be taking effect, and given the strong public
11 need for more affordable biologics, it is critical
12 for FDA and industry to focus negotiations on
13 efforts to ensure timely patient access to these
14 more affordable high quality biosimilars.

15 The Biosimilars Council thanks FDA for
16 their accomplishments under BsUFA 1, and we look
17 forward to working with the agency under BsUFA 2
18 reauthorization. Thank you very much.

19 DR. TOGIO: Thank you, David. Our last
20 speaker for this panel is Michael Levy from PhRMA.

21 MR. LEVY: Thank you. As just stated,
22 my name is Michael Levy. I'm Deputy Vice

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1 President in Science and Regulatory Advocacy at
2 Pharmaceutical Research and Manufacturers of
3 America, otherwise known as PhRMA.

4 PhRMA is pleased to have the opportunity
5 to respond to the Food and Drug Administration's
6 request for comments on the overall performance of
7 the Biosimilar User Fee Act, and to participate in
8 the upcoming reauthorization of BsUFA.

9 PhRMA is a voluntary non-profit
10 association that represents the country's leading
11 pharmaceutical research and biotechnology
12 companies, which are devoted to inventing
13 medicines that allow patients to live longer,
14 healthier, and more productive lives.

15 PhRMA's membership includes several
16 leading biopharmaceutical companies actively
17 developing biosimilar medicines and working with
18 the Food and Drug Administration to bring these to
19 patients.

20 In 2011, PhRMA was a participant in the
21 technical negotiations with FDA that together with
22 input from groups representing patients and health

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1 care providers resulted in the first BsUFA
2 performance goals letter. At that time, there was
3 little experience in reviewing and approving
4 biosimilar medicines on which to base the content
5 of the performance goals letter.

6 Now, with more collective experience,
7 PhRMA remains committed to working with FDA and
8 other stakeholders to reauthorize BsUFA in a data
9 driven manner, which ensures FDA continues to
10 receive funding necessary to review biosimilar
11 applications in a timely manner, without diverting
12 resources from the review of innovative medicines.

13 PhRMA has long backed the establishment
14 of an approval pathway for biosimilars that
15 involves the thorough assessment of their safety
16 and efficacy. We supported the enactment of the
17 Biologics Price Competition and Innovation Act,
18 and have actively participated in FDA's ongoing
19 efforts to implement the statute.

20 It is imperative to ensure that the
21 continued implementation of BPCIA matches the
22 original legislative intent to ensure patient

1 safety while at the same time balancing increased
2 competition from biosimilar products with the need
3 to provide biopharmaceutical researchers with
4 certainty to make long term research and
5 development decisions and support future medical
6 innovation.

7 PhRMA's consideration of biosimilar
8 policies is guided by our support for the
9 following five things: a science based
10 implementation of the BPCIA and regulatory
11 decision making. Patient safety through effective
12 identification of biologics and robust
13 pharmacovigilance. Health care provider and
14 patient choices, regulatory transparency that
15 enables stakeholders to understand the basis for
16 FDA's decisions, and long term stability of the
17 biosimilar user fee through financial
18 transparency, efficiency, and accountability.

19 The BsUFA agreement developed in 2012
20 provides the agency with the resources and
21 regulatory framework to meet its public health
22 mission and to ensure patient safety. BsUFA 2 and

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1 FDA's continued policy development related to
2 biosimilars should further advance these
3 activities.

4 PhRMA is committed to working with FDA
5 and other stakeholders to review the existing
6 performance goals and consider enhancements that
7 can improve the program.

8 To date, the agency has issued several
9 draft and final guidance documents to assist
10 sponsors in generating data to support biosimilar
11 applications. FDA guidance and regulation provide
12 insight into the agency's current thinking
13 regarding how it will evaluate and understand
14 significant regulatory questions.

15 Key guidance's that remain on the
16 agency's agenda include but are not limited to
17 guidance on the labeling for biosimilar biological
18 products and guidance for industry considerations
19 in demonstrating interchangeability to a reference
20 product.

21 In addition to issuing these guidance's,
22 the agency should provide clarity on how FDA will

1 interpret statutory provisions that apply to
2 biosimilar applications. For example, those that
3 reference innovative products that are covered by
4 the transition provision in Section 7002 of the
5 Affordable Care Act.

6 We urge the FDA to issue the necessary
7 guidance's and regulations to implement fully the
8 BPCIA, as these are critical to provide
9 predictability and transparency to sponsors in
10 order to help them design effective development
11 strategies to meet patient needs and FDA
12 regulatory expectations.

13 We agree with FDA that implementation of
14 a robust modern pharmacovigilance program for all
15 products is essential to ensure patient safety.
16 All biologic medicines have the potential to cause
17 unwanted immune responses in the body that could
18 have serious adverse effects.

19 A feature called immunogenicity.
20 Although rare, these serious safety risks may not
21 be detectable during pre-approval clinical testing
22 because the size of the population exposed may not

1 be large enough to assess very rare events.
2 Because of this, it is even more critical that we
3 ensure adequate pharmacovigilance systems are in
4 place as we introduce biosimilar biological
5 products to the marketplace.

6 PhRMA believes that all original
7 biologic and biosimilar products should share a
8 common non-proprietary name that is accompanied by
9 a unique memorable suffix to distinguish them from
10 one another. This will help to ensure that
11 physicians can remember the names of the biologics
12 that they prescribe, and patients can remember the
13 names of the biologics that are prescribed for
14 them. Such identifiability is essential for
15 monitoring drug side effects, and we applaud FDA
16 for issuing guidance on this critical policy area.

17 PhRMA believes that to facilitate
18 patient-centric prescribing and choice, there
19 should be appropriate regulatory transparency in
20 biosimilar labeling, including a statement of
21 biosimilarity. Biosimilar labeling should state
22 that the product has been approved as a biosimilar

1 for stated indications and routes of
2 administration. The labeling should also identify
3 the reference product. A statement on
4 interchangeability. Biosimilar labeling should
5 state whether or not the FDA has made a
6 determination of interchangeability with the
7 reference product, and include any such FDA
8 finding.

9 A description of data supporting
10 approval. Biosimilar labeling should describe the
11 basis of approval for each indication by
12 identifying the relevant data for the reference
13 product and biosimilar that support a finding of
14 biosimilarity.

15 In summary, PhRMA supports the
16 reauthorization of the Biosimilar User Fee Act in
17 a way that is consistent with the original
18 legislative intent.

19 The BsUFA performance goals agreement is
20 a means of advancing public health by making
21 adequate resources available to FDA for the
22 regulatory review of biosimilar products,

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1 consistent with the agency's high standards for
2 scientific rigor and patient safety.

3 PhRMA and its member companies are
4 committed to working closely with FDA and all
5 stakeholders to reauthorize this important program
6 to maintain, improve, and expand upon its science
7 based approach to the development and review of
8 biosimilar products.

9 PhRMA, therefore, urges Congress to
10 reauthorize BsUFA in 2017, and compliment the user
11 fees with congressional appropriations.

12 Thank you.

13 DR. TOIGO: Thank you, Mike. Thank you
14 to our panel members for presenting the industry
15 perspective, and for keeping to the time
16 commitment. We appreciate your cooperation.

17 We have one more panel, although we have
18 one panel of one person, so we have one person,
19 Dr. Antonio Moreira, who is going to talk to us
20 about the perspective of the scientific and
21 academic community.

22 DR. MOREIRA: Good morning, and thank

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1 you so much to the FDA for giving me the
2 opportunity and inviting me to be with you this
3 morning and present some perspectives from the
4 scientific and academic community on the BsUFA
5 process.

6 I feel a bit lonely being the only
7 member on this panel, but I'll do my best to
8 oblige to the request.

9 I am Tony Moreira, Vice Provost for
10 Academic Affairs at the University of Maryland,
11 Baltimore County. I'm a Professor of Chemical,
12 Biochemical, and Environmental Engineering. I
13 have been in the biotech business for about 35
14 years, both in academia and in industry. I teach
15 courses in regulatory science at UMBC, and also
16 I'm a member of a DARPA funded project that deals
17 with manufacture of therapeutic proteins at the
18 point of care, and these are applications for
19 biosimilars, so I'm very much personally
20 interested in the progress of the biosimilars
21 field and what we can do in academia to support
22 this activity.

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1 As we look at the intent of BsUFA in
2 terms of providing resources for the FDA to
3 develop at the end of the day a better managed and
4 biosimilar product review process and making sure
5 we have high quality product therapies that come
6 to the market as needed by the patients, we have
7 to realize that we are talking about developing
8 products, similar bioproducts, to very complex
9 molecules, orders of magnitude more complex than
10 simple chemical synthesized, well defined small
11 molecules.

12 Thus, the use of the language of "highly
13 similar" as opposed to being the same or identical
14 product, again, because of the unique
15 characteristics of these products as a function of
16 the manufacturing process used for that
17 manufacturer.

18 Again, the need for somehow identifying
19 what we mean by "similar structure," and the major
20 impact of having strong analytical technology
21 packages that can compare the biosimilar product
22 with the reference material from the innovator

1 compound.

2 Thus, in the definition of "biosimilar"
3 from the BPCI Act, words like "being highly
4 similar to the reference product," notwithstanding
5 minor differences in clinical and active
6 components, and the "no clinical and meaningful
7 differences" being observed between the biological
8 product and the reference product in terms of
9 safety, purity, and potency.

10 Probably the words here "highly similar
11 and no clinical and meaningful differences" bring
12 about many questions from the science point of
13 view in terms of making sound scientific decisions
14 of the biosimilarity approach in terms of the
15 product being defined.

16 I liked a previous slide from Dr.
17 Christl's presentation because I think it provides
18 a very good pictorial of the process for the step-
19 wise approach in terms of generating data and
20 evaluating what the FDA has labeled as the
21 evaluation of the uncertainty, starting from the
22 very strong analytical package and then moving

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1 down the line in terms of animal studies, clinical
2 PKPD, and potentially additional clinical studies
3 that again are looking at the totality of the
4 evidence, a decision being made for the process.

5 This leads to a pathway for biosimilar
6 development that starts by looking at the
7 reference product licensed in the U.S., reengineer
8 a clone that develops then a product that will be
9 comparable to the innovator molecule based on the
10 analytical studies, develop the manufacturing
11 process, and realizing again because of the
12 complexity of these molecules, we are always
13 talking about some differences possibly occurring
14 between the two products.

15 Following the development of the
16 manufacturing process with clinical development
17 work, again, as defined here, leading to a
18 demonstration of efficacy and safety after
19 assessing immunogenicity as well, and again, some
20 of the concepts you already heard earlier in terms
21 of how to extrapolate across indications and the
22 potential or not for interchangeability or

1 substitution decision making, again, becoming a
2 very important part of the deliberations in terms
3 of biosimilarity.

4 Again, all of these eventually lead to
5 or come as a result of scientific studies that
6 will support the decision-making. I think these
7 are just in my view some of the scientific topics
8 with the introduction of the biosimilar
9 discussions in the U.S. that has caused us to work
10 in terms of the development.

11 How to establish that the molecule
12 profile is highly comparable to the innovator
13 molecule, and then leading to the development of
14 manufacturing processes, efficient, optimized, and
15 high yield in terms of making products of final
16 high quality.

17 Science and technology has advanced
18 tremendously since the days when the innovator
19 molecule was developed, so I think we have now
20 novel expression systems, novel tools, improved
21 analytics, single use systems, a lot of new
22 technologies and knowledge that allow us to use

1 those to make these biosimilar products.

2 Science has developed to the point where
3 there are exciting opportunities to develop
4 products of high quality and compare them to the
5 innovator molecule. This comes to a question of
6 how much statistical packaging we need to
7 establish for making these decisions, so again, I
8 know the FDA is working on these concepts of how
9 to develop these statistical analyses so they are
10 scientifically sound to establish biosimilarity.

11 Also, the clinical trial design that
12 will be necessary in terms of the uncertainties in
13 decision making, a new way of looking at these
14 studies to prove the biosimilarity.

15 These are whole new ways of looking at
16 this product. It really is a paradigm shift in
17 the regulatory approval process and review, which
18 I think brings the scientific topics where again
19 the development in science can be very important
20 and helpful to make those decisions.

21 We are looking, as I was saying before,
22 in my laboratory at point of care delivery, so I

1 think we are looking at how biosimilars even can
2 interface in personalized therapies. It will be
3 an interesting topic, I think, looking at ways
4 where academic institutions, where we are doing
5 discovery and new science and bringing new
6 knowledge to the table, how can we be more
7 successful in whatever we discover in the academic
8 world that can be ultimately marketed through
9 successful clinical trials or these approaches to
10 biosimilarity. I think it will become quite
11 important for us to interface with the FDA and
12 industry.

13 Again, these are some of the challenges,
14 one might call. I would rather see them as
15 opportunities in biosimilar development. When we
16 look at what is necessary to define the target
17 profile of the biosimilar material, what are the
18 methodologies necessary that are sensitive enough
19 to look at the differences in similarities between
20 products, and understanding what's critical in
21 manufacturing, what are the quality attributes and
22 related to key process parameters.

1 The structure and functional
2 relationships and all the strengths of the
3 analytical package necessary even before we
4 initiate any pre-clinical or clinical studies.
5 Defining how similar is similar. What can we
6 tolerate or accept considering even the innovative
7 molecule, of course, is also a variable in its
8 properties.

9 As I said, with this paradigm shift, it
10 brings about as far as I can see it from my
11 academic perspective, brings in the opportunity
12 for true innovation in biologics manufacturing,
13 which will impact the biosimilar industry, but
14 also the biotech industry in general. I think we
15 are all looking at really new ways and
16 scientifically sound approaches for biologics
17 development at the end of the day.

18 When I look at these kinds of scientific
19 opportunities, my thought is at this point is
20 really as you look forward to the BsUFA
21 reauthorization, which I am obviously supportive
22 of, for the FDA to consider the academic community

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1 as a partner as well, with the scientific
2 opportunities that we can have in academia.

3 For instance, the FDA can give us
4 guidance on what are the important questions that
5 we should be looking at in academia that can
6 support the FDA's mission in specifically
7 biosimilar development. We do lots of things in
8 academia. We look at many new technologies, new
9 science, new discoveries.

10 How can we model or mold those studies
11 and that research in order to provide information,
12 provide knowledge to the FDA in helping answer the
13 questions that are part of the biosimilar process
14 flow.

15 Also, the FDA can help us in looking at
16 the training of staff that is needed by the FDA.
17 The FDA can provide the ideas for projects that
18 our students can work on at the Master's or Ph.D.
19 level. Not only they will be doing work that is
20 important and useful for the FDA, but they will be
21 trained in issues and problems and topics that
22 then they can come and work for the FDA, in terms

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1 of their knowledge of the regulatory science and
2 the needs of this kind of industry.

3 I think that interface where we can
4 really use the FDA as essentially the critical
5 component to help us design our research, design
6 our studies, so we can be helpful to the FDA, I
7 think, will be a very important component.

8 I'd like to recommend highly leveraging
9 the resources of the academic community to support
10 these efforts.

11 Ultimately, I think as we look at the
12 FDA and this industry coming together, perhaps
13 developing best practices that we all share, and
14 that could support these efforts going forward.
15 Again, we can have an efficient process that
16 brings these medicines to the market in a timely
17 manner as needed by our patients, and as we can in
18 the academic world and in scientific communities
19 support the FDA and industry in making this
20 happen.

21 I think bringing this triangle together
22 and FDA thinking of academia as a catalyst to

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1 develop these sources of knowledge that can be
2 directly supportive of the FDA's needs in terms of
3 their science and staffing levels, that is
4 something the academic world is open to, and
5 looking forward to work with the FDA and industry
6 in these endeavors.

7 Thank you very much.

8 DR. TOIGO: Thank you, Dr. Moreira. To
9 wrap up the panel presentations, we are going to
10 have Theresa Mullin do some closing remarks, and
11 then we will have a brief open public hearing
12 session. Theresa?

13 DR. MULLIN: It's still morning, so good
14 morning, everyone, and again, thank you for coming
15 today to this meeting. It's a very important
16 milestone for us, both in terms of this
17 reauthorization process and also a milestone
18 because this is the first reauthorization program
19 which is still, as I think you have been hearing
20 from the various stakeholders who have been able
21 to share their views today, still a new program.

22 This is the first reauthorization. I

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1 guess we would agree with some of the views that
2 we are also trying to get a better understanding
3 of the resources required to do these kinds of
4 reviews and to support this program.

5 I'm going to just try to close with a
6 quick recap. I have been making notes throughout
7 the morning. Recap of some of the key messages
8 that I think we have been hearing from you today.

9 I will start with we hear there is a
10 need for biosimilar competition and to improve the
11 affordability of needed biologic therapies, the
12 cost of biologics can be quite high, and
13 competition would be valuable, but yet the need
14 for rigorous science, the bulletproof science, I
15 think I heard, and sufficient staffing of
16 qualified experts to really underpin and address
17 these policy challenges, there are new regulatory
18 challenges and policy challenges associated with
19 biosimilars, and they take a much more complex
20 approach to both develop them and to manufacture
21 them than would be needed for say a small molecule
22 generic product, generic drug.

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1 There is a need for naming that would
2 minimize the confusion in the health care system
3 and at the same time support accurate, clear
4 attribution of adverse events so that you can have
5 effective risk management and follow up of any
6 safety issues that may emerge in these new
7 projects, which are again more complex as we have
8 been hearing, and we need the resources to be able
9 to accomplish this.

10 User fee reauthorization appears to be
11 generally supported by the public in the input we
12 have received today, and that the fee level should
13 be in line with the cost of running this program
14 in an efficient manner.

15 It was also noted that the development
16 pathway here is different, it's different from the
17 new drug 351(a) or from the generic drug pathway,
18 and from a scientific standpoint, there is a
19 paradigm shift, and this presents both challenges
20 and opportunities to be really pursued.

21 Also, with all that and the paradigm
22 shift, there is a need to really get an

1 understanding of the resources that are needed for
2 this program and the structure of a program that
3 would be successful in this case, considering that
4 it is a different type of pathway, and the
5 evolving program.

6 We hear there is a continuous desire for
7 continued communication between FDA and sponsors
8 as they work through these new pathways throughout
9 development, and the need for continuing guidance
10 and policy development, that there has been a
11 significant part of the workload in the early
12 years, we are really now finishing up the third
13 year of this program, and it's acknowledged that
14 guidance is much needed and additional guidance
15 may also be needed.

16 These products are complex products, and
17 complex policy issues and new products and new
18 development programs sometimes raise additional
19 new issues.

20 User fee negotiations and discussions I
21 will note focus on process. They are about
22 review, process enhancement, not policy issues.

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1 The discussions we will be undertaking in the next
2 several months with the regulated industry will
3 not involve naming, they will not involve payment
4 policy, they won't involve labeling policy.

5 They might involve identifying, industry
6 may say, more guidance is needed, but not what
7 would go in the guidance. They may identify an
8 area where they would wish for more guidance.

9 We have been successful to date in
10 funding careful, rigorous review of safety and
11 effectiveness and providing a timely and
12 predictable process using industry user fees by
13 making it clear that the timely process is a value
14 and benefit for industry, and it doesn't promise a
15 particular answer, so we do not tie fee payment or
16 we certainly don't return fees after doing that
17 careful review, depending on the answer.

18 It's quite critical that this is the way
19 the program be structured to ensure program
20 integrity and public confidence in these programs,
21 and public confidence is quite critical as we know
22 in the case of biosimilars to ensure timely

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1 uptake.

2 Finally, I want to conclude by
3 reiterating Dr. Christl's comments about our
4 priorities for BsUFA 2. We want to further
5 increase the quality and predictability of this
6 program in development of these products. We want
7 to revisit the workload assumptions as we have
8 been hearing, the paradigm shift, the complexity,
9 and even the greater than we expected desire by
10 companies for consultation throughout the
11 development phase.

12 That is very important, but we may need
13 to revisit how we structure and finance the
14 program to ensure soundness in that financing so
15 we can continue to sustain this program and meet
16 the promises that our patients and others have in
17 it, and that we recruit and retain the scientists
18 that we need for timely review, so we are able to
19 accomplish this.

20 With that, I'll close. Thank you again.
21 We look forward to a very robust discussion to
22 support timely reauthorization of this program.

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1 Thank you again for coming today. Happy holidays.

2 DR. TOIGO: Thank you, Theresa. We have
3 two people who have signed up to speak in the open
4 public session. Dr. Hillel Cohen from Sandoz, and
5 Dr. Sumant Ramachandra, from Pfizer. We will
6 start with Dr. Cohen. Gentlemen, I will ask you to
7 keep it to about five minutes. Thank you.

8 DR. COHEN: Good afternoon. I'm Hillel
9 Cohen, Executive Director of Scientific Affairs at
10 Sandoz, Inc., a Novartis company. We would like to
11 thank the FDA for holding this meeting.

12 At present, Sandoz is the only company
13 that has taken a product through the entire
14 biosimilar development FDA review and approval
15 process. We have had more than 30 meetings with
16 the FDA to discuss development of biosimilars.
17 Our experiences provide a unique perspective, and
18 we welcome the opportunity to share them at this
19 meeting.

20 There are many aspects of BsUFA that
21 worked well and that we would like to retain. Our
22 interactions with the FDA under BsUFA were

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1 excellent and constructive. The multiple meetings
2 permitted under BsUFA enabled us to obtain
3 extensive feedback, which in turn led to improved
4 dossiers.

5 We believe that the 10 month review
6 clock for biosimilars was successful and is
7 justified. The extensive interactions prior to
8 submission allow FDA to obtain an overall
9 familiarity with the contents of the dossier.

10 FDA has expended and continues to expend
11 a very significant portion of biosimilar resources
12 on drafting guidance's to industry to provide
13 clarity on the development pathway and to resolve
14 remaining regulatory and policy issues.

15 We are hopeful that the remaining issues
16 will be resolved in the near future, which will
17 allow FDA to allocate more resources to providing
18 rapid feedback to sponsors and to product reviews.

19 There are several ways in which the U.S.
20 biosimilars development pathway can be enhanced.
21 First, it is apparent that non- biased education
22 is needed to ensure that health care professionals

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1 and the public understand and accept biosimilars.
2 The FDA acknowledges this need, but at present,
3 these activities are not funded. It is important
4 that a mechanism be developed to address this
5 critical need.

6 Second, a clear process with time lines
7 is needed for follow up clarifications to a BsUFA
8 meeting. The existing guidance meetings are
9 extremely useful, but at times, there are residual
10 uncertainties about the outcomes. A mechanism
11 should be created to resolve any residual
12 uncertainty from either the meeting itself or the
13 meeting minutes. This would greatly benefit all
14 parties.

15 Third, FDA is currently taking the
16 approach that a sponsor must first obtain approval
17 of a given biological drug, that is a biosimilar,
18 and only after initial approval can the sponsor
19 seek approval of the same product as an
20 interchangeable biologic. The reason stated by
21 the FDA is that they are not yet ready to evaluate
22 interchangeability as a part of the initial

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1 application.

2 In the interim, companies must submit a
3 supplemental license application in order to
4 obtain an interchangeability designation, even if
5 the data was available, and incorporate it into
6 the initial submission. The current supplement
7 fee is in the neighborhood of \$1 million.
8 Congress never intended that FDA review of
9 interchangeability be automatically subjected to
10 an additional user fee. This situation must be
11 addressed.

12 We have specific suggestions for these
13 highlighted items, as well as other suggestions on
14 how BsUFA could be improved. We will provide those
15 to the groups that will discuss BsUFA
16 reauthorization on our behalf.

17 Thank you very much for your time.

18 DR. TOIGO: Thank you, Dr. Cohen. Dr.
19 Ramachandra?

20 DR. RAMACHANDRA: Thank you for the
21 opportunity to provide Pfizer's views on the
22 reauthorization of the biosimilar user fee

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1 program, BsUFA 2.

2 My name is Sumant Ramachandra, and I'm
3 the Senior Vice President and head of Research and
4 Development for Pfizer's Global Established
5 Products.

6 We believe that Pfizer's experience
7 under BsUFA 1 having seven products in development
8 in the U.S., including one product pending
9 approval by the FDA, may offer important insights
10 for FDA and relevant trade associations as they
11 begin the reauthorization process.

12 Any potential changes to BsUFA should be
13 data driven and informed by FDA's review
14 performance. We encourage FDA and the trade
15 associations to develop that evidence base during
16 the course of the negotiations.

17 Despite significant progress by the
18 agency, only one 351(k) BLA application has been
19 approved by the FDA to date, with another seven
20 applications still pending. Based on publicly
21 available information, this equates to an overall
22 25 percent first cycle review approval rate. By

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1 comparison, in recent years, the PDUFA program has
2 achieved a first cycle approval rate for NMEs
3 ranging from 80 to 95 percent. Furthermore, we
4 estimate the number of applications will
5 significantly increase in 2016 and 2017.

6 Understanding this performance and
7 Pfizer's experience, we have identified three high
8 level priorities for BSUFA 2. First, the program
9 should be appropriately resourced to ensure that
10 the FDA has adequate capacity to provide advice
11 and feedback to biosimilar sponsors both during
12 development and on pending applications.

13 Second, the FDA should commit to
14 training and workforce development to ensure that
15 FDA staff fully appreciate the difference between
16 the review of a biosimilar and a new therapeutic
17 biologic. This is a paradigm shift and defers
18 from both novel products and generic reviews.

19 Third, FDA should enhance the clarity,
20 consistency, and timeliness in its feedback to
21 sponsors during biosimilar product development
22 meetings and the BLA review process.

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1 In summary, based on Pfizer's experience
2 and leadership in biosimilars and biologics
3 development, we look forward to contributing to
4 the BsUFA reauthorization process. By enhancing
5 consistency in reviews and ensuring adequate
6 resources and staffing trained, we believe that
7 BsUFA 2 will provide FDA with the infrastructure
8 necessary to anticipate and respond to the next
9 wave of biosimilar applications.

10 Thank you again for the opportunity to
11 provide the views of Pfizer, and we would be happy
12 to provide any clarifications needed through the
13 process. Thank you very much.

14 DR. TOIGO: Thank you, Dr. Ramachandra.

15 That concludes our meeting for today.
16 Thank you all, to the speakers who took the time
17 to prepare and come and present, to the FDA staff
18 who did a lot of work to get the meeting
19 organized, and to our participants who came and
20 participated in the process.

21 FDA takes seriously its responsibilities
22 related to public input into our regulatory

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1 processes.

2 Thank you, and remember that the docket
3 is open until January 19 for any additional public
4 comments you want to provide.

5 Safe travels, and that's it.

6 (Whereupon, at 11:42 a.m., the meeting
7 was concluded.)

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1 CERTIFICATE OF NOTARY PUBLIC

2 I, CHRISTINE ALLEN, the officer before whom the
3 foregoing proceeding was taken, do hereby certify
4 that the proceedings were recorded by me and
5 thereafter reduced to typewriting under my
6 direction; that said proceedings are a true and
7 accurate record to the best of my knowledge,
8 skills, and ability; that I am neither counsel
9 for, related to, nor employed by any of the
10 parties to the action in which this was taken;
11 and, further, that I am not a relative or employee
12 of any counsel or attorney employed by the parties
13 hereto, nor financially or otherwise interested in
14 the outcome of this action.

15

16

17



18

19

CHRISTINE ALLEN
Notary Public in and for the
State of Maryland

20

21

22

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