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FOOD AND DRUG ADMINISTRATION (FDA)

Public Meeting

BIOSIMILAR USER FEE ACT (BsUFA)

REAUTHORIZATION

Thursday, October 20, 2016

9:03 a.m.

FDA White Oak Campus

10903 New Hampshire Avenue

Silver Spring, Maryland 20993

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Capital Reporting Company

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## 1 P R O C E E D I N G S

## 2 OPENING REMARKS

3 DR. ROACHE: All right. Good morning  
4 everyone. And welcome to this public meeting on the  
5 Reauthorization of the Biosimilar User Fee Act.

6 My name is Amanda Roache and I work in the  
7 Center for Drug Evaluation and Research in the Office  
8 of Strategic Programs and I am going to be your  
9 moderator for today's meeting.

10 As you are aware this meeting is an  
11 important step in the process on the reauthorization  
12 of the Biosimilar User Fee Act also known as BsUFA and  
13 this Public Meeting presents an opportunity for the  
14 public to provide their views on the recommendations  
15 for the second iteration of BsUFA.

16 Before we get started I would like to  
17 mention that the public docket for comments which was  
18 open on September 19 will remain open for one more  
19 week and will close on October 28. So if you would  
20 like to submit a comment following today's meeting you  
21 will still have an opportunity to do so.

22 I just want to provide a quick overview of

1 the structure of today's meeting. We are going to  
2 start with some opening remarks from our Commissioner  
3 Dr. Califf. We are very pleased that he can be here  
4 today to get us started.

5 And following his opening remarks we will  
6 have a series of FDA presentations. We will start on  
7 some background of the Biosimilar User Fee Act that  
8 will be presented by Dr. Theresa Mullin from the  
9 Office of Strategic Programs in CDER. And then we  
10 will then present the proposed enhancements for BsUFA  
11 II and these will be presented by Dr. Leah Christl who  
12 is the Associate Director for the Therapeutic  
13 Biologics in the Office of New Drugs. Following this  
14 presentation we will go over the financial  
15 enhancements for BsUFA II and these will be presented  
16 by Josh Barton who is from the Office of Strategic  
17 Programs.

18 Following these presentations we will have a  
19 short break from 10:30 to 10:45 and when we return we  
20 will resume with our first panel which will be  
21 Perspectives from Patient and Public Health Advocates.  
22 We will then go on to Panel 2 which will be

1 Perspectives from our Health Care Professionals and  
2 then we will break for lunch from about 11:30 to 12:30  
3 p.m.

4 When we come back from lunch we have our  
5 third and final panel with will be Perspectives from  
6 Regulated Industry.

7 We will then have an open public comment  
8 period. Following this Open Public Comment we will  
9 have closing remarks presented by Dr. Mullin.

10 A few housekeeping items before we get  
11 started. There are food and beverages available for  
12 purchase at the Kiosk, bathrooms are down the hall  
13 from the lobby and to the left. And if you would like  
14 to have the Wi-Fi password you can speak with the  
15 people at the desk in the lobby.

16 I would also like to mention that we are  
17 asking anyone who would like to provide a comment  
18 during the open public comment period to please  
19 register. You can go out to the registration desk  
20 where you signed in and there is a sheet there that  
21 says open public comment. If you could please write  
22 your name there if you would like to provide a

1 comment. And we ask that you preferably do this  
2 during our first break. And all of the public  
3 comments are asked to limit their remarks to five  
4 minutes.

5 I would now like to turn our meeting over to  
6 our Commissioner Dr. Califf to provide us opening  
7 remarks.

8 OPENING REMARKS

9 DR. CALIFF: Thanks. It is great to be here  
10 with you today and I shouldn't have expected anything  
11 differently than this well organized meeting.

12 Just sort of a reflection one of the reasons  
13 I was interested in being Commissioner was I knew the  
14 UFAs were going to be renegotiated and I had this  
15 anticipation I would need to come in with a heavy hand  
16 as a Commissioner and do all sorts of things to make  
17 it work. But this FDA teams and I think the  
18 corresponding teams that have been negotiating have  
19 really done an amazing job. So most of my work in the  
20 UFAs consists of giving opening remarks to meetings  
21 which go on and are well planned and turn out quite  
22 well. So actually it has been a great learning

1 experience for me.

2 The purpose of today's public meeting is to  
3 share with the public the proposed recommendations for  
4 the reauthorization of the Biosimilar User Fee Act  
5 that you all know about and to hear from you on your  
6 views on these recommendations. It is really  
7 important for us to have the public input as we go  
8 through this process and it is quite an amazing  
9 process and well evolved through experience with all  
10 the UFAs.

11 First authorization of BsUFA was 2012. This  
12 allowed the FDA to establish a biosimilar product  
13 development program. This program has shown  
14 considerable success with the approval of four  
15 biosimilars in the United States and publication of  
16 four final and five draft guidances.

17 The intent is to provide additional revenue  
18 so that the FDA can hire more staff, improve systems  
19 and established a better managed biosimilar review  
20 process. BsUFA has been critical to FDA's ability to  
21 develop the foundation needed to conduct reviews in a  
22 consistent and timely manner.

1           A well-managed review process is important  
2 to make therapies available to patients sooner without  
3 compromising review quality of FDA's higher standards  
4 for safety, efficacy, and quality.

5           I'll just note here it is a fascinating  
6 policy issue this speed versus quality thing which  
7 plays out in many areas of medicine and in many ways I  
8 think a pretty good equilibrium has been reached at  
9 this point where if you sped things up too much you  
10 would really sacrifice quality which is something that  
11 is really bad for the patients who are in need. But,  
12 of course, we should always look for way to do things  
13 faster within the context of high quality.

14           The biosimilar industry is still in the  
15 early stages of development but the number of  
16 biosimilar development programs has been steadily  
17 growing since the start of BsUFA I. Sponsor requests  
18 for meetings with FDA for consultation during  
19 biosimilar development have far exceeded our earlier  
20 projections. And the number of marketing applications  
21 is beginning to grow as well. The issues raised in  
22 these consultations and reviews are both

1 scientifically and legally complex and the volume of  
2 review work has been higher than anticipated.

3 FDA will continue to face challenges as this  
4 program evolves and there are a large number of  
5 industry biosimilar development programs under way.  
6 However, we feel that the recommendations in the  
7 proposed package for BsUFA II will help us to  
8 alleviate some of the challenges we have faced in the  
9 past. So we take these commitments very seriously.

10 Just a couple of notes here just from my  
11 experience. First of all I was very involved 25 years  
12 ago in the development of biologics in cardiovascular  
13 disease and it has been amazing to see how this field  
14 has evolved over that time. If you told me then we  
15 could even think about biosimilars it was sort of a  
16 frightening thought. But obviously things have  
17 evolved now to where we see an enormous number of  
18 things in the pipeline and growing and realistic  
19 confidence that this can work.

20 But also what I've just told you in the  
21 previous paragraphs it is sort of like the FDA  
22 administrators nightmare. We're out of space; we need

1 to hire more people; quite a few challenges here and  
2 all the while realizing something that I don't think  
3 people talk about enough the FDA's critical role in  
4 development, not just the evaluation of the final  
5 packages that come in. And I think industry has  
6 become very aware of this at these meetings that are  
7 so much in demand are a critical part of what the FDA  
8 does and what the industry does because what we all  
9 want as patients would be for the things that are not  
10 going to work to get weeded out quickly and things  
11 that will work to get sped along; and also for  
12 mistakes not to be made in the process of development.  
13 That is not in anyone's interest. And the ability of  
14 FDA to look at the entire picture of everyone coming  
15 through gives us a lot of expertise which is highly  
16 valuable to society. So it is exciting to see the  
17 demand for all these meetings and all these people but  
18 it is a challenge for us and I think the user fee  
19 negotiations are really a critical part to give us the  
20 resources that we need.

21 So the reauthorization package with industry  
22 occurred through a process of again with a public

1 meeting in December 2015 where we heard views from  
2 many of the same people who are in the room today  
3 about your experiences during the first iteration of  
4 BsUFA and expectations for the future of the program.

5 Over the past several months FDA has been in  
6 the process of developing a set of proposed  
7 recommendations for reauthorization of BsUFA. We are  
8 pleased to have the chance to discuss the proposed  
9 recommendations with you today. The recommendations  
10 represent a strong and comprehensive set of  
11 enhancements and refinements to the BsUFA program.  
12 And include enhancements in several areas and I'll  
13 just list a few of them here:

14 Application review, for example establishing  
15 a review model for biosimilars similar to the program  
16 under PdUFA for New Molecular Entity New Drug  
17 Applications and original biologic license  
18 applications and aligning the BsUFA goal for prior  
19 approval of manufacturing supplies with the goal  
20 timeframes from PdUFA.

21 Secondly enhancements to improve meeting  
22 management.

1 Third the commitments to development of new  
2 guidances for industry.

3 Fourth the enhanced capacity for guidance  
4 development, review or training, and timely  
5 communication.

6 And I'll just say I've gained a keen  
7 appreciation too for the importance of a variety of  
8 tools to increase communication across the industry,  
9 the patient advocates and the FDA not only about the  
10 rules of the game but also the knowledge base that  
11 leads to successful and useful product development.

12 And then finally management of BsUFA  
13 resources including measures for financial  
14 transparency and efficiency; something we are working  
15 on across the FDA.

16 Our goal is to submit the package of  
17 proposed recommendations to Congress by the end of the  
18 calendar year to support timely reauthorization of  
19 this program.

20 You will hear more about the proposed  
21 recommendation throughout the course of the meeting.

22 We are excited about the future of BsUFA and

1 look forward to hearing your views on the proposed  
2 recommendations.

3           Although I've got to run to a meeting  
4 downtown I'll be very interested in what's said today  
5 but having looked at this and worked with the team  
6 here I think we are in really great shape and look  
7 forward to any feedback on tweaks and improvements  
8 that you can see.

9           So thanks and have a great meeting.

10           DR. ROACHE: Thank you Dr. Califf. We are  
11 very happy that you were able to get us started today.  
12 I would now like to turn the meeting over to Dr.  
13 Theresa Mullin to provide some background on the  
14 Biosimilar User Fee Act.

15           BsUFA BACKGROUND AND REAUTHORIZATION PROCESS

16           DR. MULLIN: Thank you, Amanda.

17           Good morning. So I'm going to go through  
18 this. I noted on the Archives Building downtown that  
19 across the top engraved in the building it says "past  
20 is prologue" and you know, of course, how appropriate  
21 for the Archives Building but we thought we would just  
22 call this section by that name because for those of

1 you and maybe everyone here does follow BsUFA very  
2 closely and so this is going to be material that is  
3 very well known to you and you don't really need to  
4 hear it again. But we're going to go through and give  
5 you a little bit of a recap of the start of the  
6 authorization of biosimilars in that first program and  
7 what we were thinking of at the time and how we set it  
8 up the way we did because that is really the launching  
9 from our discussions of what to do next.

10 And this is just to review the provisions in  
11 the Statute for reauthorization of BsUFA. We've been  
12 following it very closely as we do with all the  
13 provisions that we have related to the different User  
14 Fee Programs. And they do vary a little bit.

15 This is still such a new program that the  
16 process is one that doesn't have all the provisions of  
17 a PdUFA program and it kind of makes sense. If you  
18 look around we don't have quite as much interest in  
19 it; there aren't as many products on the market yet  
20 and so on, although we are getting a good start now.

21 And so we began the process with a meeting  
22 that we had last December, December 18, 2015, where we

1 had initial consultation with the public about the  
2 program and about proposed areas for enhancement of  
3 the program. And you may have joined us at that  
4 meeting as well and provided your views then.

5 We analyzed the comments in the docket as  
6 well as what we heard in the meeting to get ready for  
7 negotiations which we started in March knowing that  
8 the same timeframe for getting the package to Congress  
9 was there for this program as for all the other User  
10 Fee Programs we worked to try to conclude those  
11 negotiations by about the end of May so that we could  
12 get the package put together for Agency ratification;  
13 industry indicated that it needed to take it and  
14 indicated that it needed to have a process and the  
15 summer is a hard time to get your senior leadership  
16 together sometimes. We then put it through a process  
17 of clearance, a review clearance by the  
18 administration.

19 And here we are today; this meeting marks  
20 one of the final milestones of this process at least  
21 as far as FDA carries it which is to hear the public  
22 comments on the package of proposed recommendations.

1 We'll again analyze the comments that we receive to  
2 the docket. We will analyze what we hear in this  
3 meeting today to see if any revisions need to be made  
4 and make any as necessary so that we can conclude this  
5 process and get the package along to the authorizing  
6 committees.

7 I was just in a session yesterday where I  
8 was able to hear the Senate senior staff on the  
9 committee indicating that you know they see challenges  
10 too this year because it is a rather unique set of  
11 circumstance for the reauthorization of these User Fee  
12 Packages because we have an administrative change  
13 occurring in January as well as transmitting and  
14 potential leadership change in Congress as well. So  
15 it creates some additional challenges for them.

16 But just to go back a bit and start with how  
17 this program got started. So the Biosimilar Price  
18 Competition and Innovation Act which was basically  
19 passed in 2010, enacted in 2010 amended the FDCNA Act  
20 to add that abbreviated pathway for biosimilars 351(k)  
21 path. And this is in addition to of course the 351(a)  
22 Innovator Biologic path. And the BPCIA also directed

1 FDA to come up with some recommendations for User Fee  
2 support for this program. One possibility when it was  
3 first enacted we were instructed to cover it under the  
4 PdUFA User Fee Program and the question really was at  
5 the time in 2010 and 2011 was should we keep it as  
6 part of PdUFA or separate it out and have its own  
7 program. And I think there sense on the part of most  
8 of the parties involved in this discussion that it  
9 really was a different pathway and it merited its own  
10 program. And so we were instructed in any case to get  
11 our recommendations to Congress within the same  
12 timeframe as those other programs that were being  
13 reauthorized or authorized like PdUFA for the first  
14 time. So we were trying to get it there within the  
15 same timeframe and so we had to work with the  
16 information we had.

17 And unlike the other User Fee Programs,  
18 unlike PdUFA, for example, with PdUFA there was a long  
19 history or at least a well established program that  
20 existed at the time that User Fees were first  
21 discussed in 1992.

22 And this on the left side of this chart you

1 see the volumes of workload coming in and what was  
2 there for PdUFA back in the early 1990s that gave us  
3 something in fact to work with as far as a fee  
4 structure goes and even trying to estimate the level  
5 of effort that would be involved or how much  
6 additional might be helpful to add to the non-fee  
7 funds so that we could figure out how to improve the  
8 process.

9 We had no history like that, of course, with  
10 BsUFA because biosimilar program was brand new; these  
11 products were new. There were no approved products at  
12 the time. There were no establishments making those  
13 products of course, no marketed products. And so we  
14 had some programs in development. We had some IND  
15 phase work going on. We had very little non-fee  
16 funding. We received some funding to go toward  
17 biosimilar so we could use it for that in fiscal year  
18 2011, non-fee funding of \$1.8 million so there really  
19 was no other existing funding stream to cover this  
20 program.

21 And that created a lot of challenges for us.  
22 And it wasn't really that helpful to look at the

1 projections of what would be coming because they were  
2 all over the place; most of them very, very optimistic  
3 and as we got -- if you go back a few years before  
4 2010 they were even more optimistic and then they were  
5 adjusted downward a little bit by the time we got to  
6 2010 and 2011 but still we thought what is the  
7 trajectory for these products. We knew there would be  
8 a lot probably in development but we didn't know how  
9 much would be coming through to be a marketing  
10 application. And so that uncertainty really effected  
11 what we did and how we figured out how to get started.  
12 And we all I think the people involved in talking  
13 about this and the consultations that we did really we  
14 thought we might as well start with something that we  
15 know.

16           What do we know? Well, we thought that the  
17 biosimilar application review would be similar in the  
18 level of effort required to that of a biologic, a new  
19 biologic, a 351(a). We thought we had to get some  
20 funding stream going during the development phase to  
21 be able to hire anybody to help even with development.  
22 So we couldn't wait for marketing applications if

1 PdUFA structure was almost all the first fees that a  
2 sponsor would pay is at the time of the marketing  
3 application submission. That wasn't going to work  
4 with biosimilars.

5 And so we had this structure, fee categories  
6 of a biosimilar product development fee and that would  
7 be paid annually. We tried to peg it to the PdUFA fee  
8 structure by saying okay ten percent of the NDA BLA  
9 application fee for that year would be what the BPD  
10 fee would be. And that would be for an active IND  
11 program under way for a 351(k). We wanted to  
12 encourage people to stay in the program. This would  
13 also help the funding stability. So there was a re-  
14 activation fee to sort of encourage sponsors to stay  
15 in the program once they were there.

16 And then there was the application fee when  
17 a marketing application would come in for a 351(k).  
18 And at the time we thought this is, you know, 2010,  
19 2011 at that time we thought this would be a pretty  
20 quick process; we thought there might be a year or two  
21 in development and then we'd get the applications. So  
22 and we didn't know how active people would be in

1 asking for meetings during the development phase. So  
2 we set the fee -- marketing application fee equal to  
3 the PdUFA fee at that time and subtracting out and  
4 netting out from that what they had paid during the  
5 IND phase.

6 And there was a supplement fee like the  
7 supplement fee for PdUFA application for a submission  
8 with clinical data. And for marketed products the fee  
9 structure we went with would be the same as PdUFA and  
10 that was our standard; that is what we referenced at  
11 the time, not really knowing how much this program  
12 would generate in terms of work and what it would  
13 cost.

14 So for goals we tried to again pattern it  
15 similar to the New Drug or the 351(a) submissions so  
16 that companies would not feel disadvantaged by the  
17 goal commitments of 351(k). We wanted it to be an  
18 attractive pathway. And so we have -- we tried to  
19 ramp up as quickly as possible to the 90% goal in ten  
20 months for review of a 351(k) application. And the  
21 resubmissions 90% in six months and that is where we  
22 are this year.

1           You can see the schedule for the BPD types  
2     1, 2, 3, and 4. We anticipated we'd get a lot of type  
3     3 because that is the most substantive kind of  
4     discussion and a larger submission would be made and  
5     we wanted to ramp up to these goal timeframes to 90%  
6     by 2017 as well. And again this is patterned somewhat  
7     like PdUFA.

8           So we've had a number of learnings and  
9     observations about how the program is going and one of  
10    the things that has come up is that there has been a  
11    convergence and the emergence of novel legal issues  
12    and complex scientific issues that come up sort of at  
13    the same time in the course of these development  
14    programs. And those issues I think are still  
15    surfacing. It is not things we well anticipated that  
16    we could have produced guidance ahead of time. We're  
17    in a sort of a learning and it is a bit of a real time  
18    kind of problem solving mode that involves both legal  
19    expertise and various kinds of scientific discipline  
20    expertise. And this means that FDA has to have a lot  
21    of thorough consultation internally among those  
22    experts in order to give consistent advice to the

1 companies that are coming in and seeking meetings with  
2 these kinds of issues being raised.

3           And the next thing you see here is just some  
4 examples of statistical issues are different for  
5 biosimilars than they would be for new drugs or new  
6 biologics. The CNC packages are we're told by our  
7 Office of Biologic Products even at least as complex  
8 as for a 351(a). And the Regulatory Project Managers  
9 have the extremely difficult job of trying to schedule  
10 this work because the clinical expertise that is  
11 involved in this work and the other expertise comes  
12 from the same divisions, the same organizations as for  
13 the new drugs. And we've had hiring challenges and  
14 difficulties in both areas. So we've been  
15 understaffed in both programs trying to get the time  
16 from people's calendars to plan these meetings where  
17 they can get together and talk before and then during  
18 a meeting with sponsors has been extremely difficult  
19 to do. And as I said that plus the complexity of the  
20 issues have created challenges for the Biosimilar  
21 Program.

22           And we have -- I mean the good news the

1 challenge is the volume but the good news is there is  
2 a lot of volume, a lot of good growth in this program.  
3 There are now 66 programs enrolled in the BPD program.  
4 And those are to develop against 20 different  
5 reference products. And so that is really good for  
6 the biosimilar industry; really good for the  
7 biosimilar product portfolio that might be out there  
8 for patients in the future.

9           And we've had a lot more meeting requests.  
10 It is good people have found these meetings helpful.  
11 That is pretty obvious by the increase in demand. It  
12 is more than we expected; so meeting requests have  
13 gone up over 80% in the first three years of the  
14 program. Our scheduled meetings are up almost 70%  
15 over that time period. And even for those where we  
16 don't have meetings FDA has typically given written  
17 advice to those sponsors because we do want to advance  
18 the development of these products. But it has been  
19 more than we expected, let's just say. There's been  
20 more demand that we expected.

21           And this is to give you a sense of the  
22 composition of those meetings. You can see the vast

1 majority are that Type 2 meeting, it is a 75 day clock  
2 and the others are pretty evenly spread out. Not very  
3 many Type 3 meetings but this is to show I think that  
4 sponsors had found it helpful to come in and navigate  
5 issues by talking to FDA.

6           And with the limited capacity among the  
7 staff that we have on board and the ramping up of the  
8 timeframe and the demand for those meetings you can  
9 not surprisingly we've not been able to meet the  
10 timeframes that we had committed to. So we've been  
11 able to only schedule about half of the initial  
12 advisory meetings within the 90 day meeting goal.  
13 We've only been able to do about 67% of the Type 1  
14 meetings within that 30 day timeframe; only able to  
15 schedule a Type 2 49% of the time. We do have these  
16 meetings; we can't meet them in the timeframes that  
17 were originally discussed and we hope to get to. And  
18 we haven't had that many of the Type 4 meetings but we  
19 have not been able to meet the Type 4 timeframe  
20 either.

21           Despite this industry had been telling us  
22 going into this process that these meetings are

1 extremely valuable and, of course, they would like  
2 more meetings and they wanted a faster turnaround from  
3 FDA. So that is part of what fed into this process  
4 and where we are going with our recommendations for  
5 BsUFA II.

6 Before we go on and Dr. Califf did mention  
7 this but just to go back and say we have despite the  
8 challenges had a number of successes already that can  
9 be described. So the first biosimilar was approved in  
10 the U.S. Zarxio in March of 2015; and since then three  
11 other biosimilars, Inflectra, Erelzi, and Amjevita  
12 have been approved. We have issued as he said four  
13 final guidances and five draft guidances and so the  
14 program is moving along and we want to build on the  
15 success to date and that is where Leah, Dr. Leah  
16 Christl, is going to tell you about the enhancement.

17 I don't know if I was supposed to introduce  
18 her.

19 Thank you.

20 FDA PRESENTATION ON PROPOSED COMMITMENTS FOR BsUFA II:  
21 PROGRAM ENHANCEMENTS

22 DR. CHRISTL: Good morning. My name is

1 Doctor Leah Christl. I am the Associate Director for  
2 Therapeutic Biologics in the Office of New Drugs and I  
3 facilitate the Biosimilar Program for CDER.

4 So I'm going to walk you through the  
5 proposed enhancements that are a part of BsUFA II. As  
6 we moved into negotiations for BsUFA II we took a hard  
7 look at what we had in BsUFA I; how things were going.  
8 We surveyed our staff internally as to what was going  
9 well, what wasn't going well. We had our own  
10 experiences with industry. My staff had their own  
11 feedback from biosimilar sponsors and interactions  
12 through the BsUFA I process and even before BsUFA I  
13 implemented. So we tried to get as much feedback as  
14 we could and really take a hard look at the program  
15 and where we thought that enhancements could be made  
16 because things can always be better.

17 So there are a number of enhancements that  
18 are in BsUFA II. They are listed here. But I will go  
19 through each one of them individually for you.

20 So one of the learnings that we had from  
21 BsUFA I was the value of the iterative process that we  
22 had established during the development phase and

1 working through these BPD meetings and having a number  
2 of touch points for communication and having those  
3 opportunities that were there to do that.

4 And we had some experience moving into the  
5 negotiations for BsUFA II with application review.

6 And based on our experience we saw the value of  
7 communication not just in the development phase but  
8 also in the application review phase. So when we  
9 thought about how to do that, we looked to what is  
10 known as the program under PdUFA and this is an  
11 application review model under PdUFA that's for New  
12 Molecular Entity NDAs and original BLAs.

13 And that program intends to promote  
14 efficiency and effectiveness of the first cycle review  
15 process; so that first review plan from the submission  
16 to when the goal date would have been. And minimize  
17 the number of review cycles that were necessary for  
18 approval of a product. So what we've done in BsUFA II  
19 is that we've adopted that same model for the program,  
20 for the 351(k) BLAs under BsUFA II.

21 So again as I had spoken about we understood  
22 the value of these communication touch points and the

1 opportunity for additional interactions between FDA  
2 and the sponsor, so there are number of parameters  
3 that are in the program and they are listed here but  
4 some of them include a pre-submission meeting where  
5 FDA and the sponsor can talk about an agreement of  
6 what the content of a complete application is; talk  
7 about expectations for how the review is going to go;  
8 expectations for timings; and really give some  
9 transparency around the process.

10 It also includes review performance goal  
11 that is ten month user fee clock which starts at a 60  
12 day filing date. So while the standard review clock  
13 was applied during BsUFA I which was a ten month  
14 review clock; under the program it will be a 12 month  
15 review clock in total.

16 It also includes mid-cycle communication and  
17 a late cycle meeting with the sponsor. Again those  
18 are those additional communication touch points  
19 between FDA and the sponsor where FDA will share  
20 information during the review process; give an  
21 opportunity for communication as to how the review is  
22 going; where deficiencies have been identified; and

1 hopefully again be able to support the first cycle  
2 review process through those communications and  
3 providing opportunities for transparency and for  
4 issues that can be fixed to be fixed.

5 The review activities are consistent with  
6 21st Century Review for the program that is currently  
7 under PdUFA. So we will be revising the 21st Century  
8 Review process to include BsUFA as well.

9 And this additional two month review clock  
10 timeframe again we are shifting from a ten month  
11 review to a 12 month review is intended to provide FDA  
12 more time to complete additional late cycle activities  
13 that are part of this review process which can include  
14 that late cycle meeting that I spoke about and then  
15 also to address other late cycle review work such as  
16 any deficiencies that may be able to be addressed  
17 within that first cycle. If there is advice that  
18 comes back from the advisory committee discussion if  
19 we do take an application to an advisory committee and  
20 also inspectional issues. And again this is all in an  
21 effort to improve the efficiency of the first cycle  
22 review.

1           The next enhancement deals with the  
2 opportunity for FDA to apply a review goal extension  
3 related to the inspection of facilities that were not  
4 adequately identified in the original application or  
5 supplement.

6           So this is an enhancement that parallels  
7 what exists already in PdUFA and this is intended to  
8 have parity amongst all of our application reviews for  
9 NDAs and BLAs whether they are 351(a) BLAs or 351(k)  
10 BLAs. And this also gets into the concept of a  
11 complete application.

12           So for this enhancement all original  
13 applications and supplements will be expected to  
14 include a comprehensive and readily located list of  
15 all manufacturing facilities included or referenced in  
16 the application or supplement. FDA needs this list  
17 and needs to have it easily identified in terms of the  
18 facilities that need to be inspected so that we can  
19 make sure that right from the beginning receiving an  
20 application that we're working towards scheduling. A  
21 lot of facilities are outside the U.S.; that can be  
22 challenging in terms of timing, getting travel booked,

1 getting other things put together. And so having this  
2 list is very helpful to make sure that we know what we  
3 need to inspect. There isn't a facility that we've  
4 missed that is maybe someplace else in the application  
5 that we didn't see and didn't identify; that can  
6 certainly lead to issues if that is identified late in  
7 the review cycle. It could be too late to schedule a  
8 facility inspection in a timely fashion.

9           So with this enhancement again this  
10 parallels what already exists under PdUFA if FDA's  
11 review of an original application or supplement -- if  
12 during that review we identify a facility that was not  
13 included in this list the goal date could be extended  
14 for three months for an original application or  
15 supplement with clinical or by two months for a  
16 manufacturing supplement.

17           In BsUFA I we had a provision for Special  
18 Protocol Assessment and agreement. The language that  
19 was included in the goals that are BsUFA I that talked  
20 about which protocols would be eligible for this  
21 Special Protocol Assessment or SPA review indicated  
22 that it would be any necessary clinical study or

1 studies to prove biosimilarity or interchangeability.  
2 But in thinking about what we had learned from BsUFA I  
3 and our interactions with sponsors in that development  
4 phase we realized that there was some additional  
5 clarity that would be helpful around what was eligible  
6 for an SPA review and what we really meant by  
7 necessary clinical studies to prove biosimilarity or  
8 interchangeability. So the text that shows in bold  
9 and underlined is text that is added for BsUFA II to  
10 provide this clarity. And it includes protocols for  
11 pharmacokinetic and pharmacodynamic studies. We say  
12 that these PK and PD studies where PD is relevant are  
13 pivotal as a part of the biosimilar development  
14 program and the demonstration of biosimilarity. So  
15 because these studies are considered necessary  
16 clinical studies to support biosimilarity or  
17 interchangeability we wanted to make clear to sponsors  
18 as well as FDA reviewers and other stakeholders that  
19 these protocols would be eligible for this Special  
20 Protocol Assessment review.

21 So this enhancement is really an issue of  
22 clarity and transparency. The goal date didn't

1 change; it still has a 45 day review clock. This is  
2 also the same review parameter under PdUFA for Special  
3 Protocol Assessments. But we just wanted to provide  
4 this clarity to make sure folks knew which types of  
5 clinical protocols were eligible for review.

6 This next addition is where we move into the  
7 enhancements around meeting management. As Dr. Mullin  
8 had gone through we have a number of meetings; we have  
9 many more meetings than originally projected and  
10 anticipated. We have certain types of meetings that  
11 are more requested versus other types of meetings.  
12 But one of the things that she noted was that in some  
13 cases where we don't grant a meeting or we would deny  
14 a meeting considering it to be unnecessary based on  
15 the questions that were asked FDA has tried to provide  
16 a written response. But one of the things that we  
17 thought about as we moved into BsUFA II was that when  
18 we do that there is no structure that is around that.  
19 There were no goal dates, it is no longer considered a  
20 meeting, and so in terms of looking at prioritizing  
21 the limited resources that we had to put towards BsUFA  
22 and biosimilar product development in review without

1 something having a goal date as folks know sometimes  
2 it gets shuffled in the mix of work. And so both FDA  
3 and regulated industry had this discussion about how  
4 we could provide another option where a face-to-face  
5 meeting or a teleconference really wasn't necessary.  
6 Maybe it was a single question that was very important  
7 to a sponsor to answer but it really didn't  
8 necessitate all the resources and all the time and all  
9 the work that would go into scheduling a meeting,  
10 holding a meeting, needing to do meeting minutes; so  
11 we wanted to try to find another option. Under PdUFA  
12 there is an option for a written response only  
13 meeting. And that has its own characteristics and its  
14 own timeframes. And so we looked to that model and  
15 then had proposed an enhancement to add a written  
16 response meeting format for the Biosimilar Initial  
17 Advisory meeting and the BPD Type 2 meetings under  
18 BsUFA.

19           These are the types of meetings where we, in  
20 our experience, think that a written response option  
21 is feasible and could be most valuable. That BPD Type  
22 3 meeting that is a very comprehensive meeting that

1 has to deal with data review really under no  
2 circumstances is going to lend itself to simply a  
3 written response; it is a very comprehensive meeting  
4 and we think that that still needs a face-to-face  
5 meeting. So here we really did try to limit it to  
6 where we thought that there could be value added in  
7 the meeting process.

8           So with this enhancement for the BIA and BPD  
9 Type 2 meetings a sponsor may request a written  
10 response to questions rather than having a face-to-  
11 face meeting, videoconference, or teleconference.  
12 Once that request is submitted FDA will review it and  
13 make a determination of whether a written response is  
14 appropriate or whether we think that a face-to-face  
15 meeting, videoconference, or teleconference is  
16 necessary. There are times, of course, that someone  
17 might think that it is a very quick question and a  
18 very easy answer but it might involve a complex  
19 scientific, regulatory, or legal issue and we think  
20 that a face-to-face discussion would be helpful in  
21 order to have that exchange rather than giving a  
22 written response that we think would potentially

1 generate the need for additional feedback. We didn't  
2 want to cut off the opportunity for that or add time  
3 to a sponsor's development program to receive a  
4 written response and then need to come in and request  
5 an additional meeting. So we'll try to identify where  
6 we think a written response is appropriate and where  
7 we think maybe the face-to-face interaction is really  
8 more necessary.

9           If a written response is deemed appropriate  
10 FDA would notify the sponsor of the date it intends to  
11 send the response and there are goal dates that are  
12 associated for both the Biosimilar Initial Advisory  
13 and BPD Type 2 meetings in BsUFA of when we would  
14 target to send those written responses.

15           The next enhancement is also a part of the  
16 meeting management enhancement under BsUFA II and this  
17 has to do with reducing the scheduling timeframe for  
18 the Biosimilar Initial Advisory meetings. So under  
19 BsUFA I the timeframe for scheduling a BIA meeting was  
20 90 days from the receipt of the meeting request and  
21 the meeting package. Under BsUFA II the proposal is  
22 that these BIA meetings will occur within 75 calendar

1 days. And if you will remember from Dr. Mullin's  
2 presentation there were some issues with us meeting  
3 the goal date for the Biosimilar Initial Advisory  
4 meeting even on the 90 day clock. But through our  
5 discussions during negotiations we think that we can  
6 manage having this shorter timeframe based on capacity  
7 planning, boosting the resources in the program, and  
8 also having a good focus on what should be covered in  
9 a Biosimilar Initial Advisory meeting which is really  
10 a meeting to discuss with the sponsor whether they  
11 have a produce that is appropriate to develop as a  
12 biosimilar. So these BIA meetings are not intended to  
13 be comprehensive scientific meetings that really gets  
14 into the meat of a development program; it is really a  
15 first pass if a sponsor has questions about whether  
16 they really have a product that is appropriate to  
17 develop as a biosimilar and for FDA to maybe give some  
18 initial advice about how to get started in that  
19 program. So we think with that renewed focus on what  
20 a BIA meeting really should be in addition to capacity  
21 planning that we can work to meet this goal.

22 This next one is also an enhancement around

1 meeting management. This has to do with increasing  
2 scheduling timeframe for the BPD Type 2 meetings and  
3 this does have a phased in performance goal. So as  
4 was noted in Dr. Mullin's presentation the most common  
5 meeting that we have is the BPD Type 2 meeting. She  
6 also noted that we have a number of novel scientific,  
7 regulatory, and legal issues that are coming up with  
8 this program. When the BPCI Act first passed our  
9 Center Director Dr. Woodcock said that what we were  
10 doing is we were essentially open for business the day  
11 that the legislation implemented and that we were  
12 essentially building the plane while we were flying it  
13 and crossing our fingers and hoping for the best. And  
14 so again a lot of these novel regulatory, legal, and  
15 scientific issues are coming up in the development  
16 programs through our conversations with sponsors,  
17 through ideas that they are coming forward with in  
18 terms of really pushing the envelope on the science,  
19 having enhancements that are there, you know we've  
20 issued guidance on a number of topics but there is  
21 always other possibilities of how to demonstrate  
22 biosimilarity. And we need to consider those

1 proposals, discuss them internally, and making sure  
2 that we are really giving comprehensive, well thought  
3 out advice to sponsors.

4           So being that these BPD Type 2 meetings is  
5 the most common meeting that we have and really where  
6 we're having all those activities we had found  
7 ourselves in BsUFA I many times not only not being  
8 able to meet the goal because of the conversations  
9 that we needed to have but if we did really push to  
10 meet the goal we weren't always providing  
11 comprehensive responses. There might be responses  
12 where we said we will have to follow up with a post  
13 meeting addendum or we need additional time for this.  
14 So what we wanted to do is extend this timeframe for  
15 the BPD Type 2 meetings. The original date in BsUFA I  
16 was a 75 day goal. In BsUFA II it is proposed with a  
17 90 day goal. And we are hoping there again through  
18 capacity planning as well as having this additional  
19 time the Agency will be able to provide more  
20 comprehensive responses to sponsors during their  
21 development program to keep those programs moving  
22 forward in a timely fashion. Again this does have a

1 phased in goal throughout the course of BsUFA II  
2 beginning at an 80% goal and then ramping up to a 90%  
3 goal by 2020.

4           With this there is also an agreement that  
5 the Agency will send preliminary responses to the  
6 sponsor's questions contained in the background  
7 package no later than five days before the face-to-  
8 face, videoconference, or teleconference meeting; but  
9 only for BPD Type 2 and BPD Type 3 meetings.

10           The next enhancement is for prior approval  
11 manufacturing supplements. In BsUFA I we had a goal  
12 date for all supplements that were supplements that  
13 didn't contain clinical data of six months. This was  
14 a different timeframe than the goal dates for certain  
15 types of supplements under PdUFA. Again because the  
16 same folks are working on PdUFA products and BsUFA  
17 products having this difference as we moved into  
18 having products that were approved and coming on the  
19 market in this space and looking at post approval  
20 manufacturing changes that could occur we wanted to  
21 create some parity between the 351(a) and 351(k) BLA  
22 review. So we proposed here that prior approval

1 manufacturing supplements will be reviewed in four  
2 months instead of the six months goal that was in  
3 BsUFA I. This does have a phased in performance goal.  
4 Again we're just moving into our product approval and  
5 having products that are coming on the market. So we  
6 did negotiate for a phased in performance goal around  
7 this for the four months and up to 90% by the end of  
8 BsUFA II.

9 This review timeframe again aligns with the  
10 goal for the same types of supplement under PdUFA so  
11 there is parity between the review programs.

12 BsUFA II also includes a number of new  
13 guidance commitments. Because we are changing some  
14 aspects of meeting management we do have a final  
15 guidance that was published on formal meetings between  
16 FDA and biosimilar biological product sponsors or  
17 applicants. We will need to update that guidance so  
18 there is a guidance commitment that we will update  
19 this guidance no later than September 30 of 2018.

20 We've also committed in BsUFA II to update  
21 the current draft guidance on best practices for  
22 communication between IND sponsors and FDA during drug

1 development. This applies to communications between  
2 IND sponsors and FDA during biosimilar biological  
3 product development and we did commit to updating this  
4 guidance either a revised draft or a final guidance by  
5 December 31 of 2018. This is a guidance that already  
6 exists; this is a practice that we have applied to  
7 PdUFA products in terms of the best practices for  
8 communication. We wanted to adopt this for the BsUFA  
9 program as well to have these additional communication  
10 methods and outline expectations; again give  
11 transparency to FDA and to sponsors about those  
12 communications.

13           So while we have the meeting management  
14 process opportunities for written request there are  
15 other communications that go on between FDA and  
16 sponsors during the development phase. So we wanted  
17 to add the BsUFA products to this best communication  
18 practices guidance during development so there is not  
19 just parity between the programs but we are again  
20 providing opportunities for communication and folks  
21 understand how to move through that process during the  
22 development phase.

1           This is a list of the additional guidances  
2           that we have goal dates for in BsUFA II. So as was  
3           stated we have some guidances that we've already  
4           published either in final or draft. And as folks  
5           likely who are familiar with the program would know  
6           there are a number of guidances that we've talked  
7           about either on the CDER guidance agenda for any given  
8           calendar year and so there is a mix of guidance  
9           commitments in here around the types of guidances that  
10          we've already discussed.

11           So the first one is that there is a  
12          commitment for issuing guidance on consideration for  
13          designating biosimilar biological products as  
14          interchangeable to a reference product. We do have a  
15          commitment to issue a draft on or before December 31  
16          of 2017 and then a revised or final guidance 24 months  
17          after the close of the public comment period. So if  
18          FDA issued the guidance prior to December 31, 2017,  
19          then the comment period would begin when that was  
20          issued and then within 24 months after the close of  
21          the public comment period FDA has committed to issuing  
22          revised or final guidance within 24 months of that

1 period.

2           The next one is the statistical  
3 considerations for analytical similarity for  
4 biosimilar biological products. There is a commitment  
5 to issue a draft on or before December 31, 2017, and  
6 then revised or final guidance 18 months after the  
7 close of the public comment period. So again just as  
8 with the first one if we issue the guidance before the  
9 December 31, 2017, period we would then look at  
10 issuing revised or final guidance 18 months after the  
11 close of that public comment period. And the public  
12 comment period would go off of whenever the guidance  
13 was published.

14           The next one deals with processes and  
15 further considerations related to post-approval  
16 manufacturing changes for biosimilar biological  
17 products. We recognize this is most valuable guidance  
18 to sponsors. This was something that was discussed.  
19 Now that we have product approvals and we have a  
20 number of development programs that are moving into  
21 the pre-application stages it is important to think  
22 about next steps for these products in the marketplace

1 and their life cycle management.

2 So we have a commitment in BsUFA II to issue  
3 a draft guidance on this topic on or before March 31  
4 of 2019, and then revised or final guidance 18 months  
5 after the close of the public comment period.

6 The next three guidances are guidances that  
7 we have already published in draft and there are  
8 commitments for the clinical pharmacology guidance,  
9 the non-proprietary naming guidance, and the labeling  
10 guidance to issue revised or final guidance on or  
11 before May 31 of 2019 for those three guidances that  
12 we've already issued in draft.

13 One of the other enhancements deals with  
14 capacity building and we've touched on this a little  
15 bit in terms of what we need to do for this program  
16 overall in terms of not just guidance development but  
17 reviewer training as well as timely communication. So  
18 the enhancements that we've gone through factor into a  
19 number of these in the guidance, timely communication  
20 and what it is that we are trying to do. So in order  
21 to meet our commitments and the goals that we've  
22 agreed to in BsUFA II FDA is committed to strengthen

1 staff capacity; to develop any new regulations that  
2 may be considered necessary as well as guidance; to  
3 clarify scientific criteria; to develop or revise any  
4 maps or SOPs; and also review templates for  
5 application review; to deliver timely information to  
6 the public; to improve public understanding of  
7 biosimilarity and interchangeability. We already have  
8 active education program, we've already engaged with  
9 some contractors. We understand FDA's role in this  
10 space of doing education and outreach to the  
11 prescribing community, patient community and other  
12 stakeholders. And so we have committed to  
13 strengthening staff capacity in that area as well.

14 And also to deliver information concerning  
15 the data first licensure and reference produce  
16 exclusivity expiry date to be included in the purple  
17 book. There are provisions in the BPCI Act related to  
18 when a biosimilar applicant can submit their  
19 application for review and then FDA can accept that  
20 application for review and then also when FDA could  
21 approve a biosimilar application. So we understand  
22 FDA's role in providing information about the date of

1 first licensure for reference product because those  
2 dates that are in the BPCI Act regarding our ability  
3 to accept an application and approve an application  
4 are driven off of the exclusivity period for the  
5 reference product. So biosimilar sponsors as well as  
6 other stakeholders definitely have an interest in  
7 knowing those expiry periods for the reference  
8 products and be able to calculate those dates as a  
9 part of their portfolio management and then also  
10 expectations for when products could be coming on the  
11 market.

12 And at this point I'm going to turn things  
13 over to my colleague Josh Barton to finish up with a  
14 couple of capacity enhancements and then he will move  
15 into the financial enhancement section.

16 FINANCIAL ENHANCEMENTS

17 DR. BARTON: Good morning. My name is Josh  
18 Barton with CDER's office of Strategic Programs. I  
19 supported the financial aspects of the BsUFA II  
20 negotiations and I'll walk through some of the  
21 administrative enhancements that are envisioned for  
22 BsUFA II.

1 I'll preface this by saying that there is a  
2 recognition really for maybe the first time going into  
3 this UFA cycle that the administrative aspects of the  
4 program are really critical to insuring the success of  
5 the program. So there are a number of enhancements  
6 here if you are familiar with PdUFA VI, the proposed  
7 recommendations there, there are a number of  
8 commonalities as there is a common infrastructure here  
9 to support these programs.

10 The first area is around enhancing hiring  
11 capacity recognizing that in order for the program to  
12 be successful we need to insure that we are able to  
13 hire and retain appropriate numbers of qualified staff  
14 to insure the success of the program. So we've  
15 committed to modernizing the hiring system and  
16 infrastructure, augmenting human resources capacity  
17 through the use of dedicated expert contractors; this  
18 it to really help move the freight through the hiring  
19 system; establishing a dedicated function for the  
20 recruitment and retention of scientific staffing;  
21 setting clear goals for hiring; and conducting a  
22 comprehensive and continuous assessment of hiring and

1 retention practices.

2 In terms of enhancing management of  
3 resources in BsUFA II we've committed to establishing  
4 a capacity planning function utilizing modernized time  
5 recording. The goal here is really to enhance our  
6 ability to be able to conduct rigorous and robust  
7 assessments of our resource needs both today and  
8 looking forward into the future. And this is common  
9 also with PdUFA as this will be a common  
10 infrastructure and the economy of scale here that will  
11 support both programs.

12 We also have commitments around enhancing  
13 financial transparency and efficiency. We've  
14 committed to a third party assessment to evaluate the  
15 financial administration of fee resources under BsUFA  
16 and to help provide us with ideas and best practices  
17 on how we could optimize administration of resources.

18 We've also committed to publishing a five-  
19 year financial plan for BsUFA as well as updating that  
20 five-year plan on an annual basis.

21 We've also committed to convening a public  
22 meeting starting in FY19 so an annual public meeting

1 starting FY19 to discuss the five-year plan as well as  
2 the Agency's progress in implementing a modernized  
3 time reporting and the capacity planning function.

4 I'll now talk about some of the changes to  
5 the fee structure for BsUFA II. As Dr. Mullin  
6 mentioned earlier in establishing BsUFA I given that  
7 there is a lot of uncertainty with what the size of  
8 the program would be and what the program costs would  
9 be for BsUFA I there was in a sense a sort of place  
10 holder program put in place where BsUFA fees were  
11 referenced the PdUFA fees. Going to BsUFA II our  
12 goals included establishing an independent efficient  
13 user fee structure for BsUFA that was based on BsUFA  
14 program costs; as well as enhancing predictability of  
15 our funding levels and sponsor invoices; minimizing  
16 inefficiency by simplifying the administration of the  
17 program; and improving our ability to manage program  
18 resources and engage in long-term planning. And this  
19 is especially important with the federal government  
20 labor model and potentially long-term timeframes to  
21 hire new staff.

22 In terms of the fee structure there are a

1 number of commonalities here between BsUFA II and  
2 PdUFA VI recommendations. However, the fees for BsUFA  
3 II are envisioned to be built off of BsUFA program  
4 costs. So you will see a number of ways that these  
5 two programs are in alignment around the fees  
6 including in order to reduce volatility in collections  
7 and simplify administration we're proposing to remove  
8 supplement fee and establishment fee. We are  
9 proposing to retain the biological product development  
10 fees. Modifying the product fee, first by changing  
11 its name to the BsUFA Program Fee and that is really  
12 in recognition that there's a bit of a misperception  
13 amongst some stakeholders that the type of fee defines  
14 how the fee resources can be used. That is not true.  
15 All the different fee types are collected and can be  
16 used for all of the activities that are defined within  
17 the scope of the BsUFA program. So we've renamed the  
18 product fee the program fee.

19 We've also proposed a provision whereby  
20 sponsors cannot be assessed more than five program  
21 fees for the number of approved products under a  
22 single application and this is also common with PdUFA.

1           Modifying the application fee to discontinue  
2 the reduction of the application fee by the BPD fees  
3 paid for by that product. And this is really to help  
4 simplify administration, enhance predictability of  
5 collections, and will work because the application  
6 fees will really be based on BsUFA program costs of  
7 BsUFA II.

8           There is also proposed modification of the  
9 Statute so that sponsors are assessed the program fee  
10 based on the approved products as of October 1. So  
11 this will really help simplify administration. It  
12 aligns with PdUFA and it really helps us to minimize  
13 the need for multiple billing cycles which we call  
14 cleanup billing.

15           There is a modification to the Budget  
16 Authority Spending Trigger. This is really to help  
17 given the relatively small size of the program and  
18 there's still a fair amount of uncertainty in the  
19 level of the program costs from year to year,  
20 enhancing the flexibility around the spending trigger  
21 will help insure that we can collect and utilize the  
22 BsUFA fee funds to support the program. So the

1 proposal here is to consider the spending trigger met  
2 if costs funded by budget authority are not more than  
3 15% below the inflation adjusted amount for that year.  
4 So the spending trigger was set at \$20 million at the  
5 beginning of BsUFA I, so we will continue that with  
6 adjustments for inflation to set the trigger amount  
7 each year.

8           This flexibility provision, there is  
9 precedent in both PdUFA and GdUFA for having a  
10 mechanism along these lines to enhance the certainty.

11           So in establishing an independent fee  
12 structure we needed to establish a target revenue for  
13 the first year of the program. And given that it is  
14 still a maturing program and there is still some  
15 uncertainty about the size of the program from year to  
16 year this was a little bit of a challenge but we  
17 agreed that the program would likely need about \$45  
18 million in fee funds to cover program costs in FY18.  
19 However given the uncertainty when we set fees for  
20 FY18 which would be next summer we would have the  
21 ability to adjust the target amount if our analysis  
22 suggested that there would be a more optimal level for

1 that target revenue amount. We think it would likely  
2 be close to \$45 million. We've also established that  
3 there is an upward cap on the adjustment so this  
4 cannot increase more than \$9 million above that \$45  
5 million. And should we make an adjustment here we  
6 will explain the methodology and the rationale for  
7 that adjustment in the Federal Register.

8 To help enhance predictability of sponsor  
9 invoices we've agreed to a provision whereby the fee  
10 amounts that are set in FY18 cannot increase above  
11 that level more than 25% until a capacity planning  
12 adjustment is available which is FY21. So once the  
13 capacity adjustment is available we would remove this  
14 restriction so as not to arbitrarily constrain the  
15 results of the capacity planning adjustment.

16 Also to help smooth out any possible  
17 fluctuations in fee amounts and invoice amounts from  
18 year to year we have proposed a process whereby we can  
19 adjust the allocation of the target revenue to each  
20 fee type each year. If you are familiar with PdUFA  
21 and GdUFA there is a set percentage that each fee type  
22 is supposed to generate from the total target revenue

1 given as we've mentioned the relative uncertainty and  
2 small size if the BsUFA program having a fixed  
3 allocation could result in widely varying fee amounts  
4 from year to year so if you went from five  
5 applications one year to ten applications the next  
6 year you would see a significant change in the fee  
7 amounts. So we will adjust that allocation on an  
8 annual basis with the best information we have to help  
9 smooth out the fee amounts from year to year and still  
10 insure that we collect the target revenue amount.

11 To establish a fee structure we had to  
12 establish a process for setting the annual target  
13 revenue each year. So I'll talk through that here.  
14 There is a number, like I said a number of  
15 commonalities with PdUFA but this is tailored to BsUFA  
16 program costs. So we are proposing a process whereby  
17 the annual target revenue provides for an annualized  
18 base. In other words there is an amount that rolls  
19 forward each year that establishes the base revenue  
20 amount. We've adapted the PdUFA inflation adjustment  
21 methodology so that we can insure we account for  
22 inflationary costs in the program. However this will

1 be tailored to BsUFA program costs.

2 We will adapt a capacity planning adjustment  
3 that once effective will allow us to adjust fee  
4 revenue and fee rates to insure that the program is  
5 optimally resourced and to keep pace with increases in  
6 program and workload and costs. This will be  
7 established in the same manner that the PdUFA capacity  
8 planning adjustment will be established which will be  
9 through a review by an independent accounting or  
10 consulting firm that will assess our data and propose  
11 recommendations for the methodology for the capacity  
12 planning adjustment which will occur no later than  
13 FY20 so that we can first utilize that adjustment in  
14 FY21.

15 We are proposing to create an operating  
16 reserve adjustment. This is the general idea is  
17 similar to PdUFA but there are a few aspects that are  
18 particular to BsUFA. So the idea here is to insure  
19 the program can survive fluctuations in fee  
20 collections; avoid accruing unnecessarily high carry-  
21 over balances; and to mitigate any potential  
22 substantial increases in fee rates.

1           So until the capacity planning adjustment is  
2 effective we can use this operating reserve adjustment  
3 to reduce the fee revenue and fees in any given year  
4 as determined appropriate. Once the capacity planning  
5 adjustment is effective we may continue to reduce the  
6 fee revenue in fees if necessary but we also have the  
7 ability to increase the fee revenue in fees so that we  
8 can maintain a carry-over reserve not more than 21  
9 weeks of the target revenue which is about 40% of the  
10 annual target revenue.

11           And we've also committed in the commitment  
12 letter to reduce that carry-over balance to that level  
13 by FY22 and if we are unable to do so we will outline  
14 a plan about how we will go about to reduce the carry-  
15 over balance to that level and update the five-year  
16 financial plan.

17           So this flow chart just summarizes how the  
18 annual target revenue will be set each year so you can  
19 kind of see how this all plays together. So we have  
20 FY18 we start with \$45 million, we have that FY18  
21 potential adjustment if necessary to establish a  
22 target, that target amount for FY18 rolls forward to

1 establish FY19 base, then we have the inflation  
2 adjustment and then an operating reserve adjustment if  
3 necessary. The inflation adjusted amount would roll  
4 forward into FY20 in which we'd have the same process  
5 and then in FY21 the capacity planning adjustment  
6 would come on line and the capacity planning adjusted  
7 amount would establish the base revenue for subsequent  
8 years.

9 And I think that is it and we have a break.

10 DR. ROACHE: Okay. So thank you to our FDA  
11 presenters for providing some overview on the  
12 Biosimilar User Fee Act and an overview of the  
13 proposed enhancements for BsUFA II.

14 We are going to have our first break now.  
15 Before you head out I just want to remind people if  
16 you would like to comment during the Open Public  
17 Comment period please sign up at the registration desk  
18 which is right outside the door.

19 When we come back from our break we are  
20 going to hear from our Panelists from Panel 1 and  
21 Panel 2. I think we are a little bit ahead of  
22 schedule right now. So we will resume the meeting at

1 10:30 a.m.

2 BREAK

3 DR. ROACHE: Okay. It looks like we are  
4 missing a couple of people. So is there anybody else  
5 from the panels who would like to come up.

6 Is there anyone here from the National  
7 Center for Health Research who would like to comment?

8 Okay. We are a little bit ahead of schedule  
9 but we are going to go ahead and proceed and if our  
10 panelists show up they can join us as we proceed.

11 So the way I'd like to structure this is I  
12 will ask the panelists from Panel 1 to introduce  
13 themselves and then they can provide their remarks and  
14 then we will go on to Panel 2.

15 So I'll turn it over to our Panel 1  
16 panelists to introduce themselves.

17 MR. SPIEGEL: Good morning. My name is  
18 Andrew Spiegel. I am with the Global Colon Cancer  
19 Association and also representing the Alliance for  
20 Safe Biologic Medicines today.

21 MS. PURVIS: Hi, my name is Leigh Purvis. I  
22 am the Director of Health Services Research, AARP's

1 Public Policy Institute where I am responsible for  
2 developing and helping to guide AARP's policy on  
3 prescription drugs.

4 MS. GREENBERG: Good morning. I'm Sally  
5 Greenberg. I'm Executive Director of the National  
6 Consumers League.

7 DR. ROACHE: Okay. Thank you all for being  
8 here today. So we will get started with the  
9 perspectives from Panel 1 which will be the  
10 perspective from patient and public health advocates.  
11 So I'd like to turn it over to Andrew Spiegel.

12 PANEL 1 - PATIENT/PUBLIC HEALTH ADVOCATE PERSPECTIVES

13 MR. SPIEGEL: Thank you. And thank you for  
14 the opportunity to comment on this important  
15 legislation today. As the Executive Director of the  
16 Global Colon Cancer Association I speak on behalf of  
17 the 1.2 million patients who have colorectal cancer in  
18 the United States. The arrival of biosimilars to the  
19 U.S. promises to offer new treatment options to  
20 patients suffering from colorectal cancer as well as  
21 other cancers and other serious conditions such as  
22 Rheumatoid Arthritis, psoriasis and Crohn's disease.

1 The patient community is excited about the potential  
2 of biosimilars to reduce treatment costs but we are  
3 mindful that we cannot value speed at the expense of  
4 safety or the quality of biosimilars over their  
5 original reference product. Simply put we recognize  
6 that in order for patients to enjoy the benefits of  
7 biosimilars the FDA must always have the resources it  
8 needs to insure both a timely yet thorough review  
9 process.

10 The Biosimilar Use Fee Act was designed to  
11 do just that. The Act will help to enhance the  
12 regulation of biosimilars and provide important  
13 resources to further a sustainable biosimilar review  
14 program and it will do this by first supporting a  
15 science based implementation of the Biologic Price  
16 Competition Innovation Act of 2009 and regulatory  
17 decision making. Second enhancing regulatory  
18 transparency and efficiency that enable stakeholders  
19 to understand the basis for FDA decisions. And third  
20 by promoting the long-term stability of the BsUFA  
21 program through financial transparency, efficiency and  
22 accountability.

1           As patient advocates we are extremely  
2 encouraged by the success of BsUFA and promoting both  
3 safe and timely introduction of biosimilars.

4           We've finally seen several biosimilars  
5 approved over the past year and numerous other  
6 products are in various stages of the pipeline. We  
7 can see the FDA's cautious science-based approach to  
8 biosimilar approval is working. Take for example its  
9 use of distinguishable names both in Zarxio approval  
10 and in subsequent approvals. It is critical for  
11 patients and providers always to be able to clearly  
12 identify which biological product is being used  
13 throughout treatment. Accurate attribution of adverse  
14 events to the correct biologic is also necessary for  
15 long-term tracking of safety and efficacy.

16           Additionally it is important that not only  
17 these funds are sufficient to meet review times but  
18 that the allocated funds remain dedicated to their  
19 intended purpose so that the FDA has the tools to  
20 perform this role. It is important to all of us who  
21 want safe and effective biosimilars to be successfully  
22 introduced that the FDA get this right.

1           The BsUFA II agreement will be critical to  
2 providing the predictable, timely, and efficient  
3 regulatory review of approval of biosimilars. The  
4 agreement will help provide the FDA with the support  
5 needed to enhance their review of new biosimilars and  
6 make sure that the standards for safety and  
7 effectiveness which will help increase competition in  
8 the marketplace to the benefit of patients is well  
9 represented.

10           In closing let me commend the FDA for its  
11 continued work in bringing biosimilar safety to  
12 American patients. BsUFA II is a critical component  
13 to the U.S. biosimilar's pathway and we unreservedly  
14 recommend that it be reauthorized.

15           Thank you again for the opportunity to  
16 comment on this matter.

17           MS. ROACHE: Okay. Thank you, Andrew. And  
18 I do apologize Diana we were running a bit ahead of  
19 schedule. We are very happy to see that you are able  
20 to make it so my apologies for that. So, I'll turn it  
21 over to you now if you'd like to introduce yourself  
22 and provide your remarks.

1 DR. ZUCKERMAN: Boy, I'd be really happy if  
2 somebody could go before me.

3 DR. ROACHE: Sure. No problem. No problem  
4 at all.

5 So I will then turn over to Leigh Purvis  
6 from AARP and I have a slide advancer for you.

7 MS. PURVIS: Hi, again my name is Leigh  
8 Purvis. And I am with AARP which happens to be the  
9 Nation's largest organization representing the  
10 interests of older Americans.

11 So I'm going to start off with explaining  
12 why this issue is so important to us and our members.

13 First of all as I think most people in this  
14 room are aware biologics represent a growing share of  
15 the drug development pipeline. A lot of our spending  
16 is being devoted on these products and the products  
17 are also being used by larger populations. We are  
18 seeing more and more biologics with more and more  
19 indications. So this is really something that is  
20 going to be impacting a lot of people whereas now it  
21 is a relatively small population.

22 The one thing that has really caught our

1 attention about these products is, of course, the  
2 costs. We are seeing more and more biologics entering  
3 the market with incredibly high prices that can range  
4 up to hundreds of thousands of dollars. We are also  
5 seeing as I mentioned the patient population size is  
6 growing without expanded medications. One example is  
7 the anti-cholesterol medications PCSK9 inhibitors  
8 which could potentially be used as many as 15,000,000  
9 people. Now uptake has not been as high as expected  
10 but the reality is that is because payers have really  
11 clamped down on utilization. And again this is one  
12 product. We are expecting to see more of these  
13 products that affect millions of people. So when you  
14 are talking about an incredibly high priced product  
15 used by an incredibly high number of people you are  
16 talking about some incredibly high costs.

17           Specific to the population that I represent,  
18 again I don't think this is a surprise to anyone in  
19 this room but older adults use more prescription drugs  
20 than any other segment of the population. They also  
21 tend to use it for chronic conditions. So when we are  
22 out here talking about high prescription drug prices

1 we are also talking about prices that people are  
2 facing every year for the rest of their lives;  
3 obviously a huge concern. We also are realizing a  
4 biologics are typically using to treat conditions that  
5 commonly affect older adults. Again this is something  
6 that is really impacting our members. And  
7 unfortunately older adults typically do not have the  
8 financial resources to be able to absorb these types  
9 of high costs. The median income for a Medicare  
10 beneficiary is less than \$25,000. Many of them have  
11 resources in terms of savings of less than \$12,000.  
12 They cannot -- they simply cannot absorb high  
13 prescription drug prices.

14 AARP is also kind of unique in the sense  
15 that we also pay attention to the programs that our  
16 members rely on. One very good example is Medicare.  
17 Under Medicare Part B spending has doubled since 2007  
18 on prescription drugs. It is now \$22 billion. And  
19 nine out of the top ten drugs that they are spending  
20 on are biologics. Again this is something that really  
21 is impacting our members.

22 Of extreme importance to us is cost sharing

1 under Medicare Part B. Medicare Part beneficiaries  
2 are responsible for 20% of their prescription drug  
3 costs. There is no out of pocket cap. That has left  
4 some beneficiaries with out of pocket costs that have  
5 exceeded \$100,000 per year.

6 Medicare Part D is also being increasingly  
7 impacted by biologics. Medicare Part D spending  
8 reached \$85 billion in 2015. And a share of spending  
9 attributable to biologics increased from six percent  
10 to ten percent. Also the share of high cost enrollees  
11 which MedPac defines as those who actually reach  
12 catastrophic coverage who filled at least one  
13 prescription drug for a biologic is also increasing.  
14 Under Part D private plans, a large number of private  
15 plans provide coverage and many of them are moving  
16 towards co-insurance which for those of you who aren't  
17 familiar with that payment is a percentage of the  
18 drug's price as opposed to the flat co-pay that most  
19 of us are used to seeing. Again expensive drug,  
20 percentage of expensive drug results in a lot of  
21 costs. Now there is unlike Part B as in Boy an out of  
22 pocket spending cap which around \$5,000 in 2017.

1 However, that cap is not a hard cap. Enrollees are  
2 still responsible five percent of their cost sharing  
3 after they reach that cap which has led to some  
4 beneficiaries having cost sharing that exceeds \$10,000  
5 per year.

6 All of which is a very long way of saying we  
7 really, really, really want biosimilars. The cost  
8 associated with biologics are simply not sustainable  
9 for the people that we represent or the programs that  
10 we are using. And we are very well aware that  
11 biologics patents are starting to expire. We are also  
12 aware that the spending that we are seeing associated  
13 with biologics is only going to increase until  
14 biosimilars become available.

15 So as far as BsUFA we do have just one  
16 overarching theme and that is that we want to make  
17 sure that biosimilars and the savings associated with  
18 biosimilars are achieved by what FDA is doing. More  
19 specifically we are aware that FDA has serious  
20 resource issues and we want to make sure that in the  
21 biosimilar review process there are no unnecessary  
22 delays in that process. We want to make sure that

1 biosimilars reach patients as soon as possible.

2 We also want to make sure that science is  
3 not set in place. The whole goal of this is to  
4 eventually reach an approval process that resembles  
5 something like what we are seeing with traditional  
6 generics. And unless those types of cost savings can  
7 be achieved from manufacturers there's a very good  
8 chance that they aren't going to use it which is a  
9 real problem for us obviously.

10 We are also aware there are a lot of people  
11 engaged in this discussion who may not have  
12 biosimilar's best interest at heart. So we really  
13 want to insure that FDA makes sure that science weighs  
14 heaviest in all of their decisions particularly when  
15 it comes to naming.

16 AARP continues to believe the unique INNs  
17 are not needed. We don't think that it is necessary  
18 and we think it actually has raised some safety  
19 concerns in terms of for example requiring prescribers  
20 to remember the names of multiple products that  
21 effectively can be used the same way.

22 We also are very well aware that FDA has

1 been tracking manufacturing changes in brand name  
2 biologics for a very long time. That gives us a  
3 pretty strong indication that they are more than  
4 capable of regulating biosimilar safely and we want  
5 that to be kept in mind.

6 As far as the future not to sound too "the  
7 sky is falling" but the reality is the cost associated  
8 with biologics are not sustainable and patients are  
9 not going to be able to afford the treatment they need  
10 without low cost biosimilars. And the final thought  
11 that I always like to leave people with in these types  
12 of discussion is that medical advances like biologics  
13 are meaningless if no one can afford to use them.

14 Thank you.

15 DR. ROACHE: Okay. Thank you very much for  
16 providing those remarks. And now I will turn it over  
17 to Diana to provide an introduction and her remarks.

18 DR. ZUCKERMAN: Yes. Thanks very much for  
19 letting me go next. I'm Doctor Diana Zuckerman. I'm  
20 President of the National Center for Health Research  
21 and our center really focuses on looking at the  
22 science of different medical products and translating

1 that information to make it useable information for  
2 patients and consumers and providers.

3 And I am particularly please to go after  
4 AARP because I can now agree with everything you've  
5 said and then I'm done. No. I'm almost done.

6 But so we share the enthusiasm for the need  
7 for these user fees and we also believe that a major  
8 goal is that this should make medications more  
9 affordable and we are concerned that sometimes that  
10 isn't happening. And so we are both concerned about  
11 any kind of backlog and how slow the process has been  
12 so far but also that the end result hasn't been the  
13 cost savings that we were hoping for.

14 That being said we still think that it is  
15 very important that we move forward and see if we can  
16 improve the situation. One of the concerns that we  
17 have is about the fees and actually I should probably  
18 go into the process.

19 So we are disappointed that the process has  
20 not included patients, consumers, and public health  
21 advocates in a meaningful way compared to other user  
22 fee processes where there have been multiple meetings

1 and much more information in this case there were I  
2 believe 14 meetings with industry and just one with us  
3 and that was in December. So that hasn't included us  
4 and even the information that's been available so far  
5 has been less information than has been available in  
6 other user fee negotiations.

7           So we are not really able to say are these  
8 fees enough. Some people might say well that's not  
9 your business because you are not paying the fees.  
10 But we believe that the patients and the consumers and  
11 American taxpayers are part of the consumers here, we  
12 are the consumers here, we are supporting all the  
13 appropriations for this for biosimilars as well and  
14 those appropriations although inadequate are still a  
15 very major part of the resources that FDA has. So if  
16 this program is to work we need to have adequate user  
17 fees as well as adequate appropriations. Many of us  
18 have been working for better appropriations but when  
19 there are so many performance goals as part of this  
20 negotiation then it becomes that much more important  
21 that there are adequate resources to make sure that  
22 these products are safe and effective and that FDA has

1 enough resources to do their job to not just meet the  
2 goals but also get these products on the market.

3 Couple of other things I wanted to say the  
4 one goal that seemed a bit unrealistic to us was that  
5 90% of the products must be reviewed and acted upon by  
6 a certain date; that seemed like a very nice goal but  
7 is that a realistic goal; can't tell because we don't  
8 know how much money is going to be available.

9 We are concerned that the user fees do not  
10 seem to include post-market surveillance which they  
11 did last round and we're not sure if that is an actual  
12 difference or if it just looks to be a difference but  
13 we do think that the post-market surveillance is  
14 extremely important and one way or another FDA needs  
15 the resources to do a really good job on post-market  
16 surveillance.

17 I think that just in conclusion just wanted  
18 to say that the FDA has made a really important effort  
19 to include patients more in the process overall for  
20 everything that the FDA is doing. And we think that  
21 patients and consumers and public health advocates  
22 need to be more of a process for all the user fee

1 negotiations as well; that we are paying for these  
2 products both as patients, as taxpayers supporting  
3 Medicare and supporting other government programs that  
4 pay for health care. We are paying for our health  
5 insurance so one way or another we are paying for all  
6 of the medical products that FDA regulates including  
7 biosimilars and we should be a more essential part of  
8 the process of pertaining to user fees and every other  
9 aspect of the FDA; that the FDA has talked a lot about  
10 customer service and just wanted to remind the FDA  
11 that we are your customers as well.

12 Thank you.

13 DR. ROACHE: Okay. Thank you very much,  
14 Doctor Zuckerman for providing those remarks. I will  
15 now turn it over to Sally Greenberg from the National  
16 Consumers League.

17 MS. GREENBERG: Thank you. Good morning  
18 everyone. The National Consumers League appreciates  
19 the opportunity to deliver these comments on the  
20 reauthorization of the Biosimilar User Fee Act for  
21 Fiscal Years 2018 through 2022.

22 Among NCL's top priorities are insuring the

1 safety and effectiveness and appropriate use of both  
2 prescription and over-the-counter OTC drugs and  
3 medication adherence which we have helped to advance  
4 through our Scrip Your Future Campaign. And I also  
5 couldn't help reflecting on the history of biologics  
6 as I walked down the how to get into this room. The  
7 poster on the hallway describes the turn of the  
8 twentieth century, the development of biologics and  
9 there were complications along the way including  
10 contaminated biologics that killed people including a  
11 lot of children until they got it right. And it just  
12 reminded me that this is an imperfect process,  
13 certainly we're more advanced, much more advanced than  
14 we were a hundred years ago. But developing biologics  
15 and biosimilars and getting the pathway to biosimilars  
16 right remains a continuous challenge and we're very  
17 happy to have the opportunity to have input into this  
18 process.

19 So we are a strong supporter of biosimilars  
20 for all the reasons laid out by my colleagues here.  
21 They do help to provide less expensive products for  
22 patients with serious diseases such as Rheumatoid

1 Arthritis, Multiple Sclerosis, and cancer. Since 2012  
2 BsUFA has helped to provide FDA with the resources the  
3 Agency needs to enhance the science-based review of  
4 new biosimilars.

5 User fees are certainly integral to FDA's  
6 ability to review the drugs and biologics in a timely  
7 manner since we continue to raise concerns about how  
8 the Agency is underfunded.

9 So the user fee program is obviously  
10 extremely important in speeding important treatments  
11 to patients. We understand that there is an across  
12 the board cut including the continuing resolution, the  
13 FDA is going to experience a funding cut over the ten  
14 week period until December 9th and so user fees are  
15 increasingly important for the FDA to carry out its  
16 drug and biological review options.

17 BsUFA II lays out some ambitious goals for  
18 the FDA. To meet these goals BsUFA II proposes to  
19 generate a total of \$45 million in user fee revenue  
20 for Fiscal Year 2018. However, we are mindful that  
21 FDA can also raise the user fee amounts to no more  
22 than \$9 million in FY2018 to reflect an updated

1 assessment of the BsUFA workload. We support the  
2 FDA's ability to increase the fees and urge the Agency  
3 to insure that the fees are sufficient to offset the  
4 increased workload under the BsUFA II agreement.

5 We also whenever we talk about a user fee  
6 program we like to remind the FDA that the Agency must  
7 be mindful of concerns expressed by some that the  
8 industry pays user fees and, therefore, industry  
9 controls the FDA's agenda and process. So we think it  
10 is critical for the FDA to act independently of  
11 industry influence and to include consumers in the  
12 process as Diana has described more fully than perhaps  
13 it has done through this particular proceeding and to  
14 uphold high standards for safety, efficacy, and  
15 quality of biologic products.

16 In reviewing the proposed BsUFA II User Fee  
17 Agreement we note that it has many good features. We  
18 support BsUFA II's emphasis on improving communication  
19 between FDA and product sponsors with the goal of  
20 promoting the efficiency and effectiveness of this  
21 first cycle review process and minimizing the number  
22 of review cycles necessary for approval of the 351(k)

1 applications.

2 NCL also supports the establishment of a  
3 biosimilars unit. We think that is a very good idea  
4 to provide a focal point for coordination to  
5 facilitate a scientific policy development, resources,  
6 operations management, program governance, and  
7 internal training as well as educational research and  
8 enhanced communications related to biosimilars.

9 We at NCL applaud FDA's commitment in BsUFA  
10 II to issue guidance documents in several areas  
11 related to biosimilar biologic product development in  
12 order to provide clarity to industry and other  
13 stakeholders on the Agency's expectations. We believe  
14 of particular importance are FDA guidances on  
15 demonstrating interchangeability with a reference  
16 product and labeling for biosimilar biologic products.

17 Improving FDA's ability to hire and retain a  
18 highly qualified biological product review staff is  
19 one of the most important components of BsUFA II. In  
20 order to carry out its mission the FDA has to be able  
21 to hire and retain these very highly qualified  
22 technical and scientific experts to efficiently

1 conduct reviews of drugs and biologics. We know there  
2 is a lot of competition for the brain power that goes  
3 into all the work that the FDA does. But we also know  
4 that there are many physicians and scientists that are  
5 committed public servants and they want to work for  
6 the public good. FDA certainly has a long history of  
7 attracting these talented and highly educated  
8 professionals. So we do believe the FDA must have the  
9 means to continue to hire and retain such talent.

10 In addition to the emphasis on guidance  
11 development we support BsUFA II's commitment for the  
12 FDA to develop and deliver timely comprehensive  
13 training to all CDER and CBER review staff and special  
14 government employees to deliver timely information to  
15 the public, to improve the understanding of  
16 biosimilarity and interchangeability. We think there  
17 is probably a lot of confusion out there among  
18 patients, among consumers on those issues. We want to  
19 see the delivery of information concerning the date of  
20 first licensure and reference product exclusivity  
21 expiration dates to be included in the purple book.

22 And with regard to education NCL believes

1 there's an urgent need for health professional  
2 consumer education about biologics and biosimilars to  
3 enhance the understanding and acceptance of  
4 biosimilars in the treatment of disease.

5           So in conclusion we very much appreciate  
6 BsUFA II's role in continuing to improve the  
7 efficiency of the science-based FDA review process for  
8 biosimilars. We are very pleased to have the  
9 opportunity to work with the FDA to offer these  
10 comments and to share the platform with our colleagues  
11 who are doing such great work on these issues and  
12 important work. We look forward to continuing to work  
13 collaboratively with the FDA, the advocacy community  
14 and the industry stakeholders to insure that consumers  
15 and patients have expanded and affordable access to  
16 safe and effective biologic medicines they need to  
17 maintain their health and enjoy a positive quality of  
18 life.

19           Thank you.

20           DR. ROACHE: Okay. Thank you to all of our  
21 Panel 1 panelists for being here today and providing  
22 the perspective from the patient and public health

1 advocates. We are very glad that you were able to be  
2 here today.

3 I would now like to move on to Panel 2 and  
4 ask that each of the presenters introduce themselves.

5 DR. WORTHING: I'm Angus Worthing. I'm a  
6 practicing Rheumatologist in the Metro area and I'm  
7 incoming Chair of the American College of Rheumatology  
8 Government Affairs Committee.

9 MS. SCHULTE: Hi, I'm Jillanne Schulte. I  
10 am the Director of Federal Regulatory Affairs at the  
11 American Society of Health-System Pharmacists or ASHP.

12 MS. CARDEN: Good morning I am Mary Jo  
13 Carden. I'm Vice President of Government and Pharmacy  
14 Affairs at the Academy of Managed Care Pharmacy, AMCP.

15 DR. ROACHE: All right. Thank you all for  
16 being here today. I will now turn it over to Dr.  
17 Worthing to provide the perspectives.

18 PANEL 2 - HEALTH CARE PROFESSIONALS PERSPECTIVES

19 DR. WORTHING: Thanks. I'm grateful to be  
20 here representing thousands of Rheumatologists across  
21 the country and the prescribers of these exciting new  
22 medications.

1 I'm going to talk about three major topics.  
2 The guidance on interchangeable designation, labeling,  
3 and enhancing capacity FDA.

4 As health care providers we're going to jump  
5 into a couple of the details in order to use my time  
6 efficiently. We expect as noted the draft of  
7 interchangeable guidance will be out next December and  
8 before then, however, self-administered biosimilars  
9 could be dispensed to our patients such as adalimumab-  
10 atto n etanercept SZZS. It could be that the lower  
11 cost or the higher margin on these products could  
12 incentivize insurance payers, pharmacy benefit manager  
13 and pharmacies to switch patients who are stable  
14 taking a specific reference biologic to a non-  
15 interchangeable biosimilar. And noting the change in  
16 formularies and insurance year to year they could be  
17 switching back and forth. This is potentially  
18 setting up a situation that could provide the kind of  
19 clinical data that the FDA will be using in the future  
20 to approve whether drugs are interchangeable.

21 In order to prevent this kind of switching  
22 and substitution FDA has posted text on the website

1 sort of preamble to the purple book stating "in  
2 contrast to interchangeable drugs FDA expects that a  
3 biosimilar product will be specifically prescribed by  
4 the health care provider and not be substituted for a  
5 reference product at the pharmacy level." ACR  
6 completely agrees with this and my point in bringing  
7 this up is we would simply ask that the FDA provide a  
8 specific guidance document for biosimilar substitution  
9 and the rationale for it and provide it on the  
10 website. Also embed it in that purple book the list  
11 itself which might be copied, emailed, and utilized  
12 just using that text at the top or the bottom of the  
13 purple book would be great.

14 Also recommend post-marketing programs for  
15 potential adverse effects after substitution of non-  
16 interchangeable biosimilars.

17 With regard to FDA labels I think it would  
18 be and we think it would be very helpful to include  
19 whether or not a compound is interchangeable or state  
20 that the compound is not interchangeable at the top of  
21 the label. Currently with the four products so far  
22 the products are listed as biosimilar. And I think it

1 would be helpful to use interchangeable or not  
2 interchangeable.

3 Doctors expect to learn a lot. I myself  
4 look a lot at clinical data from FDA labels. And so to  
5 increase prescriber confidence and enhance the market  
6 update for biosimilars the ACR suggests including  
7 clinical data on the FDA labels or via a hyperlink  
8 since many of us are looking at these online. This  
9 will encourage the discussion of clinical data between  
10 manufacturers, health care providers and other people.

11 One thing that I think many on both panels  
12 here will agree and the audience is the need to  
13 enhance FDA capacity for biosimilars. Rheumatologists  
14 look forward to the day when biosimilars improve  
15 access to biologic treatments through lower costs.  
16 However the price of the first rheumatology reference  
17 product in the biosimilar space increased 70% between  
18 2010 when Congress initiated the biosimilar pathway  
19 and today. Yet the biosimilar to this product only  
20 offers a 15% discount. So clearly it will take  
21 multiple biosimilar drugs for each reference product  
22 to net an overall discount in the space. And to

1 shepherd this along FDA has used biosimilar program  
2 funding from BsUFA I from approximately \$20 million  
3 trigger per year that is used from other FDA programs  
4 but except for where we heard earlier a small \$1.8  
5 million amount spent early on in the development of  
6 the 351(k) pathway there's been no congressional  
7 appropriations for this marketplace.

8 ACR is calling on Congress to increase FDA  
9 capacity to hire staff and issue rules and guidances  
10 and we intend to work with Congress and the FDA on  
11 this and I welcome my fellow panelists and the  
12 audience today to connect and discuss advancing this  
13 goal forward.

14 In summary ACR calls on specific guidance  
15 document on the substitution to help pharmacists avoid  
16 inappropriate substitution of biosimilars we ask to  
17 include biosimilar and interchangeable status and the  
18 clinical data or hyperlink on the FDA labels. We  
19 support congressional appropriations to enhance FDA  
20 capacity. And overall American College of  
21 Rheumatology supports safe and effective biosimilars  
22 to improve access to treatments.

1                   Thanks .

2                   DR. ROACHE:   Okay.   Thank you Dr. Worthing  
3   for providing remarks from the American College of  
4   Rheumatology.   I would now like to turn it over to our  
5   next panelist to provide views from the American  
6   Society of Health-System Pharmacists.

7                   MS. SCHULTE:   Good morning again to  
8   everyone.   So just a little level setting on what ASHP  
9   does.   We represent pharmacists who serve as patient  
10   care providers in acute and ambulatory settings.   We  
11   have more than 43,000 members and they include  
12   pharmacists, student pharmacists and pharmacy  
13   technicians.   For over 70 years ASHP has been on the  
14   forefront of efforts to improve medication use and  
15   enhance patient safety.

16                   We appreciate the opportunity to provide  
17   some comments on the BsUFA II commitment letter.

18                   Let me just begin by saying that ASHP is  
19   extremely supportive of FDA's work to insure the  
20   safety and efficacy of drugs, biologics and medical  
21   devices.   No other agency or private sector entity  
22   serves this vital public health purpose.   So

1 sufficient funding to support the FDA's mission is  
2 absolutely essential.

3 We support increased appropriations for the  
4 Agency largely through our work with the Alliance for  
5 a Stronger FDA. While drug user fees do not replace  
6 the need for increased appropriations from Congress we  
7 do recognize that with the increase in applications  
8 for biologic products the Biosimilar User Fees provide  
9 important supplemental funding to help bring safe and  
10 effective biologic products to market.

11 So I'm not going to torture you all by going  
12 through our very robust policy but I think it will  
13 come as no surprise that our comments sort of track  
14 along with what our policy says. And a lot of what I  
15 will say has shades of what other folks at the table  
16 have said as well.

17 So ASHP has long supported the development  
18 and implementation of legislation, regulation that  
19 promote increased patient access to less expensive  
20 biological products. Thus we were pleased to note the  
21 draft BsUFA Commitment Letter identifies a hard  
22 deadline on guidance on the interchangeability of

1 biologic medications. While we understand that the  
2 Agency has to be thorough and deliberative in its  
3 processes and of course we support that to the  
4 greatest degree possible. We really encourage FDA to  
5 if at all possible move this guidance even faster than  
6 the December 31, 2017, deadline. As many of you in  
7 the audience know a lot of what is done at the state  
8 level around substitution, a lot of our educational  
9 initiatives for our own members are really  
10 inextricably linked to interchangeability guidance; so  
11 the sooner we have that the easier it is for us to  
12 move forward with educating our members on how to use  
13 these medications appropriately especially in the  
14 hospital and health system settings.

15 ASHP also supports FDA's proposed review of  
16 proprietary names to reduce medication errors  
17 associated with naming related confusion as outlined  
18 in the commitment letter. On the non-proprietary  
19 naming side we remain concerned if the proposed  
20 framework for the non-proprietary name process may  
21 confuse clinicians and complicate post-market  
22 surveillance. Specifically because four consonant

1 non-meaningful unpronounceable suffixes are unlikely  
2 to be readily recalled or associated accurately with  
3 specific products. Names with these suffixes may be  
4 unlikely to achieve FDA's goal of product recognition  
5 and recall by prescribers, patients and others.

6 Further because the proposed naming framework also  
7 extends retroactively to approved biologics it will  
8 necessitate extensive clinician education as well as  
9 potential reprogramming of some health information  
10 technology systems.

11 Finally moving away from the shared non-  
12 proprietary naming may adversely impact post-market  
13 surveillance efforts. Absent a well-designed testing  
14 it is unclear if FDA's proposed naming convention  
15 would support high level Pharmaco vigilance. If for  
16 both reference biologics and biosimilars FDA intends  
17 to rely on proprietary names for self-reporting we ask  
18 that FDA provide stakeholders with a clear statement  
19 to that effect as it prevents a deviation from  
20 standard Pharmaco vigilance practice for small  
21 molecule engineered drugs. And while that might not  
22 seem hugely important when you are a pharmacist and

1 you are used to doing things in a very specific way  
2 for all of your drugs and your post-market  
3 surveillance field then having that one change for a  
4 certain subset of drugs does create a lot of ripple  
5 effects. So we really do want to make this post-  
6 market surveillance strong but we also have to make it  
7 workable within the current systems.

8           So generally for post-market surveillance  
9 purposes ASHP supports an approach predicated on  
10 tracking medications by NDC or another standard  
11 product identifier rather than relying on naming.  
12 While we recognize that hospitals may not currently  
13 have the ability to fully track drug products by NDC.  
14 The Drug Supply Chain Security Act requires package  
15 level NDC tracking by 2023. So as our hospitals  
16 prepare for full DSCSA implementation and compliance  
17 they may apply a surrogate NDC in the interim to  
18 reflect an array of NDC for related drug and biologic  
19 products.

20           Additionally there are other Pharmaco  
21 vigilance options that do not rely on naming that  
22 could be applied including the VAERS model, which is

1 the Vaccine Adverse Event Reporting System model that  
2 already applies to other biological and biosimilar  
3 products or manual entry of NDC into the patient's  
4 electronic health record. Given that the current  
5 universe of biologic and biosimilar products approved  
6 by FDA is small manual entry of NDC's can serve as an  
7 initial solution while a more permanent one is  
8 developed. ASHP and its member pharmacists are  
9 prepared to work closely with FDA on these and other  
10 policy options.

11 Finally in spite of the concerns outlined  
12 above around the naming and post-market surveillance  
13 given the number of biologic products entering the  
14 market we encourage FDA to move expeditiously to  
15 finalize the non-proprietary naming framework and  
16 provide definitive guidance to stakeholders. We seek  
17 to provide our members with up-to-date objective  
18 information regarding all biologic products and we are  
19 concerned that a naming paradigm shift of this  
20 magnitude carries significant risk for medication  
21 errors. Definitive naming guidance would facilitate  
22 the development of comprehensive educational programs

1 for our member pharmacists as well as other members of  
2 the health care team.

3 We appreciate the opportunity to comment at  
4 this meeting today and we look forward to working with  
5 Agency and other stakeholders moving forward.

6 Thank you.

7 DR. ROACHE: Thank you. I would now like to  
8 invite our third panelist Mary Jo Carden to provide  
9 perspective from Academy of Managed Care Pharmacy.

10 MS. CARDEN: Thank you very much. And as  
11 Jillanne said a lot of my comments will also echo her  
12 comments. AMCP is the national professional  
13 association of pharmacists and other practitioners who  
14 serve society by the application of sound medication  
15 management, principles and strategies to improve  
16 health care. The Academy's 8,000 members develop and  
17 provide a diversified range of clinical, educational,  
18 medication and business management solutions and  
19 strategies on behalf of more than 200,000,000  
20 Americans covered by a managed care pharmacy benefit.

21 AMCP supports the implementation of a robust  
22 biosimilars pathway to insure that the American

1 population continues to receive access to safe,  
2 effective, and affordable biologics and biosimilars.  
3 AMCP has been working extensively with FDA and other  
4 stakeholders on federal and state legislation and  
5 regulations that impact the biosimilars pathway. AMCP  
6 has added biosimilars education for health care  
7 priorities as a key priority for 2016 and 1017. AMCP  
8 is please that FDA will release additional guidance on  
9 the biosimilars pathway particularly  
10 interchangeability and will finalize guidance on  
11 naming and labeling.

12           However, as Jillanne had mentioned AMCP  
13 would like to see guidance released earlier than the  
14 anticipated date of December 2017 which is more than a  
15 year after the initial anticipated date of December  
16 2016.

17           AMCP also submitted extensive comments to  
18 the docket but I will review those today.

19           First AMCP urges FDA to issue  
20 interchangeability draft guidance as expeditiously as  
21 possible and as stated before before the December 2017  
22 deadline after consultation with the regulated

1 industry and affected stakeholders. This guidance  
2 will be important for health care providers, payers,  
3 and others as they seek to implement programs and  
4 services to allow patient access to biosimilars.  
5 State pharmacy practice laws and Medicare and Medicaid  
6 and private payment policies will be affected by the  
7 scope of this document. And as FDA approves more  
8 biosimilars clarity on interchangeability will be  
9 important. AMCP supports clear rules designating  
10 biosimilars as interchangeable with a reference  
11 product similar to the AB ratings for small molecule  
12 agents.

13 FDA should implement a two-step process by  
14 first determining biosimilarity and then  
15 interchangeability. A determination of  
16 interchangeability should not be a requirement for a  
17 condition to biosimilar approval and interchangeable  
18 biologic products should not be granted exclusivity.  
19 Pharmacist substitution should be permitted without  
20 additional steps in the dispensing process including  
21 prescriber notification and record keeping.

22 In regard to naming while AMCP is pleased

1 that FDA has indicated a timeline for a final draft or  
2 revised draft guidance on naming and labeling; final  
3 draft guidance documents should be released as quickly  
4 as possible. To take steps toward a robust biosimilar  
5 regulatory pathway and provide certainty to  
6 stakeholder AMCP urges FDA to finalize these documents  
7 in a timely manner and to not issue draft guidance  
8 with an additional comment period. AMCP had  
9 previously suggested that FDA re-release naming  
10 guidance with a new comment period but in light of  
11 recent actions related to biosimilar approvals FDA  
12 should finalize its intent as soon as possible to  
13 provide needed clarity in the biosimilars pathway.

14 If FDA proceeds with the current approach of  
15 a four letter randomized suffix it should consider the  
16 impact of this approach through cognition testing for  
17 pharmacists, providers and patients. AMCP continues  
18 to encourage the use of a shared non-proprietary name  
19 for biosimilars, reference products, and  
20 interchangeable biosimilar products plus a requirement  
21 to use national drug codes on all claims to identify  
22 product as well as identify lot number and package

1 size.

2 With regard to labeling AMCP encourages FDA  
3 to reconsider the use of a biosimilar statement in the  
4 label and to insure that the labeling guidance is  
5 consistent with naming and interchangeability  
6 guidance.

7 Third, AMCP is pleased that FDA is committed  
8 to providing additional staffing and resources toward  
9 educational efforts on biosimilars. AMCP has made a  
10 significant commitment to educating health care  
11 providers including pharmacists, physicians, and  
12 nurses. In 2016 AMCP launched the biosimilars  
13 resource center available at  
14 [www.biosimilarsresourcecenter.org](http://www.biosimilarsresourcecenter.org) to provide an  
15 unbiased, policy neutral, repository of educational  
16 resources and information on biosimilars. AMCP is  
17 joined in these efforts by the American Association of  
18 Colleges of Pharmacy, Americas Health Insurance Plans,  
19 the American Pharmacists Association, the American  
20 Society of Consultant Pharmacists, the Hematology and  
21 Oncology Pharmacists Association, the National  
22 Alliance of State Pharmacy Associations, and the

1 National Committee Pharmacists Association. In 2017  
2 AMCP intends to enhance the resources on the website  
3 and also provide educational presentations including  
4 webinars and live seminars on biosimilars to health  
5 care providers.

6 Finally as FDA finalizes policies on the  
7 biosimilars pathway it should consider the use of  
8 active post-marketing surveillance to determine the  
9 safety and efficacy of biosimilars in patients outside  
10 of clinical trials. FDA has indicated support for  
11 these efforts but should provide additional guidance  
12 on this information.

13 Thank you again for this opportunity and  
14 AMCP looks forward to continuing its work with FDA and  
15 others.

16 DR. ROACHE: Okay. Thank you very much to  
17 all of our panelist on Panel 2 for providing your  
18 remarks.

19 FDA will be taking all the remarks that we  
20 hear today into consideration following today's  
21 meeting.

22 At this time we would like to take our break

1 for lunch. So we'll take a break now and we will  
2 resume at 12:30.

3 And when we come back we will have our third  
4 panel for the day and we will hear perspectives of  
5 regulated industry.

6 Thank you.

7 LUNCH

8 DR. ROACHE: Okay. So we will go ahead and  
9 resume this public meeting. And the next item on our  
10 agenda will be perspectives from regulated industry.

11 So I'd like to thank all of our industry  
12 panelists for being here today and ask you all to  
13 introduce yourselves and then we will proceed with  
14 your remarks.

15 MR. GAUGH: Good afternoon. I'm David  
16 Gaugh, Senior Vice President for Sciences and  
17 Regulatory Affairs for the Biosimilars Council.

18 MR. HAVERFIELD: Good afternoon. I'm Sasha  
19 Haverfield, SVP for Science and Regulatory Advocacy at  
20 PhRMA.

21 MS. HOLCOMBE: I'm Kay Holcombe, Senior VP  
22 for Health Policy at BIO.

1 MS. REED: Hi, I'm Juliana Reed. I'm the  
2 President of the Biosimilars Forum.

3 DR. ROACHE: Okay. Thank you all for being  
4 here today. I will now turn it over to David.

5 PANEL 3 - REGULATED INDUSTRY PERSPECTIVES

6 MR. GAUGH: Thank you Amanda. And thanks to  
7 the FDA for holding this public meeting today.

8 Again I'm David Gaugh from the Biosimilars  
9 Council. Biosimilars Council is a division of Generic  
10 Pharmaceutical Association and works to insure a  
11 positive environment for patient access to biosimilar  
12 medicines. The Biosimilars Council is a leading  
13 source of information about the safety and efficacy of  
14 these more affordable alternatives to costly brand  
15 biologic medicines. We represent manufacturers who  
16 currently produce high quality safe and effective  
17 biosimilars approved in the U.S., Europe and other  
18 regulated markets around the world.

19 Biologic medicines are often the only life  
20 saving treatment for many of the most severe diseases  
21 encountered by patients today. In many aspects they  
22 represent the future of medicine. Their high price

1 tag however can keep them out of the reach of many  
2 patients.

3 During negotiations the Council focused on a  
4 number of key goals, additional staff for the FDA,  
5 finalizing outstanding policy guidances, increased  
6 communications with applicants, and biosimilar public  
7 education.

8 The Council believes that the agreement  
9 reached will strengthen the BsUFA program and will  
10 specifically address key goals that we outlined. The  
11 Council expresses its enthusiastic support of the user  
12 fee funding to provide FDA with additional resources  
13 to apply consistent regulatory standards to all  
14 biologics including both originators and biosimilars  
15 and to review new applications thoroughly and in a  
16 timely manner. Both industry and patients will  
17 benefit from this user fee program by gaining a higher  
18 degree of certainty in the timeliness of application  
19 reviews.

20 We applaud the FDA for recognizing the  
21 importance of biosimilars and the need to apply state  
22 of the art science in the Agency's activities

1 governing and reviewing and approving these important  
2 drugs. While the FDA has set a promising foundation  
3 fewer biosimilars are approved today than originally  
4 projected. BsUFA II is designed to reverse that  
5 trend.

6 The proposed reauthorization under BsUFA II  
7 will provide shifting from a ten month to a 12 month  
8 review timeline in order to improve and increase the  
9 opportunities for application touch points between the  
10 FDA and the industry for first cycle reviews. The  
11 extended timelines will allow for increased  
12 communications in the interactions between FDA and the  
13 sponsors. FDA and sponsors are able to structure the  
14 nature and timing of communications interactions by  
15 mutual agreement through a formal communication plan.

16 FDA and industry want to insure the program  
17 is adequately resourced. Modifications to the user  
18 fee structure through a standalone fee model  
19 independent of PdUFA. Fees would be limited to the  
20 biosimilar development program, reactivation fees,  
21 application fees and product fees.

22 FDA will establish priorities of management

1 of the metric goals for targeted hires within the  
2 biosimilar review for BsUFA II. In particular FDA  
3 will target hiring 15 FTEs in Fiscal Year 2018 to  
4 enhance capacity for biosimilar guidance, guidance  
5 development, reviewer timing, and timely  
6 communications.

7 FDA will conduct activities to develop a  
8 resource capacity planning function and modernize time  
9 reporting approach for BsUFA II including inflation  
10 and workload adjustment, carryover balance and methods  
11 for settling target allocations. FDA will work toward  
12 a goal of producing revised draft guidances. Final  
13 guidance documents on or before May 31, 2019, for  
14 draft guidances that were published between January 1,  
15 2014, and September 30, 2017. Reduction of scheduling  
16 timelines for BIA meetings from 90 to 75 days.

17 Increase the schedule timeline for BDP II meetings  
18 from 75 to 90 days to allow for a more robust  
19 conversation between the applicants and FDA.

20 Manufacturing supplements that require prior approval  
21 supplement subject to a four month review time point.

22 In conclusion FDA and industry need to

1 continue to work to create a public education campaign  
2 around the benefits of biosimilars. These educational  
3 efforts will provide a key source of information  
4 regarding biosimilar products, their safety, and their  
5 scientific development. Additionally other key  
6 stakeholders should contribute to these educational  
7 efforts.

8 Moving forward is critical for FDA and  
9 industry to continue to discuss strengthening the  
10 biosimilar review infrastructure and expertise at FDA.  
11 Together we can promote access to more affordable high  
12 quality biosimilars for the patients who rely on these  
13 essential medicines.

14 Thank you very much.

15 DR. ROACHE: Thank you, David. I'll now  
16 turn it over to Sasha Haverfield from PhRMA.

17 MR. HAVERFIELD: Thank you, Amanda. PhRMA  
18 appreciates the opportunity to participate in the  
19 BsUFA II public meeting to discuss the benefits that  
20 the new user fee agreement will have for public  
21 health, the FDA, the biopharmaceutical industry, and  
22 most importantly the patients we all serve.

1           The BsUFA program provides the resources and  
2 support needed for FDA to achieve its core mission of  
3 protecting and promoting the public health. Since its  
4 creation in 2012 BsUFA has helped benefit patients and  
5 promote public health through the review and approval  
6 of biosimilar products that meet FDA's high standards  
7 for safety, purity, and potency.

8           The BsUFA II agreement will continue to  
9 build on the success of the program through the new  
10 review enhancements that will help provide more  
11 predictable and timely access to biosimilar products  
12 and the inclusion of other regulatory enhancements  
13 that will result in increased biopharmaceutical  
14 competition in the marketplace. BsUFA II will enhance  
15 the regulation of biosimilars and provide important  
16 resources to FDA to insure the biosimilar review  
17 program thrives and is sustainable in the future by  
18 supporting science based implementation of the BPCIA  
19 of 2009 in regulatory decision making, enhancing  
20 regulatory transparency and efficiency that enables  
21 stakeholders to understand the basis for FDA's  
22 decisions, promoting the long-term stability of the

1 BsUFA program through financial transparency,  
2 efficiency and accountability.

3 BsUFA II will provide resources to establish  
4 dedicated centralized staff capacity as we heard  
5 earlier today known as the biosimilars unit to provide  
6 a focal point for biosimilar regulatory and policy  
7 activities. The biosimilar's unit responsibilities  
8 will include scientific coordination among review  
9 staff and policymakers, development of biosimilar  
10 policy through the publication of new draft guidances  
11 and finalization of existing guidance, educational  
12 outreach to external stakeholders that will allow the  
13 delivery of information about similars to the public  
14 in a more timely manner and last but not least  
15 enhanced communication for sponsors and others related  
16 to biosimilars reviews.

17 As we already heard during the FDA's  
18 presentation by Dr. Christl to enhance communication  
19 between FDA and biosimilar sponsors and to encourage  
20 more first cycle review decisions FDA and industry  
21 agree to adopt a new review model for biosimilars  
22 applications based on the Prescription Drug User Fee

1 Act New Molecular Entity Review Program, the NME  
2 review program as it is often referred to. This model  
3 will provide a two months filing period to allow  
4 enhanced engagement opportunities during the review  
5 cycle and to provide sponsors with more timely  
6 feedback on potential review issues that might arise.

7 BsUFA II will help insure that the FDA can  
8 hire and retain a strong scientific and medical work  
9 force to advance its public health mission. The BsUFA  
10 II goals letter included hiring initiatives and  
11 staffing goals that will help the biosimilars program  
12 to have the capacity and capabilities for the duration  
13 of the reauthorization and beyond.

14 PhRMA supports the reauthorization of the  
15 Biosimilars User Fee Act. The BsUFA II performance  
16 goals letter is a means of advancing public health by  
17 making adequate resources available to FDA for the  
18 regulatory review of biosimilar products consistent  
19 with the Agency's high standards for scientific rigor  
20 and patient safety.

21 PhRMA and its member companies are committed  
22 to working closely with the FDA and all stakeholders

1 to reauthorize this important program and to maintain,  
2 expand and improve upon its science based approach to  
3 the development and review of biosimilar products.

4 PhRMA, therefore, urges Congress to  
5 reauthorize BsUFA in 2017 in a timely manner and to  
6 compliment the user fees with congressional  
7 appropriations.

8 Thank you.

9 DR. ROACHE: Thank you Sasha. I will now  
10 turn it over to Kay Holcombe from BIO.

11 MS. HOLCOMBE: Thank you for including BIO  
12 in this important meeting.

13 BIO supported enactment of the Biologics  
14 Price Competition and Innovation Act because we  
15 believed then and continue to believe that patient's  
16 access to medications they need can be enhanced by the  
17 availability of FDA approved safe and effective  
18 biosimilar products. These products can provide  
19 additional choices for patients, caregivers and health  
20 care providers in a system that also promotes  
21 continued innovation.

22 We recognize that user fees are essential to

1 accomplish the goal of timely availability of safe and  
2 effective biosimilars. The reauthorization of the  
3 Biosimilars User Fee program is necessary for the  
4 continuation and improvement of the new biosimilars  
5 pathway and BIO strongly supports it.

6 The BsUFA II technical agreement reflects  
7 key principles that guided BIO in its deliberations  
8 about this reauthorization: science based effective  
9 implementation of BPCIA, an efficient and transparent  
10 regulatory process with appropriate timelines,  
11 guidance and feedback to sponsors, long-term stability  
12 of the BsUFA program through transparent and  
13 sustainable financing, and enhancement of staff  
14 capacity through effective hiring and clear hiring  
15 goals. One of our key objectives for this was  
16 modification of processes and procedures to insure  
17 appropriate staffing of the biosimilars program.  
18 Importantly the technical agreement includes clear and  
19 reportable FDA commitments related to improving  
20 recruitment, hiring, and retention of necessary  
21 personnel with the ability for stakeholders to track  
22 success. The BCPIA required specifically that the

1 reviewers of biosimilars applications be the same as  
2 those who review applications for new biological  
3 products. This makes it all the more important to  
4 insure a sufficient number of full time equivalents  
5 for both types of review to meet performance goals for  
6 both functions. It will be particularly important for  
7 the third party evaluation of all hiring and retention  
8 activities to focus on evaluating the impact of those  
9 activities on improvements for the biosimilar program  
10 specifically.

11 Financial predictability and stability are  
12 also crucial to the success of the biosimilars program  
13 and it is important to BIO that the current system  
14 will be appropriately tailored to achieve these  
15 objectives. A five-year financial plan will be  
16 developed and implemented with public input. The new  
17 capacity adjustment will allow the Agency to assess  
18 workload more accurately which will yield appropriate  
19 fee changes from year to year. These modifications  
20 will advance both predictability and transparency of  
21 the finances of the biosimilars program. The planned  
22 evaluation by a third party of progress against the

1 financial plan is essential.

2 Modernization of the time reporting system  
3 which is already underway at FDA will yield  
4 significantly more precise data and a better  
5 understanding of resource needs for biosimilars  
6 program activities than currently are possible. A  
7 clear and accurate accounting of time devoted to  
8 351(a) reviews which are part of the PdUFA program and  
9 351(k) biosimilar reviews is essential. PdUFA fees  
10 should be allocated only for PdUFA related activities  
11 and BsUFA fees for biosimilars related activities.  
12 The modernized time reporting system will help assure  
13 appropriately strict accountability.

14 Modification of the fee structure is a third  
15 component of improving financial predictability and  
16 stability. Although we know more now than we did four  
17 years ago about the number and stages of biosimilar  
18 product development programs the number of  
19 applications that will be submitted to FDA in any  
20 given year remains speculative. The number of  
21 biosimilars applications is the least predictable  
22 among the sources of user fees and the number of

1 products the most accurately ascertained. We are  
2 pleased, therefore, that the fee collection structure  
3 will be modified to recognize this collecting a  
4 smaller portion of the total fees from applications  
5 and a larger percentage from a new program fee based  
6 on the number of products.

7 BIO strongly supports several program  
8 enhancements also included in this BsUFA goals letter.  
9 First is the establishment of a new biosimilars review  
10 program patterned after the successful NME BLA  
11 program. The program aims to increase the likelihood  
12 of an application moving through the review process in  
13 a single cycle principally by improving communication  
14 between FDA and sponsors during the review. The  
15 effectiveness of this new biosimilars program will be  
16 evaluated by a third party through onsite evaluation  
17 and interviews of both sponsors and FDA staff.

18 Importantly FDA commits in the goals letter to the  
19 completion or development of guidance to help sponsors  
20 understand FDA expectations and by clarifying  
21 regulatory requirements to help achieve the goal of  
22 getting biosimilars to market as expeditiously as

1 possible.

2 In conclusion BIO supports the FDA  
3 biosimilars program and the BsUFA II technical  
4 agreement. We believe this agreement helps to meet  
5 our ultimate goal of insuring that safe and effective  
6 biosimilar products reach patients in a timely way  
7 after appropriately rigorous fully science based  
8 evaluation by FDA. BIO believes in innovation and in  
9 the value of innovative biological products for  
10 patients. We also believe that biosimilars can  
11 provide an important therapeutic option. We support a  
12 well managed sustainable program of user fees to help  
13 the timely review and availability of these important  
14 products.

15 Thank you for inviting us to participate in  
16 this meeting.

17 DR. ROACHE: Thank you Kay. Next we will  
18 have Juliana Reed from the Biosimilars Forum.

19 MS. REED: Thank you Amanda.

20 The Biosimilars Forum appreciates the  
21 opportunity to have participated in the BsUFA II  
22 negotiations and to provide our perspective today on

1 the commitment letter. The Forum is a non-profit  
2 trade association representing biosimilar  
3 manufacturers and is dedicated to expanding patient  
4 access to biosimilars in the United States. Forum  
5 member currently represent the majority of the U.S.  
6 biosimilar programs in development and are a key  
7 stakeholder in BsUFA II.

8 The Forum is proud to have participated in  
9 industry negotiations with the FDA and greatly  
10 appreciates the cooperation of the Agency and the  
11 other industry groups represented during the  
12 negotiations. We feel the resulting commitments will  
13 provide the necessary time and resources needed by the  
14 Agency to support a successful biosimilars program.

15 The Forum believes that the commitment  
16 letter meets our overarching goal of providing ongoing  
17 support to this important program which ultimately  
18 will benefit patients by advancing biosimilar  
19 approvals and access in the U.S.

20 Within BsUFA II there are significant  
21 enhancements to the Biosimilar User Fee program that  
22 support the review and approval of biosimilar

1 medicines in the U.S. These agreed to enhancements  
2 include a revised review process meant to increase  
3 transparency and communication between the FDA and  
4 biosimilar sponsors that is expected to facilitate an  
5 increase in the likelihood of first cycle approval;  
6 Agency commitments to complete and publish several  
7 draft and final guidance documents that will provide  
8 industry with additional clarity and certainty  
9 regarding the biosimilar development and review  
10 processes; Agency commitments to augment and  
11 strengthen biosimilar staffing and enhancements to the  
12 user fee structure and management that will allow  
13 greater transparency, predictability and long-term  
14 stability of the program.

15 The Forum believes the negotiations resulted  
16 in improvements in communication and accountability  
17 between sponsors and FDA and the focusing of the  
18 industry's contributions of BsUFA funds on matters  
19 related to the FDA biosimilars program. We encourage  
20 Congress to support the BsUFA II agreement and also to  
21 provide the FDA with the necessary funding it needs to  
22 continue building this program.

1           The commitments by the FDA combined with the  
2 financial support of Congress and industry ultimately  
3 will benefit patients by getting these important  
4 products to market.

5           Thank you for the opportunity to be here  
6 today and to share our support of the BsUFA II  
7 commitment letter.

8           DR. ROACHE: Thank you Juliana and thank you  
9 to all of our panelists for attending today and  
10 providing your perspective on regulated industry.

11           So we are going to move into our final  
12 section of the meeting which is the open public  
13 comment session. And we had three brave souls who  
14 signed up to provide a comment during today's public  
15 meeting.

16           I just want to remind everybody that FDA is  
17 not going to be providing a specific response to the  
18 comments today but these comments will be transcribed  
19 and will be a part of the public record. And since we  
20 would like this to be a transparent process we invite  
21 you to note any financial interest that you may have  
22 that are related to your comment. If you don't have

1 any financial interest you are also welcomed to state  
2 that for the record as well. And if you do not want  
3 to state you financial interest you are still welcome  
4 to provide a comment.

5 So the list of speakers we have today. We  
6 have Bruce Leicher from Momenta Pharmaceuticals. We  
7 have Dennis Cryer from Biologics Prescribers  
8 Collaborative. And we have Thair Phillips from  
9 RetireSafe. So that will be the order of our  
10 speakers. I ask that everybody limit their comments  
11 to about five minutes. And we have a microphone up  
12 here in the center of the room that we invite you to  
13 speak into. So Bruce I will turn it over to you.

14 OPEN PUBLIC COMMENT

15 MR. LEICHER: Thank you Amanda. I'm Bruce  
16 Leicher, Senior Vice President and General Council,  
17 Momenta Pharmaceuticals and I would disclose that I am  
18 an employee of Momenta so I would certainly have a  
19 financial interest in that company and an equity  
20 interest in that company as well.

21 Momenta is a biotechnology company engaged  
22 in development of biosimilar and interchangeable

1 biologics as well as complex generics and novel  
2 products. We use innovative, analytical and  
3 biocharacterization tools and methods to develop  
4 biosimilars, to assure their quality, and to  
5 demonstrate similarity and interchangeability. Rapid  
6 advances in the sciences associated with biosimilar  
7 development along with the growing number of  
8 applications anticipated in the next five years  
9 demands significant additional resources over current  
10 levels of the Agency for the biosimilar pathway to  
11 succeed. The proposed BsUFA II User Fee  
12 recommendations are a major step forward in assuring  
13 that the FDA has the needed staffing and expertise.

14 The proposed revisions to the regulatory  
15 process included in BsUFA II are highly innovative and  
16 seek to apply these resources more efficiently to  
17 these needs. We are pleased with the recommendations  
18 and endorse their adoption and submission to Congress.

19 As a member of the Biosimilars Council I had  
20 the opportunity to participate in discussions leading  
21 to the BsUFA II recommendations. From that vantage  
22 point we would like to thank the Agency staff in

1 particular for its careful consideration of the  
2 industry proposals as well as its providing its own  
3 recommendations for regulatory improvement. The  
4 result should be more effective and timely review of  
5 high quality biosimilar applications. This matters to  
6 all of us as biosimilars and interchangeable biologics  
7 offer society one of the best means for insuring  
8 access for affordable medicine.

9 In particular we are pleased with  
10 enhancements introduced in BsUFA II to the pre-  
11 application meeting process. The explicit adoption of  
12 Agency best practices for meeting management will help  
13 assure that development programs are well designed and  
14 can deliver the data and information to reviewers that  
15 provide a high level of confidence to patients and  
16 physicians that biosimilars and interchangeable  
17 biologics are subject to the same rigorous review and  
18 quality requirements and offer the same safety and  
19 effectiveness as the reference products.

20 The adoption of a written meeting review  
21 process will also accelerate the process of advice for  
22 applicants when a face-to-face meeting is unnecessary

1 saving Agency staff time for other activities.

2           The adoption of the program review model  
3 developed under PdUFA for originator products is  
4 likewise a highly innovative regulatory reform. It  
5 will help assure that the Agency review staff has the  
6 information it requires at the right time during the  
7 application review. It facilitates timely  
8 communication with each applicant and assures the  
9 Agency is in the best position possible when it  
10 receives a qualified application to approve the  
11 application in a first cycle review. This should also  
12 free up Agency resources to handle more applications  
13 and should lead to more timely approvals and to more  
14 access to affordable medicine.

15           Additional improvements such as the four  
16 month review of post-approval manufacturing  
17 supplements and the use of Special Protocol  
18 Assessments for biosimilar clinical studies will  
19 likewise enhance the review process and make  
20 biosimilar development more predictable and  
21 affordable.

22           The additional fees contemplated for BsUFA

1 II and the use of reserves from BsUFA I will also  
2 enable a significant increase in staffing which should  
3 insure that the enhanced goal commitments for meetings  
4 and applications can be achieved as the number of pre-  
5 application meetings and applications increase  
6 substantially.

7 In addition the inclusion of staffing for  
8 guidance development, reviewer training and increased  
9 communication should increase the overall quality and  
10 efficiency of applications and the review of  
11 applications.

12 With these program improvements the tools  
13 will be in place to let science write policy  
14 development and support the biosimilar pathway.

15 We encourage the FDA to use these additional  
16 resources to combat interference with biosimilar  
17 applications by using its depth of expertise and its  
18 growing experience. For example FDA has the  
19 scientific expertise to thwart citizen petition abuses  
20 that seek to prevent biosimilar review and approval.  
21 FDA has the experience and now the resources to help  
22 assure that originator companies do not interfere with

1 commercially reasonable access to reference products  
2 that will be needed for biosimilar testing. FDA had  
3 the policy expertise to adopt naming, labeling, and  
4 interchangeability guidelines that do not mislead  
5 patients and physicians about the safety and  
6 effectiveness of biosimilars by suggesting the  
7 products are different. And FDA can assist CMS in  
8 understanding that interchangeable biologics are  
9 substitutable with originator products and are thus  
10 therapeutically equivalent. This finding will enable  
11 CMS to provide for reimbursement of interchangeable  
12 biologics in the same manner as it does today for  
13 generic product and enhance patient access to  
14 affordable medicine by avoiding the cost of  
15 unnecessary sales and marketing activities.

16 BsUFA II offers all of us and especially  
17 patients a clear and more predictable path for  
18 licensing and access to affordable medicine and we  
19 applaud the recommendations and look forward to their  
20 implementation.

21 Thank you for the opportunity to present our  
22 views.

1 DR. ROACHE: Thank you. Now we will have  
2 Dennis Cryer from the Biologics Prescribers  
3 Collaborative.

4 DR. CRYER: Thanks very much and good  
5 afternoon. My name is Doctor Dennis Cryer. I'm the  
6 lead physician co-convener of the Biologics  
7 Prescribers Collaborative or BPC as we call it. I  
8 have no financial disclosures to make. Would that I  
9 did.

10 I'm here on behalf of physicians who  
11 routinely prescribe biologics medicines and  
12 professional organizations with numerous biologics  
13 prescribers as members.

14 I think my quick executive summary of my  
15 comments are simply that we are concerned about the  
16 timelines around the guidances. We understand the  
17 challenge of putting these together. If that could be  
18 accelerated in some way that would be wonderful. But  
19 we are totally supportive of all the resources that  
20 can be garnered for the FDA and for these efforts. So  
21 maybe there is an opportunity for acceleration at some  
22 point.

1           But to go on with my formal remarks. The  
2 BPC supports the FDA's continuing careful deliberation  
3 on biosimilar related issues along with your recent  
4 expert and diligent review of medical products. In  
5 particular the Collaborative is please the FDA has  
6 stated that it will make decisions on a case-by-case  
7 basis until it has the knowledge to impose a  
8 comprehensive regulatory framework for the approval  
9 and safe use of biosimilars.

10           BPC realizes that it is a time and resource  
11 intensive process; therefore, we applaud the FDA for  
12 the proposed recommendations being submitted for the  
13 BsUFA reauthorization for Fiscal Years 2018 through  
14 2022 and for taking the opportunity to set aggressive  
15 drug review timelines and goals to refine your  
16 existing activities and to remove provisions that are  
17 no longer needed.

18           The Collaborative acknowledges that in order  
19 to accelerate patient access to safe and effective  
20 biosimilars and to assure accuracy, consistency, and  
21 timeliness of these guidances FDA needs additional  
22 resources; the common theme here today. Therefore, we

1 support the FDA request of increasing staff capacity  
2 and for the review and development of biosimilar  
3 related regulations.

4           While it is important that a timeframe has  
5 been provided for receiving a draft guidance on  
6 interchangeability by December of next year and  
7 revised draft or final guidances on non-proprietary  
8 naming of biologics and on labeling of biosimilars by  
9 May of 2019 we are concerned that this still permits a  
10 considerable period of time during which additional  
11 products will be approved and brought to market  
12 without final policy decisions. As such we encourage  
13 the FDA to consider the implications of the lack of  
14 finalized guidances as it may negatively impact  
15 physician confidence but more importantly it may  
16 impact patient safety.

17           Thank you for this opportunity for the  
18 Biologics Prescribers Collaborative to share our  
19 perspective on these issues critical for the safe use  
20 of biosimilars and other biologics. We  
21 enthusiastically support all your efforts.

22           DR. ROACHE: Thank you Dr. Cryer. I would

1 now like to invite Thair Phillips from RetireSafe.

2 MR. PHILLIPS: Good afternoon. I'm Thair  
3 Phillips. I'm the President and CEO of RetireSafe. I  
4 have no financial disclosures.

5 RetireSafe is a nationwide advocacy  
6 organization representing 250,000 older Americans both  
7 supporters and email activists who are concerned about  
8 safety and about biosimilars.

9 We support BsUFA and its promise of offering  
10 the hope of biosimilars to more people while also  
11 insuring the safety of the approved biosimilars and  
12 the safety of the ongoing manufacturing process.

13 It is the subject of safety that I want to  
14 direct my comments. The issues of naming has come up  
15 more than once today. RetireSafe believes that unique  
16 names are required to insure safety. The manufacturer  
17 of a reference product for which a biosimilar was  
18 seeking approval who was also the developer of a  
19 biosimilar seeking approval agrees with us. Someone  
20 who is on both sides of this question believes that  
21 unique names for biosimilars is necessary. We should  
22 take note.

1           My last point concerns interchangeability.  
2       To put it bluntly the question of what constitutes  
3       interchangeable, interchangeability and whether a  
4       biosimilar is interchangeable is becoming mute. The  
5       lack of guidance on interchangeability has allowed  
6       health insurers beginning in January to in essence  
7       declare some biosimilars interchangeable by excluding  
8       the reference product from their formulary. FDA needs  
9       to respond to this safety threat. America has counted  
10      on the FDA to keep them safe. Please don't turn your  
11      backs on their trust.

12           Thank you.

13           DR. ROACHE: Thank you. So this concludes  
14      our open public comment session.

15           Again these comments will be a part of the  
16      record and will be considered following this meeting.  
17      And also another reminder that the public docket will  
18      remain open until October 28, so you still have an  
19      opportunity to provide a comment in writing.

20           At this time I would like to turn it over to  
21      Dr. Mullin to let us know what the next steps are and  
22      also provide closing remarks.

1 CLOSING ERMARKS

2 DR. MULLIN: Okay. Thank you very much for  
3 coming today. We weren't sure if we would -- I think  
4 we actually are ending about at the time we would  
5 like. We appreciate everyone's feedback on the  
6 package that has been put together. And we very much  
7 appreciate your comments and your support for the  
8 resourcing as well. That has been a theme and it is  
9 going to be complicated with the way this works in  
10 terms of a new program that didn't have footprint and  
11 appropriated funds prior to -- or rather I should say  
12 non-fee funds prior to its start.

13 And so what we've got here and you may  
14 recall if you were here last December we were  
15 somewhere to the left on this chart but this is to  
16 give you a sense of the process that has been  
17 followed. It just tracks what needs to be done in  
18 terms of the reauthorization process outlined in the  
19 statute with other touch points along the way.

20 And we're getting close to wrapping up the  
21 part that FDA does. Last week we were able to brief  
22 the Health Committee staff and the Energy and Commerce

1 Committee staff on the package that we have told you  
2 about today. And we're hoping as we close the comment  
3 period toward the end of this month and then take some  
4 time to analyze those comments that we'll be able to  
5 complete the process of analysis of those comments and  
6 then we can on that basis go forward with the package  
7 and the recommendations to the Secretary. And the  
8 Secretary would then transmit whatever is recommended  
9 to the authorizing committees. And so we hope to have  
10 that done well on the way to give it to -- perhaps  
11 give it to this Congress and then it will be available  
12 for the next Congress as well which will start in  
13 2017.

14 So as Amanda said we have the docket that is  
15 still open if there is anything further that you think  
16 you want to add please do so. Please submit that to  
17 the docket by the deadline and we'll be taking  
18 everything that we receive and doing that analysis as  
19 quickly as we can to keep this moving along so that we  
20 can transmit the package.

21 And again thank you for your comments today  
22 and your continuing engagement and support for the

1 program and giving us the feedback. It really helps  
2 to make the program stronger. And we're looking  
3 forward to working over the next year for timely  
4 reauthorizations so that we really can move this  
5 forward.

6 Thank you and have a nice day. The last day  
7 of summer I think, we hope.

8 Thank you.

9 (Whereupon, the Biosimilar User Fee Act  
10 meeting concluded at 2:07 p.m.)

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CERTIFICATE OF NOTARY PUBLIC

I, ERICK McNAIR, the officer before whom the foregoing deposition was taken, do hereby certify that the witness whose testimony appears in the foregoing deposition was duly sworn by me; that the testimony of said witness was recorded by me and thereafter reduced to typewriting under my direction; that said deposition is a true record of the testimony given by said witness; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this deposition was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.



ERICK McNAIR

Notary Public in and for the  
District of Columbia

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## CERTIFICATE OF TRANSCRIPTION

I, CHERYL LaSELLE, hereby certify that I am not the Court Reporter who reported the following proceeding and that I have typed the transcript of this proceeding using the Court Reporter's notes and recordings. The foregoing/attached transcript is a true, correct, and complete transcription of said proceeding.



10/31/2016

CHERYL LaSELLE

Transcriptionist

<b>1</b>	<b>20</b> 1:9 27:4 57:4 71:2 89:2 <b>200,000,000</b> 96:19 <b>2007</b> 70:17 <b>2009</b> 65:16 108:19 <b>2010</b> 19:19,19 20:5 22:4,6 23:18 88:18 <b>2011</b> 20:5 21:18 22:6 23:19 <b>2012</b> 10:11 80:1 108:4 <b>2014</b> 106:15 <b>2015</b> 14:1 17:22 29:10 71:8 <b>2016</b> 1:9 97:7,16 100:12 <b>2017</b> 25:6 47:16 47:18 48:5,9 71:22 92:6 97:14 97:21 101:1 106:15 111:5 132:13 <b>2018</b> 45:19 46:5 78:21 80:20 106:3 127:13 <b>2019</b> 49:4,11 106:13 128:9 <b>2020</b> 44:3 <b>2022</b> 78:21 127:14 <b>2023</b> 94:15 <b>20993</b> 1:14 <b>21</b> 61:8 <b>21st</b> 33:6,7 <b>22</b> 70:18 <b>24</b> 47:16,20,22 <b>25</b> 12:11 58:11 <b>25,000</b> 70:10 <b>250,000</b> 129:6 <b>28</b> 6:19 130:18 <b>29</b> 4:12 <b>2:07</b> 133:10	<b>3</b>	<b>85</b> 5:5 71:8
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