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FOOD AND DRUG ADMINISTRATION  
  
FACILITATING COMPETITION AND INNOVATION  
IN THE BIOLOGICAL PRODUCTS MARKETPLACE  
  
PART 15 PUBLIC HEARING

White Oak Campus  
10903 New Hampshire Avenue  
Silver Spring, MD 20903  
Tuesday, September 4, 2018  
9:00 A.M.

Reported by: Michael Farkas

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A P P E A R A N C E S

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1 P R O C E E D I N G

2 DR. SHERMAN: All right. It's nine o'clock.  
3 Let's get started. Good morning and welcome to the  
4 Part 15 hearing on Facilitating Competition and  
5 Innovation in the Biological Products Marketplace.

6 My name is Rachel Sherman. I'm the Principal  
7 Deputy Commissioner of Food and Drugs, and will serve  
8 as the presiding officer for this hearing. The purpose  
9 of the hearing is to provide an opportunity for broad  
10 public input on FDA's approach to enhancing competition  
11 and innovation in the biological product marketplace,  
12 including facilitating greater availability of  
13 biosimilars and interchangeable products.

14 Before we begin I will make a few  
15 administrative announcements. First, please silence  
16 any cell phones, as we on the panel have done, or other  
17 mobile devices, as they may interfere with the audio in  
18 the room.

19 Second, we ask that all attendees sign in at  
20 the registration tables outside the meeting room.

21 Third, the rest rooms are located in the lobby  
22 past the coffee area, to the right and down the

1 hallway.

2           And finally, and I'll mention this again,  
3 copies of today's presentations are available upon  
4 request, and the contact information is available at  
5 the registration table, and for those of you watching  
6 on webcast, we will have a slide later that will give  
7 you the contact information.

8           For media inquiries, our press officer is  
9 Linsey Mayor, but she's taking -- today is the first  
10 day of school at Montgomery County, so to all FDAers  
11 with school-aged kids, thank you for juggling. Sandy  
12 Walsh is here. Sandy, can you -- Sandy Walsh will be  
13 here most of the day and Lindsey -- we'll introduce  
14 Lindsey when she arrives.

15           If any members of the media are here today,  
16 please sign in, and if you have any questions or are  
17 interested in speaking with the FDA about this public  
18 hearing, please contact Sandy or Lindsey. Because this  
19 hearing is intended to give FDA the opportunity to  
20 listen to comments from presenters, the panelists and  
21 other FDA employees will not be available to make  
22 statements to the media.

1           Although there are no rules of evidence for  
2 this public hearing, I note that the lawyers on our  
3 panel outnumber the physicians, so we're all going to  
4 behave. There are some general procedural rules. No  
5 participant can interrupt the presentation of any other  
6 participant and only FDA panel members will be allowed  
7 to question the presenters.

8           There will be an open public comment period at  
9 the end of the day, after the presentations have  
10 finished.

11           Public hearings are public administrative  
12 proceedings and are subject to FDA policy and  
13 procedures for electronic media coverage.  
14 Representatives of the electronic media are permitted,  
15 subject to certain limitations, to videotape, film or  
16 otherwise record FDA public procedures, including the  
17 presentations of the speakers today.

18           The hearing will also be transcribed and  
19 copies of the transcript can be ordered through the  
20 docket or accessed on our website approximately 30 days  
21 after the meeting.

22           Turning to today, we have 27 speakers, and

1 each will have eight minutes to present. After each  
2 speaker presents, we will have three minutes for the  
3 panel to ask questions. If a speaker finishes early or  
4 the panel does not use the full three minutes, we  
5 intend to move on to the next speaker.

6 This means the speakers may find themselves  
7 asked to give their presentations before the time that  
8 it listed on the agenda, so please keep that in mind as  
9 you schedule your day.

10 Although we may be adjusting the speaker  
11 schedule, we intend to keep to our scheduled breaks,  
12 including lunch. For the speakers, and this is the  
13 crucial part, we have timer lights to guide you.  
14 Theresa can point to those. The light will indicate  
15 when to begin speaking and when to stop. The timer  
16 will give you a one-minute warning. It will turn  
17 yellow. You have a minute left.

18 If you have not concluded your remarks by the  
19 time a light turns red, I apologize in advance but I  
20 will interrupt you and ask you to stop. And any time  
21 that is over the eight minutes will unfortunately have  
22 to come out of the panel question time.

1           Please remember that the hearing is being  
2 transcribed, so please be sure to use the microphones.  
3 If you did not register to make an oral presentation  
4 but wish to do so, you may be able to speak during the  
5 open public comment period, which begins at  
6 approximately 3:30. If you're interested, please sign  
7 up for one of the available slots, three-minute slots,  
8 by 10:00 a.m., and that's again at the table outside.

9           And I will be emphasizing this throughout the  
10 day. Please submit your comments to the docket, both  
11 what you present and on any other thoughts that you  
12 have. The Federal Register notice will have -- has the  
13 detail of how to submit, and we will again have a slide  
14 later for the folks who are viewing us remotely.

15           And as you can see, not from this slide, but  
16 from a slide eventually, the docket will remain open  
17 until Friday, September 21st, of this year.

18           This hearing is being webcast live, however,  
19 it is not interactive, so webcast viewers cannot  
20 comment or ask questions, but of course they can submit  
21 to the docket.

22           So turning to today, thank you all for coming,

1 particularly, again, the morning after Labor Day, and  
2 now let's turn to our first speaker.

3 Oh, I'm sorry. I forgot to ask the panel to  
4 introduce themselves.

5 MS. ABRAM: Anna Abram, Deputy Commissioner  
6 for Policy, Legislation and Analysis.

7 DR. FRANKLIN: Good morning. Joe Franklin,  
8 Director, Policy Staff in the Therapeutic Biologics and  
9 Biosimilars Staff within CDER.

10 DR. CHRISTL: Leah Christl. I'm the Director  
11 of the Therapeutic Biologics and Biosimilars Staff in  
12 CDER.

13 DR. KOZLOWSKI: Steve Kozlowski, Director of  
14 the Office of Biotechnology Products and OPQ, CEDR.

15 DR. MALONEY: Good morning. I'm Diane  
16 Maloney, Associate Director for Policy, in the Center  
17 for Biologics.

18 DR. UNLU: I'm Unlu Mustafa at the Office of  
19 Chief Counsel.

20 DR. SHERMAN: Thank you. And before I begin,  
21 thank you to the staff for giving me the phonetic  
22 spelling, but if I butcher anyone's name, I apologize

1 in advance.

2 Our first speaker is Dr. Andrew Greenspan from  
3 Johnson & Johnson.

4 DR. GREENSPAN: Good morning and thank you for  
5 the opportunity to speak on this important topic. As  
6 you heard, my name is Andrew Greenspan, and I'm the  
7 Vice President of Medical Affairs responsible for  
8 immunology biologics at Janssen Biotech.

9 I've split my 15 years with Janssen between  
10 medical affairs and research and development. Prior to  
11 that I was a practicing internist in New Jersey. I  
12 hope my perspective will be helpful and I'd like to  
13 commend the FDA for convening today's forum.

14 We'll also be submitting written comments to  
15 the docket following this public hearing. At Janssen  
16 we have extensive experience with the development,  
17 manufacturing and post-marketing safety of biologics.  
18 A long history included OKT3, the first monoclonal  
19 antibody ever approved and Remicade, a TNF blocker, for  
20 which there are three approved biosimilars plus seven  
21 additional biologics across a wide range of  
22 indications.

1           We'd like to be clear at the outset about two  
2 points. First, we support policies for biosimilars,  
3 while ensuring an open and competitive marketplace.

4           Second, we believe that patient safety and  
5 clinical considerations should guide all policies  
6 related to biosimilars. From the beginning we have  
7 been a leader in advocating for a biosimilar framework  
8 in line with these principals.

9           As FDA considers ways to facilitate greater  
10 available of biosimilar products, it is valuable to  
11 consider the potential ramifications of various  
12 switching scenarios, which I will discuss later in my  
13 presentation.

14           These scenarios include patients switching  
15 from innovator to biosimilar, switching between  
16 biosimilars and multiple switches. I will be using a  
17 Remicade experience today for illustration.

18           We have four recommendations to share today.  
19 Policies -- FDA policies must facilitate innovation to  
20 advanced patient care and outcomes. Regulatory  
21 exclusivities and patents incentivize the development  
22 of new life-changing treatments. Developing new

1 biologic products is resource intensive, and the risk  
2 of failure is high, and as policies must respect the  
3 intellectual property rights of innovator companies.  
4 Policies should protect life cycle product improvements  
5 that provide benefits for patients. The FDA issued  
6 guidance that clarifies that improvements, such as new  
7 indications, will be protected under the products  
8 initially granted exclusivity, also known as umbrella  
9 exclusivity.

10 Second, FDA should finalize robust standards  
11 for interchangeability. Many biologics treat chronic  
12 progressive diseases requiring a lifetime of therapy.  
13 It can take years of trying multiple medications for a  
14 patient to find a therapy that is effective. As a  
15 result it our experience that many prescribers prefer  
16 not to switch a stable patient, unless there is  
17 evidence that this switch will improve outcomes.

18 Biosimilars, which by definition do not offer  
19 improvements in efficacy or safety, offer no clinical  
20 reason to switch. The potential risk of switching back  
21 and forth between innovator and biosimilar requires  
22 rigorous clinical evaluation.

1           As discussed in the draft interchangeability  
2 guidance, such studies are particularly important in  
3 the case of monoclonal antibodies with known  
4 immunogenicity concerns. For example, in a large study  
5 of Remicade in patients with rheumatoid arthritis,  
6 nearly half of patients had anti-drug antibodies after  
7 seven months.

8           We support well-designed and rigorous studies  
9 as described in FDA's draft interchangeability  
10 guidance, because of both their value in providing  
11 confidence to patients and prescribers and the  
12 importance of resolving these unanswered scientific  
13 questions.

14           Third, FDA should address biosimilar-to-  
15 biosimilar switching. This switching is already  
16 occurring in the real world. Consider the VA system.  
17 Prior to 2017 Remicade was the exclusive infliximab in  
18 the VA hospital system. In 2017 Inflectra became the  
19 preferred infliximab. And Renflexus will become the  
20 preferred infliximab starting this month. This change  
21 in the formula has already resulted in Remicade  
22 patients switching to Inflectra and will resulted in

1 switches from Inflectra to Renflexis.

2 Prescribers have many questions regarding such  
3 switching between biosimilars, with few, if any studies  
4 that evaluate the consequences of it. Biosimilar  
5 approval is based only on comparison between the  
6 innovative product and biosimilar. We ask that FDA  
7 address the clinical questions about the safety and  
8 utility of switching between biosimilars, especially if  
9 their data suggests physical, chemical or functional  
10 differences between one biosimilar and another that  
11 could translate into a clinically meaningful effect.

12 We also ask that FDA acknowledge the potential  
13 concerns regarding biosimilar -- switching between  
14 biosimilars, by requiring biosimilar labels to convey  
15 that there are no data about switching between  
16 biosimilars.

17 Additionally, we ask that FDA require  
18 manufacturers make clear in the labeling of  
19 interchangeable products that a designation of  
20 interchangeability refers only to interchangeability  
21 with the reference product.

22 Fourth, FDA should consider requiring post-

1 marketing studies for biosimilars. Post-marketing  
2 studies provide useful information about a product when  
3 it is used in ways or settings that were not evaluated  
4 during the approval process. While the purpose of  
5 post-marketing safety studies is to provide additional  
6 long-term real world data, such studies have the added  
7 benefit of increasing prescriber confidence. There are  
8 no post-marketing commitments for biosimilars.

9 FDA should consider working with biosimilar  
10 sponsors to establish post-marketing registries or  
11 other methods for gathering longer-term safety data,  
12 particularly on the topic of switching between  
13 biosimilars, extrapolated indications and special  
14 populations.

15 I'd like to address uptick in use of  
16 biosimilars. The current system is an open and  
17 competitive environment that FDA policies should  
18 maintain and foster. We're seeing that biosimilar  
19 uptick and price competition have lowered the costs for  
20 both patients and the healthcare system.

21 For example, the net price of infliximab  
22 products, including Remicade, is falling. Biosimilars

1 have access to both public and commercial channels.  
2 And, in fact, the uptick of infliximab biosimilars is  
3 consistent with biologic launches in the US immunology  
4 market, even those that provide a clear clinical  
5 benefit over the standard of care.

6 As we discussed earlier, when patients are  
7 stable, many prescribers prefer not to change  
8 treatments, so we should not be surprised that  
9 biosimilars take some time to penetrate the market.

10 The primary driver of biosimilar adopted is  
11 prescriber confidence. The more confident prescribers  
12 are in FDA biosimilar and interchangeable approvals and  
13 the safety of these products, the more uptick there  
14 will be.

15 Finally, policies that give an advantage to  
16 either biosimilars or reference products may limit the  
17 potential savings generated by competitive pressure.

18 In closing, at Janssen we support the  
19 maintenance of robust and competitive environment for  
20 biologics, including biosimilars, and environment where  
21 patient safety and clinical considerations guide FDA's  
22 biosimilar decisions and policies. We ask that FDA

1 provide additional clarity in the areas of biosimilar  
2 to biosimilar switching, and interchangeable status.  
3 We believe that patient and prescriber confidence and  
4 use of biosimilars will increase with assurance that  
5 FDA is implementing and enforcing rigorous standards.

6 Finally, our experience with Remicade shows  
7 that when biosimilars are approved and marketed,  
8 competitive pressure will meaningful reduce net price.

9 Thank you again for this opportunity to speak.

10 DR. SHERMAN: Thank you for your comments and  
11 getting us kicked off on time. Questions from the  
12 panel.

13 DR. KOZLOWSKI: So you mentioned the need to  
14 look at biosimilar to biosimilar switching. So how do  
15 you think that differs from switching within a product  
16 class? So anti-TNF's, you know, are switched in  
17 patients all the time between different products, so  
18 what is the difference between that scenario and  
19 biosimilar switching again? Not interchangeable  
20 products but biosimilar switching?

21 DR. GREENSPAN: Yeah. Thank you for the  
22 question. So the molecules that inhibit TNF are

1 significantly different from each other, and there have  
2 been some data suggest that there may be concerns when  
3 you switch across the class of anti-TNF's. So there is  
4 one example of a study that was published a few years  
5 ago in patients with Crohn's Disease were stable on  
6 Remicade but switched to another TNF, with just a sub-  
7 cu delivery and patients lost response, and I think  
8 that data was very informative to show that not all  
9 TNF's are created equal.

10 When it comes to biosimilar to biosimilar  
11 switching and how that's different, there's really no  
12 data at this point at all, and we speak to physicians  
13 who have questions around that, and I think generating  
14 data on that would be valuable. And I think the reason  
15 why it's an important question is for a couple reasons.

16 One is from the patient perspective, they've  
17 taken quite a bit of time to reach Remicade. Many of  
18 them are untreated for many years by the time they get  
19 Remicade. They deal with infusion reactions, as I  
20 mentioned, is not uncommon with Remicade. Often  
21 prescribers spent a lot of time optimizing the dose, so  
22 they have a lot invested in Remicade. And from a

1 patient perspective, there's concern about switching.

2 From a scientific perspective I would focus on  
3 two things. The first is immunogenicity concerns,  
4 particularly with Remicade, which I acknowledge might  
5 be less significant for other biologics, but it's quite  
6 significant for Remicade.

7 And the second is that there are suggestions  
8 that there may be differences in infliximab  
9 biosimilars. Actually, thank you for the question. I  
10 brought up a publication from just last week that  
11 looked at structural and functional differences between  
12 the two marketed infliximabs that did show differences  
13 in glycosylation patterns, particularly afucosylation  
14 and I think some of the FDA panelists may be familiar  
15 with this during the approval of Inflectra, this came  
16 up, and in functional differences and antibody  
17 dependent cellular toxicity, they suggest that may have  
18 clinical meaningful consequences. Whether it does, I  
19 don't know, but I think it's worth on a case-by-case  
20 basis for the FDA to look into such cases like that.

21 DR. KOZLOWSKI: Thank you.

22 DR. SHERMAN: Other questions? Ms. Malone.

1 DR. MALONEY: I had a question. Could you  
2 just expand on your statement on the previous slide  
3 about where you say policies that advantage either  
4 biosimilars or reference products may limit the  
5 potential savings --

6 DR. GREENSPAN: Sure.

7 DR. MALONEY: -- generated by competitive  
8 pressure?

9 DR. GREENSPAN: Yeah, I'd be happy to. So it  
10 speaks to competition will drive down prices. We've  
11 seen that already. As one biosimilar entered the  
12 marketplace for Remicade, the price decreased. With  
13 two, the prices decreased. With increasing -- there's  
14 a third approved but not yet marketed, infliximab  
15 biosimilar, and we expect the price to continue to  
16 fall. It's probably best answered by Allen Greenspan,  
17 not Andrew Greenspan, but my understanding is more  
18 products into the marketplace, the price should  
19 continue to fall.

20 I will reference CMS policies. That seemed to  
21 be advantaging biosimilars, particularly on Fee 43  
22 pricing, and that's what we were referring to.

1 I would just like to add on though, in the  
2 biosimilar action plan there were several suggestions  
3 about how to accelerate the development and  
4 availability of biosimilars, and some examples of those  
5 would be in silico modeling and simulation and the use  
6 of real world evidence, and we think those are great  
7 suggestions and they apply just as well to the  
8 development of biologics, so we encourage you for some  
9 of those innovative approaches to consider them to  
10 apply to biologics and all drugs, as well.

11 DR. SHERMAN: Any other questions? Just one  
12 point of clarification. If you could on Slide 5, you  
13 said if approved as interchangeable, it should only be  
14 with reference practice. Is that because you were  
15 assuming that's what the studies were done, or if you  
16 feel there were similar data with a biosimilar-to-  
17 biosimilar, then that could be interchangeable, as  
18 well?

19 DR. GREENSPAN: Yeah, thank you for the  
20 question. An opportunity to clarify. If -- the  
21 interchangeability claim should only be made with the  
22 drug that's used as a reference of that, and the

1 concern was that there might be confusion in the  
2 marketplace if another biosimilar, which doesn't have  
3 an interchangeability claim would be confused as an  
4 interchangeable product.

5 DR. SHERMAN: Thank you for the clarification.  
6 Other questions? Thank you for your remarks.

7 DR. GREENSPAN: Thank you.

8 DR. SHERMAN: Our next speaker is Mr. Randall  
9 Rutta from the American Autoimmune Related Disorders  
10 Association.

11 MR. RUTTA: Good morning. Thank you. I'm  
12 Randall Rutta, Federal Policy Consultant for the  
13 American Autoimmune Related Diseases Association or  
14 AARDA. Thank you on behalf of AARDA for this  
15 opportunity to participate in today's public hearing,  
16 on behalf of people living with autoimmune diseases.

17 The FDA's goals and key questions concerning  
18 discovery, development and marketing of biologics,  
19 biosimilars, and interchangeable products are well  
20 founded, timely and critical of critical interest to  
21 the autoimmune community. At every step AARDA believes  
22 that patient engagement is essential to the success of

1 the FDA in advancing its mission and role regarding the  
2 evolution of the biological products marketplace.

3 AARDA is dedicated to the eradication of autoimmune  
4 diseases and the alleviation of suffering and negative  
5 socioeconomic impact of autoimmunity through education,  
6 public awareness, research and patient services.

7           As many as 50 million Americans are affected  
8 by one or more of the 100 plus autoimmune disorders  
9 that originate in an aberrant immune response and span  
10 a multiple of diverse conditions. AARDA recognizes  
11 that biologics and biosimilars are advancing patient  
12 access to new therapy options and affordable care.  
13 Patients with autoimmune diseases have extremely  
14 sensitive immune systems, which results in variations  
15 in how patients with autoimmune diseases experience  
16 their disorders, the manifestation of symptoms and the  
17 responses to treatment.

18           Even with small molecule drugs autoimmune  
19 patients can experience vast variations in responses  
20 due to their immune systems reactions, to both active  
21 and inactive ingredients in different medications. For  
22 highly complex therapy, such as biologicals, patients'

1 reactions may often vary even more greatly than the  
2 variances experienced between branded drugs and  
3 generics. We urge the FDA to insure that  
4 interchangeability determinations are not made unless  
5 it's truly the case for the statutory standard that the  
6 same clinical result can be expected in any given  
7 patient.

8 Data shows that patient responses to  
9 immunosuppressants and other immune modulating  
10 therapies vary greatly. As a result these drugs are  
11 often not interchangeable for particular patients and  
12 their specific experiences with autoimmunity and other  
13 co-occurring conditions.

14 AARDA believes that the approval of standards  
15 for a biosimilar product must meet the same standards  
16 of rigor and accountability as those set for the  
17 innovator biologic. Efficient development of  
18 biosimilar and possible future interchangeable products  
19 must use state-of-the-art experience and different  
20 biologic products that is sensitive to unique patient  
21 characteristics. Human testing that meets the highest  
22 safety standards is key, and special consideration

1 should be given to the application of biosimilar --  
2 biosimilars in pediatric patients and those with  
3 complex multiple conditions.

4 We urge the FDA to fully enforce the rigorous  
5 statutory standard for interchangeability and to ensure  
6 that no interchangeability determinations are made  
7 unless it's truly well established, proven and  
8 unequivocally supported by data. Interchangeability  
9 between biosimilars and reference products, and between  
10 interchangeable biosimilar products themselves must be  
11 equally data driven. Patient awareness of and  
12 participation in clinical trials and other  
13 developmental steps in bringing these products to  
14 market should be optimized, including through  
15 collaboration with AARDA and other patient groups that  
16 are trusted by and have access to patients and their  
17 physicians.

18 In regulating biologic products, including  
19 biosimilars and the possibility of future  
20 interchangeable products, AARDA strongly encourages the  
21 FDA and other HHS agencies to support biologics and  
22 biosimilar innovation, while recognizing the important

1 distinctions between different therapies.

2           The Biologics Price Competition Innovation Act  
3 created hope for patients with autoimmune diseases with  
4 respect to encouraging the development and availability  
5 of additional therapies for a number of diseases that  
6 currently have very limited treatment options.  
7 Biosimilars hold great promise to expand the  
8 therapeutic options for patients and to encourage  
9 competition, which in turn may also lead to improved  
10 affordability for many drugs.

11           We support initiatives focused on biosimilars  
12 innovation and policies that facilitate appropriate  
13 access and affordability to these medicines. AARDA  
14 supports the FDA's draft guidance that would require  
15 sponsors to consider immunogenicity risks and studies  
16 conducted for potential interchangeable determinations.  
17 AARDA recommends that autoimmune disease patients be  
18 included in clinical trials, post-marketing studies and  
19 other evaluations of potential interchangeability.  
20 AARDA believes that all stakeholders including patients  
21 and their healthcare providers must have access to  
22 information that distinguishes the biosimilars from

1 innovative biologics for appropriate prescribing.

2 As noted, even small differences between  
3 biologic products can have serious implications for  
4 autoimmune patients. As a result, distinct names,  
5 identifiers and labeling are critical to facilitate  
6 prescriber and patient awareness, minimize confusion  
7 and help ensure appropriate treatment management.  
8 These steps will enable an accurate, effective use,  
9 encourage development and support the marketing of  
10 biosimilar in interchangeable products.

11 One fundamental priority in this area, AARDA  
12 believes patients and their physicians must have the  
13 final choice on what products a patient receives.  
14 Significant harm can result for patients, particularly  
15 vulnerable individuals with complex conditions, when  
16 medication switches or substitutions occur. Given the  
17 implications, any potential interchangeability  
18 determinations that might occur in the future must  
19 consider the safety risk that substitutions present,  
20 and must avoid disruptions in care for patients.

21 This includes patients who are stabilized on a  
22 biological medication, those who may incur

1 immunogenicity, and those for whom substitutions could  
2 cause a loss of response to the originator medicine.  
3 For patients with complex conditions who are already  
4 stabilized on a therapy, it's not appropriate to impose  
5 automatic substitutions or non-medical switching made  
6 by a pharmacist without the intervention and consultation of  
7 the prescriber and consent of the patient.

8           The BPCIA allows biosimilar substitutions  
9 without a physician's intervention, only for  
10 interchangeable products as designated by the FDA and  
11 not for other biological products and biosimilars.  
12 AARDA believes that the FDA and HHS must exercise  
13 extreme caution with respect to any policy or practice  
14 that interferes with physician independent clinical  
15 judgment and treatment recommendations.

16           Interchangeability determination should remain  
17 an extremely high bar that cannot be cleared unless it  
18 is true and supported by meaningful and unequivocal  
19 data, that any and all patients could be expected to  
20 experience the same clinical result in response to the  
21 therapy as required by statute.

22           Lastly, AARDA believes that accurate tracking

1 and tracing of biologicals, including biosimilars in  
2 any possible future interchangeable products must be  
3 assured for the purpose of monitoring, tracking and  
4 monitoring.

5 As these products gain traction in their  
6 availability and use, transparency for, among and with  
7 patients and their providers is essential. Documents  
8 of any substitution that does occur should be tracked  
9 and reported to patients' providers on a timely basis  
10 via effective channels. We strongly urge the FDA to  
11 take necessary steps to monitor, evaluate and assure  
12 biologic, biosimilar and interchangeability safety and  
13 effectiveness, directly and across the healthcare  
14 ecosystem.

15 AARDA will submit detailed written comments  
16 per this request. It is readily available as partner  
17 and resource to continue to assist the FDA in this very  
18 important and worthwhile area.

19 Thank you so much.

20 DR. SHERMAN: Thank you for your comments.

21 Questions from the panel? Dr. Franklin?

22 DR. FRANKLIN: Thanks. You emphasized the

1 importance of information to patients. Are there  
2 particular information resources, types of information  
3 that FDA could provide, particularly with the focus on  
4 interchangeability and providing information about  
5 interchangeability to patients?

6 MR. RUTTA: I think if FDA can continue to be  
7 a leader in bringing this information forward, both  
8 directly in terms of the education outreach that you  
9 support and the Agency supports, but then also to use  
10 your influence across all of the stakeholders in the  
11 system to encourage that kind of information and  
12 participation and collaboration occurs, is going to be  
13 key.

14 I mean, patients, particularly people with  
15 autoimmune diseases, have no greater stake than anyone  
16 in having the success of this discussion go forward and  
17 to see more of these options for their treatment move  
18 forward, but safely and with their full knowledge, so  
19 that these patients can be full participants in every  
20 step of the evolution, use and then marketing and  
21 development of new treatment, so thank you for that.

22 DR. SHERMAN: Other questions from the panel?

1 Okay. Then I have one.

2 Oh, you talked about for substitution that it  
3 should be tracked and reported. And we have the  
4 example from Dr. Greenspan that's going on at the VA.  
5 Tracked by whom, reported by whom, and to whom?

6 MR. RUTTA: Everywhere across the board as  
7 much as possible, please. I think for the purposes of  
8 patients, that tracking and reporting absolutely occurs  
9 very close to where they're seeking their treatment, so  
10 it's really that patient-physician partnership that  
11 needs to be well informed and that anywhere within the  
12 system the decisions are being made about a medication  
13 that an individual receives, particularly a change in  
14 the -- that medication's history, should be tracked.  
15 It may be at the pharmacy level. It may be at the  
16 distribution level. It may be at any level where that  
17 -- where that medicine is -- a decision about that  
18 medicine is kind of changing hands. So thank you.

19 DR. SHERMAN: Great. Thank you. Additional -  
20 - Dr. Kozlowski? Or no?

21 DR. KOZLOWSKI: So in terms of education, so  
22 I'm -- is there an interest in an education on the

1 power of analytics, because a lot of what you discussed  
2 were clinical evidence? And I think we've heard about  
3 small differences being measured but many cases those  
4 are small differences that don't matter, and they  
5 actually speak to the power of analytical tools to be  
6 able to really discriminate and understand these  
7 molecules.

8 So it would seem part of confidence in both  
9 biosimilars and interchangeable is understanding  
10 analytics and the power of analytics.

11 MR. RUTTA: Absolutely. I think that's going  
12 to be key for kind of a confidence level to occur  
13 across both the prescribing and the patient  
14 communities, as well as factoring in risk. You know,  
15 for a lot of autoimmune patients, they're living with  
16 such challenges day to day, that if they understand,  
17 you know, what the risks are, what the ramifications  
18 might be, what the potential benefits might be, versus  
19 some of those tradeoffs that analytics can really help  
20 us understand, that's going to be key to a more  
21 informed patient and a more informed patient community.

22 And groups like AARDA and other patient groups

1 should be considered a ready resource at every step to  
2 be a part of both the analytics component and then the  
3 interpretation of those analytics to the field.

4 DR. SHERMAN: Dr. Mustafa.

5 DR. UNLU: You said that patients and  
6 prescribers must have access to information about  
7 biosimilar that make them different -- I'm  
8 paraphrasing. Does your organization and the patients  
9 that they serve have a similar interest in knowing  
10 about differences, for example, in batch-to-batch  
11 variation in innovator products or differences that  
12 occur after manufacturing changes in innovator product?

13 MR. RUTTA: Absolutely. I mean, anything  
14 that's going to represent a change, both in what their  
15 understanding of a particular intervention might be or  
16 what the experience might be following the kind of  
17 scenario that you described, would be of key interest.  
18 Helping to interpret that in a way in which patients  
19 and their prescribers can understand and then put into  
20 practice, that's the challenge. But I think knowing  
21 that groups like ours are ready to be a partner in that  
22 process and that anything we can do to have a system

1 that's better informed at every step, will give us  
2 better results and hopefully greater efficiencies, more  
3 effective use, et cetera.

4 DR. UNLU: All right. So just as a follow-up,  
5 so maybe the best we can do is to put the context the  
6 variability between innovators and biosimilars, by  
7 pointing to variabilities inside innovator product, as  
8 well?

9 MR. RUTTA: Absolutely. That would be  
10 extremely helpful.

11 DR. SHERMAN: No more questions? Thank you  
12 for your comments.

13 MR. RUTTA: Thank you.

14 DR. SHERMAN: Thank you, Theresa. I missed my  
15 light. Our next speaker is Ms. Juliana Reed from the  
16 Biosimilars Forum.

17 MS. REED: Hi. Good morning, everyone. I am  
18 Juliana Reed. I'm the Vice President of Corporate  
19 Affairs in the Global Biosimilars Lead for Pfizer, but  
20 I am also and very proud to say I'm the President of  
21 the Biosimilars Forum.

22 The Biosimilars Forum is a nonprofit

1 organization whose mission is to advance biosimilars in  
2 the United States with the intent of expanding access  
3 to biologic medicines and improving healthcare.

4 The Forum works on a consensus basis to  
5 develop policy positions to ensure the United States  
6 has a competitive and sustainable biosimilars market,  
7 providing more options to patients and physicians. We  
8 appreciate the opportunity to comment today on FDA  
9 support for streamlining the development of  
10 biosimilars, enhancing the efficiency of FDA review,  
11 and providing additional scientific and regulatory  
12 clarity to stakeholders.

13 The Forum applauds the efforts the FDA made --  
14 the efforts made by the FDA to facilitate greater  
15 availability of biosimilars in the marketplace and  
16 thanks the FDA for holding this public hearing. The  
17 Forum has reviewed FDA's public hearing notice and  
18 plans to submit detailed comments in the docket, and I  
19 will highlight a few of those today.

20 Regarding the utility of the Purple Book, we  
21 believe the FDA can and should make the Purple Book  
22 more useful for all stakeholders, by making it

1 available as an interactive functional and searchable  
2 database. We suggest providing an additional column  
3 for each biosimilar and interchangeable product, where  
4 the identity of the corresponding reference product is  
5 listed, along with the date of exclusivity expiration.  
6 We further encourage the FDA to provide a single  
7 product list that includes both CDER and CBER regulated  
8 products, which will assist stakeholders who may not be  
9 aware of which center regulates the product.

10 We strongly support FDA's ongoing stakeholder  
11 educational efforts. We encourage FDA to increase its  
12 efforts to educate pharmacists, physicians and  
13 patients, as well as to address the inaccurate  
14 perceptions.

15 For example, FDA can increase efforts to  
16 promote the message that the same quality standards are  
17 applied to both biosimilars and interchangeable  
18 biologics, as well as the fact that biosimilars can be  
19 given to both naïve patients, as well as to established  
20 patients, who have previously been treated with the  
21 reference product.

22 Furthermore, FDA should develop and offer a

1 continuing education program focused on biosimilar  
2 products to increase provider and pharmacist  
3 understanding of biosimilars. The forum encourages FDA  
4 to expand its educational footprint beyond its website,  
5 and place additional focus on patient and patient group  
6 educational efforts, including development of patient  
7 focused educational materials.

8 To further support the advancement of  
9 biosimilar programs, we urge FDA to exercise increased  
10 flexibility and clinical approaches, without  
11 sacrificing scientific rigor. We encourage FDA to  
12 exercise flexibility and reference product bridging,  
13 allowing for the use of non-U.S. referenced products,  
14 when it is scientifically justified.

15 FDA should also exercise flexibility regarding  
16 the structure and design of bridging studies, allowing  
17 for discussions with sponsors to determine the  
18 necessary requirements on a case-by-case basis. FDA  
19 should remain flexible regarding study end points and  
20 overall study design of the comparative clinical study  
21 or switching study.

22 Recent comments by Commissioner Gottlieb

1 suggest FDA is considering not making the naming  
2 paradigm retroactive, because of the potential high  
3 cost associated with retrospective application across  
4 the healthcare system.

5 The Forum is concerned that assigning suffixes  
6 to biosimilars but not to their reference products may  
7 hinder appropriate pharmacovigilance efforts and could  
8 lead to inaccurate perceptions regarding biosimilar  
9 products.

10 We suggest that one approach to addressing  
11 cost effectiveness is for the FDA to require  
12 application of the suffix paradigm only to biologics  
13 that are reference products.

14 The Forum requests FDA work collaboratively  
15 with stakeholders to find efficient means of applying  
16 suffixes to reference products.

17 We further support FDA's efforts to ensure  
18 reference product samples are made available to  
19 biosimilar product sponsors for development purposes.  
20 We stress the vital importance of ensuring adequate and  
21 timely access to samples of reference products in order  
22 to avoid delays and impediments to biosimilar

1 development.

2 We applaud the efforts made by the FDA to work  
3 with industry and other agencies to support market  
4 competition and increase the uptick of biosimilars. We  
5 strongly support CMS's decision to assign individual  
6 billing and payment codes to each biosimilar,  
7 reflecting the important differences FDA has  
8 acknowledged between biosimilars and small molecule  
9 generics. We further support CMS's decision to make  
10 all biosimilars eligible for pass-through payment  
11 status.

12 However, the Forum is concerned about  
13 advancing alternatives to current payment models, as  
14 they may stifle innovation. It is with this concern  
15 that the Forum urges the Administration to continue to  
16 examine new distribution models and options.

17 The Forum echoes FDA's concerns regarding the  
18 existing rebate systems for reference biologics that  
19 create and compromise the entrance of biosimilars into  
20 the U.S. marketplace. We urge the Administration to  
21 ensure rebates focus on patient access and out-of-  
22 pocket costs, and not list price.

1           Thank you for the opportunity to be here today  
2           and to offer comments on behalf of the Biosimilars  
3           Forum. The Forum looks forward to continuing our work  
4           with the FDA as to serve a resource and to advance  
5           biosimilars in the U.S. And I'm happy to respond to  
6           any questions.

7           DR. SHERMAN: Thank you very much and for  
8           remaining on time. Questions from the panel? Dr.  
9           Kozlowski?

10          DR. KOZLOWSKI: So you mentioned having the  
11          same quality standard for biosimilar biological  
12          products and interchangeable products, which actually  
13          is the statute, but do you think there should be a way  
14          of advancing analytical tools being considered, both  
15          for biosimilar and interchangeable biological products,  
16          that there be a fixed standard, but that standard  
17          evolves in some way?

18          MS. REED: Our comments are related to -- and  
19          I'll let a more scientific person answer the scientific  
20          part of the question, but our comments are related to  
21          the education piece, that the quality standards for  
22          both a biosimilar and an interchangeable biosimilar are

1 not different. And that's a very important piece.

2           You'll hear, and this is something through our  
3 experience, you'll hear folks talk about that there  
4 should be a difference between a biosimilar or an  
5 interchangeable biosimilar and perhaps that someone  
6 should expect a different clinical result. And we want  
7 and urge the FDA to simplify that, so that's what we're  
8 addressing in our response.

9           DR. KOZLOWSKI: Thank you.

10          MS. REED: Thank you.

11          DR. SHERMAN: Dr. Franklin.

12          DR. FRANKLIN: You mentioned some additional  
13 information in the -- information and formatting and  
14 kind of function of the Purple Book that would be  
15 useful. Can you provide some insight into what the  
16 utility of additional reference product or exclusivity  
17 expiration information would be, and how we might  
18 incorporate that into the Purple Book?

19          MS. REED: I think it's an important part. If  
20 you look back at how we're trying to figure out, and I  
21 think you guys have a requirement to establish the  
22 exclusivity piece. Looking for that within the Purple

1 Book, but also as the biosimilar comes on, how long did  
2 it take to get to the biosimilar to be approved to the  
3 marketplace, et cetera, and further clarity for the  
4 developers.

5 DR. FRANKLIN: So you're describing -- so this  
6 would be for approved biosimilar and interchangeable  
7 products, and it would show past expired exclusivity  
8 dates?

9 MS. REED: Yes.

10 DR. FRANKLIN: Okay, thanks.

11 DR. SHERMAN: Dr. Christl.

12 DR. CHRISTL: In terms of the education and  
13 outreach, you talked about FDA expanding its  
14 educational footprint beyond FDA's website. So as you  
15 know, we've done some videos. We have done a CE course  
16 and some webinars. Do you have other recommendations  
17 on, you know, all the stuff that we've done is housed  
18 on the website, so can you give a little bit more  
19 clarity about sort of your thoughts on expanding beyond  
20 the website?

21 MS. REED: Yeah, and first of all, thank you,  
22 because you guys are doing a great job and we

1 appreciate what you're doing with us at the Forum, so  
2 thank you.

3 This is -- our recommendation is to get it  
4 down to the patient in the physician office level.  
5 That simplicity of taking it off the website and  
6 perhaps something -- because it's the physician, as we  
7 talk about the physician confidence, in relaying  
8 confidence and using the biosimilar, having something  
9 from the Agency as you got, you know, you're the FDI  
10 and having you in that patient visit with that  
11 physician or pharmacist, to talk about it at that level  
12 is even a greater use.

13 DR. CHRISTL: Thank you for your comments.

14 MS. REED: Thank you.

15 DR. SHERMAN: Our next speaker is Dr. Cartier  
16 Esham from BIO.

17 DR. ESHAM: Okay. So on behalf of BIO I would  
18 like to thank the FDA for the opportunity to  
19 participate in today's public hearing. This is an  
20 important topic for BIO and its members.

21 Of particular relevance to today's hearing,  
22 BIO's membership includes all of the leading companies

1 on the cutting edge of biological product innovation,  
2 many of whom are also actively involved in the  
3 development and bringing to market biosimilars and  
4 interchangeable biological products.

5 As the FDC predicted in its 2009 reporting  
6 regarding the future development of the biosimilar  
7 marketplace in the United States, the complexity of  
8 developing and administering such product means that  
9 this marketplace is likely to take on the  
10 characteristics of a brand-to-brand competition rather  
11 than the generic competition we see under the Hatch  
12 Waxman Act of today.

13 This is an important and fundamental  
14 consideration to keep in mind as we discuss how best to  
15 foster a robust competitive marketplace for biological  
16 products. BIO believes that safe and effective  
17 biosimilars and interchangeable products are good for  
18 patients and good for public health, and we were a  
19 leader in developing the statutory pathway developed  
20 over a decade ago.

21 We are committed to helping grow a robust  
22 marketplace in which innovators and biosimilar

1 manufacturers can compete on a level playing field,  
2 providing a limited period of innovator exclusivity to  
3 provide the incentive necessary for companies and  
4 investors to devote the tremendous amount of resources  
5 and risk required to bring a new medicine to market.

6 BIO believes that robust competition at each  
7 stage of the biopharmaceutical life cycle, from other  
8 branded biological products in the same therapeutic  
9 class, to biosimilars following expiration of innovator  
10 exclusivities is the best mechanism to control cost for  
11 patients and payers, while still encouraging the  
12 continued investment in innovative treatments for cures  
13 and patients over time.

14 At the same time BIO believes that a level  
15 playing field requires that reference produce sponsors,  
16 biosimilar developers and the FDA work together to  
17 ensure that reasonable access to the product samples  
18 needed to safely and efficiently conduct biosimilar  
19 development programs is achieved without impeding the  
20 ongoing product operations of the reference product  
21 sponsor.

22 We have been a strong supporter of the

1 Agency's efforts to advance implementation of the  
2 BPCAA. It is through the Agency's hard work that in  
3 only eight years since the passage of this Act, 12  
4 biosimilars for eight reference products have been  
5 approved.

6 By comparison, during the same initial eight  
7 years of the companion European Union process, the MA  
8 approved five unique biosimilars to two different  
9 reference products, excluding products not classified  
10 as biosimilars in the United States, such as transition  
11 products, with duplicative marketing authorization by  
12 the EMA.

13 There are important steps needed to be taken  
14 by FDA in order to further advance the growth of the  
15 biosimilar market, such as the current commitment and  
16 activities to educate health professionals, payers,  
17 patients and caregivers regarding the meaning, use and  
18 value of biosimilars in interchangeable products.

19 Additionally, the Agency has already finalized  
20 much needed guidances, including those on scientific  
21 considerations for demonstration biosimilarity,  
22 clinical, pharmacology data, and labeling of

1 biosimilars.

2           Of particular importance to BIO's members is  
3 the finalization of interchangeability guidance, which  
4 has been discussed a lot so far today. The criteria  
5 for demonstration interchangeability are legally and  
6 scientifically different from the standards for  
7 establishing biosimilarity. And consequently,  
8 demonstrating interchangeability requires additional  
9 data. FDA should ensure for products that are  
10 administered more than once that the risk in terms of  
11 safety or diminished efficacy of alternating or  
12 switching between use of the biological product and the  
13 reference product is not greater than the risk of using  
14 the reference product without such alteration or  
15 switching.

16           These additional criteria, which should be  
17 mapped through the use of clinical switching studies,  
18 are critically important to patient safety and to the  
19 Agency's faithful execution of the Act. In fact, only  
20 an interchangeable product and its reference product  
21 should be subject to pharmacy level substitution  
22 without the intervention of a healthcare practitioner

1 who prescribed the reference product, reference  
2 medication.

3           Therefore, finalization of this important  
4 guidance in its most recent form would establish how  
5 developers can meet these additional statutory  
6 requirements to demonstrate interchangeability and  
7 further promote and grow the competitive marketplace  
8 for all biological products.

9           BIO continues to support the FDA in its  
10 development of guidance on the analysis of analytical  
11 similarity. BIO believes that analytical similarity  
12 should be determine with the scientifically sound and  
13 evidence-based approach, and the determination of the  
14 appropriate statistical approach is best determined on  
15 a product specific basis.

16           FDA should work with product developers to  
17 identify scientifically appropriate ways with which to  
18 deal with changes in reference product attributes over  
19 time and how statistical methods may be used  
20 appropriately in this context.

21           Additionally, as FDA noted in its public  
22 hearing notice, in many cases patents or statutory

1       exclusivities may protect one or more conditions of use  
2       for a reference product. We are aware that biosimilar  
3       products sought licensure for less than all of the  
4       reference products conditions of use. In some  
5       instances this may be because the reference product has  
6       patented, as well as unpatented uses, or uses protected  
7       by regulatory exclusivity.

8               We generally support the principle that a  
9       biosimilar manufacturer should be able to sell its  
10       product for uses not protected, while the reference  
11       product holder should be able to continue to benefit  
12       from patent or regulatory exclusivity. The biosimilar  
13       label should be clear about which conditions of use are  
14       licensed. In instances where this means less than all  
15       of the reference product conditions of use, the label  
16       should be clear and should only contain information  
17       related to the approved uses, except as otherwise  
18       required.

19               In the same vein, supplemental and subsequent  
20       approvals of reference products for new uses, changes  
21       in product presentation and certain structural  
22       modifications of a reference product, should receive

1 the product's original data exclusivity, a well-  
2 established construct that is known as umbrella  
3 exclusivity. They do not receive such exclusivity,  
4 then a reference product sponsor is actually  
5 disincentivized to research and demonstrate any new  
6 uses or other improvements to the original product,  
7 since such changes would not only be not protected  
8 against immediate copying, but could also undermine the  
9 remaining data exclusivity of the original reference  
10 product.

11 Accordingly, applying umbrella exclusivity to  
12 such improvements is done under the Hatch Waxman Act  
13 with respect to small molecule drugs, strikes a  
14 reasonable balance.

15 It is critical that the FDA apply statutory  
16 exclusivities fairly and evenly, be in the context of  
17 reference products or modified reference biologics, or  
18 in the context of biologics that were approved under  
19 new drug applications prior -- prior to the -- I'm  
20 sorry, I lost my place here.

21 It is with this respect that BIO urges FDA to  
22 rethink its 2016 draft guidance on the application of

1 data exclusivity to transition biologics approved  
2 biologics under the FDCA that would be deemed licensed  
3 under the PHS on March 23rd, 2020 and could lose  
4 exclusivity protection.

5 As the biosimilar market continues to grow,  
6 BIO will continue to advocate for policies that  
7 encourage robust competition, protect patient access to  
8 the medicines their providers deem most appropriate for  
9 them, and ensure continued investment in innovative  
10 biological medicines.

11 BIO appreciates this opportunity and we will  
12 be submitting further detailed comments to the docket  
13 later this month.

14 DR. SHERMAN: Thank you for your comments.  
15 Questions from the panel? Dr. Kozlowski.

16 DR. KOZLOWSKI: So you mentioned that BIO  
17 supports access to reference products for development  
18 of biosimilars. So being a trade group for many of the  
19 companies which, in fact, can make those materials  
20 available, what is BIO planning to do to support that  
21 goal?

22 DR. ESHAM: I'm happy to discuss in more

1 detail offline, as well, and we are in the process of  
2 submitting -- developing more detailed comments, but  
3 generally speaking we are appreciative of the direction  
4 FDA is taking presently. I look forward to working out  
5 the details as it progresses.

6 DR. KOZLOWSKI: Thank you.

7 DR. UNLU: You mentioned applying exclusivity  
8 transition products in 2020, but you said -- you seemed  
9 to say that products that would be losing exclusivity  
10 on that date. Did you mean to include all transition  
11 products in your comment or just those that might have  
12 exclusivity on that date?

13 DR. ESHAM: I think generally speaking, and  
14 again we'll provide more details, more specific details  
15 in our comments that we submit later this month, but in  
16 its simplest terms I think what we're saying is any  
17 products that fall under that transition should not  
18 lose the exclusivities they hold due to the transition.

19 DR. UNLU: Thanks.

20 DR. SHERMAN: Any other questions from the  
21 panel? Thank you for your remarks.

22 DR. ESHAM: Thank you very much.

1 DR. SHERMAN: Our next speaker is Ms. Sarah  
2 Aoanan, Global Healthy Living Foundation.

3 MS. AOANAN: Good morning. My name is Sarah  
4 Aoanan. I am the Patient Advocate and Community  
5 Outreach Manager for the Global Healthy Living  
6 Foundation. I have no disclosures to make regarding my  
7 travel here today. The Global Healthy Living  
8 Foundation accepts grants and charitable contributions  
9 from pharmaceutical companies, government, private  
10 foundations and individuals.

11 I would like to thank the FDA for this  
12 opportunity to provide comments today. The Global  
13 Healthy Living Foundation is a 20-year-old 501(c)(3)  
14 patient advocacy organization representing chronically  
15 ill patients and their caregivers across the U.S.,  
16 Western Europe, Australia and South America. We work  
17 to improve the quality of live for people living with  
18 chronic disease, by making sure their voices are heard  
19 and advocating for improved access to care at the  
20 community level.

21 Our patients are suffering from chronic  
22 conditions, including arthritis, psoriasis,

1 osteoporosis, chronic pain, cardiovascular disease and  
2 migraine, and many of them have been living with these  
3 conditions for years. Many patients in our community  
4 make sure of biological products to effectively treat  
5 their chronic disease. However, they also experience  
6 significant out-of-pocket expenses as a result of  
7 policies that shift financial burden onto the patient.

8           Biosimilars have the potential to drastically  
9 reduce costs for our patients and we believe in  
10 creating a system that will incentivize biosimilar  
11 manufacturing and increase competition. We are  
12 encouraged to see the steps that the Administration has  
13 taken and have outlined in the Biosimilars Action Plan,  
14 to ensure that there is an appropriate balance between  
15 innovation and competition.

16           We were particularly happy to see the emphasis  
17 on the importance of educating clinicians, patients and  
18 payers. We believe that the proper education of  
19 stakeholders will help to build confidence in  
20 biosimilars and ultimately increase their utilization.

21           GHLF has worked to harness social media, to  
22 educate patients and providers about these new

1 therapies and their potential to reduce the cost of  
2 care. People with autoimmune disease want to know  
3 about biosimilars. Often medical and scientific terms  
4 are not patient friendly, so we simplify them and  
5 incorporate patient lifestyle issues, using social  
6 media to reach patients through mediums they already  
7 use.

8           Our monthly Twitter chat averages five million  
9 impressions, which helps achieve this educational  
10 objective. Many of our patients go through years of  
11 trial and error to find a treatment plan that  
12 adequately manages their disease, making switching to a  
13 biosimilar seem daunting. We believe that education  
14 campaigns need to focus on building confidence among  
15 patients that these treatments are just as effective as  
16 innovator biologics.

17           GHLF also believes that in order for any  
18 educational activities to be successful they need to  
19 include robust data that showcases the safety and  
20 effectiveness of biosimilars, including those that are  
21 ultimately considered interchangeable. These include  
22 putting all clinical trials on the product label.

1           When it comes to demonstrating  
2 interchangeability, we have commented extensively on  
3 the importance of conducting thorough studies. It is  
4 our belief that rigorous switching studies are  
5 essential, not only to ensure patient safety, but also  
6 to build patient and provider confidence.

7           As we've stated in previous comments, we agree  
8 with the FDA's approach to require clinical studies for  
9 multiple switches between the biologic reference  
10 product and the proposed biosimilar. We feel that this  
11 is important as it will mimic the real world experience  
12 of patients and the insurance companies and PBM's  
13 frequent alteration to their formulary tiers from plan  
14 year to plan year.

15           Also needed is greater understanding and  
16 safety evidence surrounding interchangeability between  
17 biosimilars. In the near future patients will likely  
18 face switching between two different biosimilars, with  
19 or without FDA interchangeability guidance, again,  
20 because of formulary tier changes.

21           We also are supportive of the use of real  
22 world data to provide additional evidence on safety and

1 effectiveness. Patient reported outcomes should be  
2 used by the FDA to understand why a patient decides to  
3 switch from one product to another. Our 17,000 member  
4 patient registry, Arthritis Power, allows patients to  
5 actively engage in health research, while monitoring  
6 their own progress, in collaboration with their  
7 physicians.

8 Our primary mission is to provide patient  
9 reported data to researchers interested in  
10 understanding how patients respond to treatments over  
11 time. Often the data collected by researchers does not  
12 reflect outcomes that matter most to patients. Our  
13 patient center data points can further cement  
14 confidence in biosimilar products by providing critical  
15 usage data.

16 Additionally, just like generics, patients  
17 must share in biosimilar cost savings, through  
18 patients' out-of-pocket reductions. This will give  
19 patients and physicians another reason to embrace  
20 biosimilars. The price of a drug to a patient is their  
21 out-of-pocket cost, not an arbitrary list price or the  
22 price after rebates, discounts and fees, that an

1 insurance company, Medicare, Tricare, or a PBM pays.

2 Therefore, when the country talks about  
3 reducing drug prices, we think the conversation must  
4 focus on the price the patient pays. In the case of  
5 biosimilars, patients must share in the cost savings.  
6 Savings to the system, government or private, are not  
7 relevant to someone who has a multi-thousand dollar  
8 drug expense every year.

9 A patient's right to know is a priority for  
10 GHLF. As odd as it seems to patients they and their  
11 healthcare provider may not know what drug they are on.  
12 GHLF has successfully advocated for legislation at the  
13 State level that requires patients and providers to be  
14 notified when an interchangeable biosimilar product has  
15 been substituted in place of the innovator at the  
16 pharmacy.

17 These laws also require the pharmacist and the  
18 physician to keep track of these substitutions and as a  
19 result ensure that patients are aware of any changes to  
20 their patient's treatments. Patients assume this  
21 protection is baked into the system, but without  
22 legislation it is not.

1           Finally, GHLF feels that the responsibility  
2           for helping to build confidence around biosimilars also  
3           lies with the payers. It should be working with  
4           physicians, patients and patient groups to help them  
5           understand that these alternatives are not only just as  
6           effective in managing diseases, but will also reduce  
7           costs to patients.

8           GHLF looks forward to partnering with all  
9           stakeholders to continue patient education. Thank you  
10          again for the opportunity to provide comments on this  
11          issue. We will be submitting written comments to the  
12          formal docket. If you have any additional comments or  
13          questions, please reach out.

14          DR. SHERMAN: Thank you for your comments.  
15          Questions from the panel? Ms. Abram.

16          MS. ABRAM: Thank you for your comments. I'm  
17          wondering if you could expand on your comment during  
18          your remarks on the patient reported outcomes, and that  
19          the data being collected is not capturing what matters  
20          most to patients?

21          MS. AOANAN: There are patient powered  
22          research networks like Arthritis Power, which are a

1 part of PCORnet and PCORI with patient reported  
2 outcomes. I think patients need to be at the center  
3 and at the beginning of those conversations before  
4 they're collected, and I'm not always sure they are.

5 DR. SHERMAN: Other questions? Dr. Kozlowski.

6 DR. KOZLOWSKI: So this is a theme that got  
7 covered a little bit before, but you mentioned the  
8 importance of patients understanding all the clinical  
9 information, and it should be readily available. So  
10 again, a lot of the evidence for biosimilarity and  
11 interchangeability will be analytical data, which  
12 patients may not really have a sense about how to  
13 interpret, and so what are your thoughts on how  
14 education could include that, because that truly is  
15 something that's very precise and although clinical  
16 data is ground truth, analytical data is a key part of  
17 this, and really the foundation, because no matter how  
18 large the clinical studies, they will not address  
19 everything.

20 MS. AOANAN: Well, we initially hope that we  
21 can put clinical trials on the label and the inserts,  
22 to be as transparent and provide the maximum amount of

1 analytical data for the prescriber and patients.

2 DR. KOZLOWSKI: So by analytical data I mean,  
3 you know, laboratory data on the structure of the  
4 molecules, so not necessarily analysis of the clinical  
5 data. So again, I think that that's a harder concept  
6 for somebody to grasp, because as a patient you say  
7 well here are patients, they were treated, I can  
8 understand the outcomes. Analytical data is different  
9 and I think again I'm very interested in how that could  
10 be conveyed, because that's harder to convey, but it is  
11 a very important part of confidence around  
12 biosimilarity and interchangeability.

13 MS. AOANAN: I think that's working with  
14 patient groups to demystify the language, to break it  
15 down for them step by step, data point by data point.  
16 I think they can understand if you take it slowly with  
17 them, but really emphasize the educational aspect.

18 DR. KOZLOWSKI: Thank you.

19 DR. SHERMAN: Thank you for your comments.

20 MS. AOANAN: Thank you.

21 DR. SHERMAN: Our next speaker is Ms. Samantha  
22 Reid from Patients for Affordable Drugs.

1 MS. REID: Hi. First of all I would just like  
2 to say thank you to the FDA for having me and giving me  
3 the opportunity to speak today. My name is Samantha  
4 Reid, and I was diagnosed with Crohn's Disease in 2010.

5 For the first several years my disease was  
6 controlled with mesalamine but after that was no longer  
7 enough, it became clear that I needed to try biologic  
8 medication. In 2015 I went on Humira, but after nine  
9 months I stopped the drug because I wasn't seeing  
10 meaningful improvement.

11 I'd like to share my story with you to  
12 underscore the importance of enhancing competition and  
13 innovation in the biological products marketplace for  
14 people like me.

15 In late 2015 I became so ill that I was  
16 admitted to the hospital. From then on my journey with  
17 Crohn's proceeded on a downward spiral. I had to move  
18 back home with my parents, go on a high dose of  
19 steroids with terrible side effects, like insomnia and  
20 hair loss, and I couldn't eat solid foods.

21 When I could sleep, I was sleeping upwards of  
22 16 hours a day. Life was pretty untenable for a 24-

1 year-old who was just trying to support herself and  
2 start her career.

3 In the spring of 2016 I was started on the  
4 biologic drug Entyvio. While I have faced other health  
5 hurdles since, Entyvio has controlled by Crohn's  
6 Disease well over the last few years. I regained a  
7 basic quality of life that I didn't have before. I can  
8 exercise, travel and even eat out at restaurants, which  
9 probably doesn't sound like much but it was a basic  
10 luxury that my disease was preventing me from before.  
11 But Entyvio and biologics in general are expensive. I  
12 am painfully aware of how dependent I am on Entyvio's  
13 Connect Program in affording my drugs, and how  
14 capricious it is for my life and health to go on at the  
15 whim of a pharmaceutical company.

16 I don't have the same flexibility and  
17 opportunities as my health peers, because access to  
18 quality health insurance is always at the top of my  
19 mind. I know there's no way I could afford the list  
20 prices of my drugs if it came to that. I live in fear  
21 of losing access to the medications that have given me  
22 my life back.

1 I grew up in a middle-class family. We didn't  
2 take lavish vacations, and I bought my first car, which  
3 was a 1998 Ford Escort, with \$2,000 that I saved up  
4 from working shifts at Applebee's. I afforded college  
5 largely on a scholarship. I don't have a huge safety  
6 net to fall back on. All I want is for me and for  
7 patients like me to be able to afford the medication we  
8 physically need to go forward living our lives. I  
9 don't want to spend the rest of my life in debt, simply  
10 because I was unlucky enough to inherit an incurable  
11 disease.

12 That's why I know how important access to  
13 cheaper biosimilars would be for patients. Another  
14 patient who could benefit from faster access to  
15 biosimilars is a friend of mine, Stacey Ransom. She is  
16 a mom to an eight-month-old son from Southern  
17 California and she also lives with Crohn's Disease.

18 Humira, a blockbuster anti-inflammatory drug,  
19 for which there is no generic or biosimilar, has given  
20 her her life back, but it is draining her family's bank  
21 account. Because AbbVie is making delay deals that  
22 will maintain the company's monopoly, the Ransoms will

1 be forced to pay \$15,000 for Humira through 2023, money  
2 that could instead be saved, used for retirement or put  
3 in her son's college fund.

4 In light of patient experiences with  
5 biosimilar drugs in competition or lack thereof, we  
6 would like to offer comments in three primary areas.  
7 The FDA should seriously reconsider whether biosimilars  
8 found to be interchangeable, safe and effective, should  
9 be required to perform switching studies, or if the  
10 scope of these studies could be limited. We believe  
11 that biosimilars should be regulated in this regard as  
12 closely as possible to generics.

13 Switching trials at high costs, which drive up  
14 prices and delay biosimilar market entry. If the  
15 biosimilar has demonstrated effectiveness and safety,  
16 we prefer to minimize time and expense to market in  
17 order to capture the greatest possible savings. We  
18 believe that labeling conventions should be the same as  
19 for generic drugs. The biosimilars should be able to  
20 rely on brand biologically bling to ensure that  
21 professionals and patients understand clearly that the  
22 two drugs are interchangeable and have no clinically

1 meaningful differences.

2           One goal of biosimilars should be to encourage  
3 substitution at the pharmacy counter for patients first  
4 starting on a biologic or biosimilar. Manufacturers  
5 say they would benefit from greater regulatory clarity  
6 in this regard. And there should be a clear direction  
7 from the FDA to states in favor of substitution,  
8 provided that safety and efficacy have been  
9 demonstrated. But we do not support forced switching  
10 of patients currently on a biologic, especially for  
11 complex diseases, switching should only be by informed  
12 choice for those patients.

13           Drugs don't work if people can't afford them  
14 and access to treatment shouldn't depend on your  
15 socioeconomic status. If young people like me have  
16 access to affordable biosimilars, we give them the  
17 chance to enter the work world on a level playing  
18 field. Without cheaper options than these \$25,000 per  
19 dose medications, young people like me are entering  
20 adulthood at a deficit that is going to be nearly  
21 impossible to climb out of.

22           I thank you for giving me the opportunity to

1 speak today.

2 DR. SHERMAN: Thank you for sharing your story  
3 with us. Questions? Dr. Franklin?

4 DR. FRANKLIN: Thanks. You mentioned that for  
5 substitution at the pharmacy counter is important and  
6 also that patients should be involved in the decisions  
7 to switch if they are already established on a  
8 biologic. Those two concepts are compatible from your  
9 perspective, and how does that work when the patient  
10 interacts with the pharmacist?

11 MS. REID: So they are. I know it's a very  
12 specific circumstance but I think that if you are on a  
13 biologic that's working for you and you are stable on  
14 that biologic, switching should not occur unless it is  
15 you and your doctor's decision to do so, because it is  
16 such a precarious situation for patients on biologics  
17 to find one that works for them and to stay on it.

18 But I think if, for example, you're like me,  
19 where I was on mesalamine first and then just entering  
20 the biologic market, I think that it should be an  
21 option for -- and it should be encouraged for  
22 interchangeability from the pharmacy counter for

1 patients to -- if, you know, they've been started on  
2 biologics and should be on Remicade, to be offered the  
3 biosimilar of Remicade, for that first entrance into  
4 biologics, but I think from there it should be very  
5 dependent on what is working for the patient and what  
6 the medical provider and the patient think.

7 DR. FRANKLIN: And just as a follow-up, so if  
8 the -- if interchangeability of that designation by FDA  
9 results from a showing that the product has met the  
10 requirements for interchangeability, is there -- do you  
11 think that there needs to be more understanding of the  
12 -- what those interchangeable products are required to  
13 show to get approval by FDA, to enhance the confidence  
14 of -- regarding substitution among patients?

15 MS. REID: Absolutely. Absolutely. I think  
16 that there's some skepticism from patients on  
17 biosimilars, truly because they just don't know enough,  
18 and because of what you all were talking about earlier  
19 in terms of analytical data being more difficult than  
20 clinical data for patients to understand. And so I  
21 think that the more information you could put out  
22 there, the better, and not just from FDA websites but

1 on the ground floor from patient visits with providers  
2 and getting in there, because not all patients are  
3 going to have the knowledge base to go out there and  
4 seek out that information themselves. It needs to be  
5 brought to them from the very beginning.

6 DR. SHERMAN: Other questions? I have one.  
7 From a patient's perspective, labeling, because I think  
8 we heard slightly different things this morning,  
9 putting aside interchangeability for a moment, what do  
10 you think should be reflected in the labeling? What  
11 would be most useful to a patient in terms of what kind  
12 of -- how much information other than the fact that it  
13 is a biosimilar, be communicated?

14 MS. REID: I think that, like I said, it is a  
15 scary prospect for a patient switching to any new  
16 medication, let alone a biosimilar, and because there  
17 isn't as much information, people tend to get a little  
18 nervous about making that switch. So I think that  
19 making the labeling as close as possible to generic  
20 labeling is key in creating that confidence in patients  
21 that it really is interchangeable, and that's if the  
22 FDA has proven that it is and has shown that it is and

1 has approved it as such. It should be labeled as such,  
2 because I think any other type of labeling just leads  
3 to more uncertainty from patients.

4 DR. SHERMAN: Thank you. Any other questions?  
5 Thank you. We are a little ahead of schedule but not  
6 enough ahead to squeeze another speaker, so do any of  
7 the panelists have questions for any of the previous  
8 speakers? Dr. Kozlowski.

9 DR. KOZLOWSKI: So to go back to the original  
10 presentation, I think by Janssen, where we talked about  
11 switching between biosimilars and the difference  
12 between switching between different anti-TNF's in the  
13 class, so I was kind of curious what you think is a  
14 higher risk, switching between a different anti-TNF in  
15 the class or switching between a biosimilar?

16 DR. SHERMAN: Please do. Thank you.

17 DR. GREENSPAN: So as you may be familiar,  
18 some of the drugs within the TNF class have different  
19 indications. For example, etarnecept Enbrel has not  
20 been shown to be effective in IBD, so those would be  
21 obvious examples of how the molecules are so different  
22 enough that some of them don't seem to work in

1 indications where some of the other drugs do work.

2 DR. KOZLOWSKI: Right. But if they were  
3 switched sort of, again, it's not substituted, it's  
4 switched, obviously it's by a healthcare provider and  
5 it's for an appropriate indication.

6 DR. GREENSPAN: Yeah.

7 DR. KOZLOWSKI: Because you mentioned some  
8 risks about that, even in the context -- same  
9 indications, so I'm sort of curious what do you think  
10 is a higher risk?

11 DR. GREENSPAN: I think it's fair to say the  
12 similarities between an innovator and a biosimilar are  
13 closer than two different molecules within the TNF  
14 class, but just to highlight, the absence of data on  
15 biosimilar switching is a real concern for prescribers,  
16 and I think having some data around that, whether it be  
17 postmark and commitment safety data, I think would be  
18 valuable and increase the confidence of prescribers on  
19 this issue.

20 DR. FRANKLIN: Thank you.

21 DR. SHERMAN: Thank you. Any other questions  
22 from any of the speakers? Okay.

1           Then we will take our break and we will start  
2 promptly at 10:26. Thank you.

3           (Break, 10:14 a.m. until 10:24 a.m.)

4           DR. SHERMAN: Just one announcement. Linsey  
5 Mayor has now joined us from OMA. Linsey, can you just  
6 wave, if any members of the press need to contact?  
7 Thank you.

8           Okay, our next speaker, first speaker after  
9 the break is Nathan Doty from AbbVie.

10          MR. DOTY: Good morning. My name is Nathan  
11 Doty and I work on Bara Therapeutics Regulatory Matters  
12 at AbbVie. AbbVie is encouraged that FDA is holding  
13 this Part 15 hearing today to collect important  
14 feedback from all stakeholders.

15          We agree with FDA that we will eventually see  
16 multiple biosimilar products approved as  
17 interchangeable with a single reference product. We  
18 urge FDA to respond with science-based policies that  
19 will provide clarity to stakeholders.

20          Today I will discuss the issue of automatic  
21 substitution between two biosimilars, each found  
22 interchangeable with a single reference product. I

1 will present three points for FDA to consider.

2 First, the likelihood of automatic  
3 substitution between two interchangeable biosimilars of  
4 the same reference.

5 Second, the lack of scientific evidence to  
6 support such substitution.

7 And third, some proposed actions the Agency  
8 can take to address the challenges of automatic  
9 substitution in a complex environment.

10 So first let's look at the likelihood of  
11 automatic substitution between interchangeable  
12 biosimilars of the same reference product. Consider  
13 the following situation. Three medicines are approved  
14 to treat a chronic condition. We have a reference  
15 product A and two biosimilar products, B and C. B is  
16 interchangeable with reference A, and so is C.

17 Now let's imagine you're a patient with that  
18 chronic condition. You go to the doctor and she  
19 prescribes you reference A. You take that prescription  
20 to your pharmacist. She knows that there are  
21 interchangeable products approved for reference A, and  
22 she appropriately substitutes interchangeable B.

1           The next month you need a refill. You go back  
2 to your pharmacist or maybe you're changing pharmacies,  
3 again carrying a prescription for reference A. This  
4 time your pharmacist automatically substitutes  
5 interchangeable C for the prescribed reference A, and  
6 this substitution seems consistent with the  
7 interchangeability determination for interchangeable C.

8           So what just happened? You were switched from  
9 interchangeable B to interchangeable C without the  
10 intervention of your doctor, an automatic substitution.  
11 Yet these two products have not been determined  
12 interchangeable with one another. You can imagine  
13 these substitutions happening again and again over the  
14 course of your treatment. And the issue is compounded  
15 as more interchangeable products become available.

16           But your pharmacist did what she was supposed  
17 to do. And such cross-substitution feels appropriate  
18 and familiar. After all, A-rated generic drugs of the  
19 same reference are substituted all the time.

20           And that bring us to our second point. We  
21 don't have the clinical data needed to scientifically  
22 justify the automatic substitution we've just

1 described. We can't use the generic paradigm for  
2 interchangeable biosimilars. For generics generally  
3 active ingredients are chemically synthesized to be  
4 structurally identical to the reference. That means  
5 that two generics of the same reference contain the  
6 same active ingredient.

7 But that's not true for biologics. Even  
8 biologics demonstrated to be biosimilar to one another  
9 will have structural differences. Plus biologics that  
10 are interchangeable with the same reference will have  
11 differences from one another.

12 We might like to assume that the structural  
13 differences between two interchangeable biosimilars of  
14 the same reference would be relatively subtle. Even  
15 so, as FDA recognized in the draft interchangeability  
16 guidance published last year, subtle differences  
17 matter. I'm quoting from the draft guidance here.

18 "With switching multiple exposures to each product can  
19 prime the immune system to recognize subtle differences  
20 in structural features between products, and the  
21 overall immune response could be increased under these  
22 conditions."

1           Now, FDA has made clear that this immune  
2 response in patients cannot be fully predicted from  
3 structural comparisons or pre-clinical data. An  
4 interchangeability application doesn't include  
5 analytical structural comparisons between two different  
6 interchangeable biosimilars of the same reference.  
7 More importantly that interchangeability application  
8 doesn't include clinical, multiple switch studies  
9 between two biosimilars. That's to say it doesn't  
10 include the clinical studies that FDA asks for in  
11 making statutory interchangeability assessments.

12           So we can see these issues present a real  
13 challenge and here's my third point. How do we respond  
14 to that challenge? In navigating complex healthcare  
15 environments, we all count on guidance from you. The  
16 key role for FDA in addressing the issues we're  
17 raising, is to educate stakeholders on the scope of  
18 FDA's interchangeability determinations.

19           All stakeholders need to understand that  
20 interchangeable biosimilars of the same reference are  
21 not themselves automatically substitutable with one  
22 another. A pharmacist who understands this issue would

1 more carefully examine a patient's medication history  
2 when deciding which interchangeable product to  
3 dispense.

4           Efforts to educate stakeholders on the scope  
5 of FDA interchangeability determinations can take a  
6 number of forms. It should be included in the planned  
7 ramp-up and education efforts as described in the  
8 Biosimilars Action Plan. It should be included in the  
9 labeling of all approved interchangeable products. And  
10 most importantly, it should be included in the Purpose  
11 Book.

12           At a minimum there should be a statement in  
13 the Purple Book making clear that an FDA  
14 interchangeability determination does not imply  
15 interchangeability with other interchangeable  
16 biosimilars of that reference.

17           The Orange Book primarily serves as guidance  
18 to the states regarding pharmacy dispensing practices.  
19 The Purple Book should play that same role. Many  
20 states have already developed laws, guidance, rules and  
21 practices around automatic substitution of biosimilars.  
22 Other states are still working on this issue.

1                   Importantly, the states need good guidance  
2 that will clarify the relationship between biologics  
3 and clarify the scope of FDA interchangeability  
4 determinations.

5                   Like the Orange Book the Purple Book can give  
6 them that guidance.

7                   Let's put this altogether. A complex  
8 biosimilars world is coming, a world with multiple  
9 interchangeable biosimilars approved for a single  
10 reference. Science must drive the policies needed to  
11 navigate the coming complex environment. And we need  
12 to educate stakeholders on those policies.

13                   I'd like to thank you again for the  
14 opportunity to provide input and look forward to any  
15 questions that you might have.

16                   DR. SHERMAN: Thank you for your comments.  
17 Questions from the panel? Dr. Kozlowski.

18                   DR. KOZLOWSKI: So obviously the FDA draft  
19 guidance recognizes such a possible risk, but do you  
20 think that the residual risk is the same after two  
21 products have already undergone switching studies with  
22 a potentially subtly different reference product and

1 not had differences, that that risk is the same as if  
2 none of those studies were done, or in fact does that  
3 reduce the residual uncertainty?

4 MR. DOTY: Thank you for the question. I  
5 think what we would identify is that we have subtle  
6 differences between those two products, and those  
7 differences could be differences in degree or  
8 differences in kind between the differences that were  
9 evaluated between the interchangeable products and the  
10 reference.

11 What we're asking is that FDA think about the  
12 scientific evidence that was needed to demonstrate  
13 interchangeability between the reference and the  
14 interchangeable product. Think about whether that  
15 similar evidence is needed to make a determination  
16 between interchangeable products of the reference.  
17 There could be subtle differences that could matter.

18 DR. KOZLOWSKI: Yeah, but I think the question  
19 though is there's always some level of uncertainty as  
20 you look at things. The question I would ask is does  
21 having two products with two switching studies already  
22 with a reference product and not having an issue, does

1 that change your starting point? In other words, is  
2 that a different place in risk that you're starting  
3 from than if you were de novo with no experience in  
4 switching at all?

5 MR. DOTY: I think the reason that the Agency  
6 does clinical switching studies and asks for those  
7 studies and the reason the BPCIA asks for the Agency to  
8 look at those issues is because we can't predict in  
9 advance what differences between products might prompt  
10 a response in the immune system.

11 And so what we're asking the Agency to do is  
12 to think about the importance of that scientific  
13 evidence and what that scientific evidence is showing  
14 us and why we need to collect that evidence before we  
15 can make a determination that those two products would  
16 be interchangeable with one another.

17 I think the key takeaway that I would give  
18 here is that we need to understand that there are  
19 fundamental differences here between biologics and  
20 generics, and that we can't just port the A rated  
21 generic model onto the interchangeable biosimilar  
22 model, and we need to understand that that's going to

1 be a different market and we need to educate  
2 stakeholders about that different market and explain to  
3 them those differences?

4 DR. KOZLOWSKI: Thank you.

5 DR. SHERMAN: Dr. Unlu?

6 DR. UNLU: To kind of build upon your example,  
7 manufacturer of reference product A makes a  
8 manufacturing change that results in a subtly different  
9 reference product, let's call that A prime. And the  
10 patient goes to the pharmacy and gets dispensed with A  
11 prime, so she just got switched from A to A prime.  
12 What do you think is the amount of scientific evidence  
13 we should be asking for to justify that kind of  
14 switching?

15 MR. DOTY: So it's an interesting question. I  
16 think I would just say that we have to focus really  
17 clearly on the standards that are set out in the  
18 statute and the evidence that FDA is asked to collect  
19 as a result of that. And so there's the specific  
20 standards set out for interchangeable biosimilars and  
21 the kind of data that needs to be collected to support  
22 that. And it's collected because there is a concern

1 about the switching back and forth between two  
2 products, and in my view it's a recognition of some of  
3 the complexities that we're talking about here.

4           Where FDA is looking for that specific  
5 evidence to make a determination about immunogenicity  
6 risks between a reference product and an  
7 interchangeable product, it makes sense that that same  
8 data would be collected to demonstrate  
9 interchangeability between two interchangeable  
10 biosimilars.

11           DR. SHERMAN: Great. Thank you for your  
12 comments.

13           MR. DOTY: Thank you.

14           DR. SHERMAN: Our next speaker is Dr. Steven  
15 Lucio from Vizient.

16           DR. LUCIO: Good morning. My name is Steven  
17 Lucio and I am speaking today on behalf of Vizient, the  
18 largest member group in healthcare performance  
19 improvement company in the United States. Vizient  
20 provides innovative day-to-day solutions, expertise and  
21 collaborative opportunities that lead to improved  
22 patient outcomes and lower costs.

1           We would like to express our appreciation to  
2           FDA, not only for this public forum, but also for its  
3           continued efforts to establish, implement and enhance  
4           the biosimilar approval process. We fully endorse the  
5           scientific principles of biosimilarity and the  
6           biosimilar approval pathway.

7           Part of Vizient's core capabilities is our  
8           sourcing services represents over 100 billion in annual  
9           healthcare expenditures, much of it associated with  
10          pharmaceuticals. Give the size and the diversity of  
11          our membership, we are critically akin to all  
12          strategies, managing, increasing drugs costs.

13          Since 2010 Vizient has provided ongoing  
14          training and education on the biosimilar paradigm in  
15          the form of over 200 in-person presentations and web  
16          conferences, and have displaced clinical resources to  
17          support formulary evaluations of biosimilars and  
18          ongoing contractual relationships with biosimilar  
19          manufacturers to maximize the value and cost savings of  
20          our membership.

21          We have over 50 pharmacists and other subject  
22          matter experts that are currently facilitating

1 appropriate biosimilar adoption and documenting the  
2 value and sustained high quality of care these products  
3 provide.

4           Based upon our experiences and more  
5 importantly that of the endorsed membership of leading  
6 academic medical centers, pediatric facilities,  
7 community hospitals, integrated health networks and  
8 critical access providers, we would like to share our  
9 insight of our experiences with the biosimilar paradigm  
10 in the form of these full-in recommendations.

11           Our first recommendation is that FDA should  
12 provided increased detail concerning aspects of  
13 biological drug approvals to address the continued  
14 hesitancy some clinicians still possess regarding  
15 biosimilar safety and efficacy.

16           We applaud FDA's efforts at enhancing the  
17 educational information available on its website.  
18 Still the disclosure and ease of accessibility of two  
19 additional data sources would further facilitate  
20 understanding of biosimilars.

21           First we encourage FDA to publish a summary  
22 review documents for all biosimilar approvals at the

1 time of initial approval, regardless of whether or not  
2 a biosimilar was subject to an advisory committee  
3 discussion. While a concept such as totality of the  
4 evidence can be well articulated in principle,  
5 documentation of those precepts and practice greatly  
6 enhances clinicians' understanding.

7 We've witnessed the impact, the availability  
8 of this information or its absence has had on  
9 biosimilar uptick. Whereas member formulary reviews of  
10 infliximab DYYB were enabled by the availability of the  
11 summary review information, the consideration of  
12 infliximab ABDA has been hindered by its absence. The  
13 availability of this documentation increases awareness  
14 of the value, relevance and importance of analytical  
15 data in the characterization of a biosimilar.

16 Second, we request that FDA publish  
17 information concerning the history and timing of  
18 manufacturing changes for originator biologics. Few  
19 practitioners are cognizant of these changes that occur  
20 throughout the life cycle of an originator and view the  
21 role of analytical characterization as something novel  
22 to the biosimilarity determination experience.

1           Information on manufacturing changes, such as  
2           the content disclosed by the European Medicines Agency,  
3           has been incredibly beneficial in explaining the  
4           variability of originators as evidenced by the comment  
5           that you see from one of our member clinical pharmacy  
6           experts. If FDA were to disclose this information  
7           about originator changes to the originator biologic,  
8           which are measured and monitored via analytical  
9           techniques, the validity of these studies would find  
10          greater acceptance within the discussion of  
11          biosimilars.

12           Recommendation number two, the FDA should  
13          revise and expand the content in the Purple Book, as  
14          well as increase the ease of data review and  
15          interpretation. Information in the Purpose Book  
16          ideally would reflect a more user friendly, searchable  
17          database that would clearly represent the relationship  
18          between originator reference biologics and any  
19          associated biosimilar and/or interchangeable product.

20           When searching for a biosimilar, a user should  
21          be able to see quickly to what extent a products label  
22          matches that of the originator reference product and

1 what absent indications is a result of various  
2 exclusivity, such as orphan exclusivity.

3 Third, the Purple Book would be an excellent  
4 place for the previously requested information such as  
5 the links to the summary review documentation for  
6 approved biosimilars and information concerning the  
7 manufacturing changes of originator reference  
8 biologics.

9 Recommendation three, FDA should finalize the  
10 interchangeability guidance to maximize the efficiency  
11 of approval of interchangeable biologics and to further  
12 clarify the utility and relevance of the  
13 interchangeability designation.

14 Our members understand that final guidance on  
15 this issue remains pending and that no formal trials to  
16 assess interchangeability have been completed; however,  
17 in addition to the absence of this information, there  
18 remains a lack of understanding regarding the utility  
19 of this specification beyond the overt definition in  
20 the Biologics Price Competition and Innovation Act.  
21 Our members continue to struggle with the long-term  
22 impact of interchangeability designation, particularly

1 given the wealth of clinical data already present for  
2 approved, non-interchangeable agents.

3 As seen above, our members even reference the  
4 Agency's website, detail of the assurance of comparable  
5 safety efficacy of non-interchangeable biosimilars,  
6 further calling into question the extent to which an  
7 interchangeable biologic would be further  
8 differentiated.

9 To the extent to which both biosimilar  
10 suppliers and the FDA itself should invest  
11 substantially in this designation remains an  
12 uncertainty among many clinicians themselves and  
13 requires additional clarification.

14 Recommendation number four, FDA should review  
15 its decision on the devoid of meaning suffix, when it  
16 comes to biologic nomenclature. Vizient continues to  
17 receive numerous comments from its membership regarding  
18 the devoid of meaning suffix, and its utility and  
19 clinical practice. Our members understand the  
20 significance of pharmacovigilance for all  
21 pharmaceuticals. Still our clinicians continue to  
22 question whether or not the current application of this

1 strategy is most useful or whether this differentiates  
2 or actually conveys that a biosimilar is, in fact, not  
3 similar to an originator.

4 Vizient and its membership agree that the  
5 documentation of safety and efficacy of biosimilars  
6 will increase the level of acceptance of these  
7 products. In addition, we believe there are multiple  
8 options to make an identifier approach more effective  
9 and efficient.

10 Option one, you could be utilizing the  
11 serialization strategy of the Drug Quality and Security  
12 Act to promote improved monitoring pharmacovigilance of  
13 all medications. One alternative to the devoid of  
14 meaning suffix is the tracking and monitoring of the  
15 unique serialization requirements established by DQSA.  
16 The unique designation at a product level would enable  
17 tracking not just a version of the biologic, but the  
18 specific law providing the higher level of specificity.

19 Option two, the FDA considers modification of  
20 the proper name to include the separate identifier as a  
21 necessary element. Vizient recommends using a  
22 meaningful differentiator to convey useful information

1 about the product, such as whether it is an originator  
2 or a biosimilar, whether or not it's interchangeable,  
3 the extent of indication coverage.

4 And option three, if FDA maintains the  
5 approach of the devoid of meaning suffix, we recommend  
6 the application of this standard to all biologics,  
7 originators and biosimilars. This approach would  
8 address the aforementioned member concern that  
9 biosimilars are in some way meaningfully different from  
10 originators.

11 Vizient affirms the important of the  
12 biosimilar approval pathway and the absolute necessity  
13 of creating a sustainable market of competing biologics  
14 and we appreciate FDA's willingness to review and  
15 revise the approval process and to call attention to  
16 other factors that affect the uptick of biosimilar,  
17 even those outside of the Agency's scope.

18 Such efforts will enable us to achieve that  
19 virtuous cycle of innovation and competition that  
20 benefits patients and the healthcare community as a  
21 whole.

22 In closing, we would like to highlight that

1 the success of biosimilars is more than simply whether  
2 or not we can support competing biologics, but if we  
3 can achieve a more stable, predictable and value-based  
4 approach to medication supply and management. We will  
5 be submitting written comments and I now look forward  
6 to entertaining your questions.

7 DR. SHERMAN: Thank you for your comments.  
8 Questions from the panel? Dr. Franklin.

9 DR. FRANKLIN: Hi. On the recommendations for  
10 the Purple Book, I think could you clarify a little bit  
11 or expound upon the -- some of the recommendations that  
12 you have, including the inclusion of information about  
13 manufacturing changes? Is that intended to be useful  
14 to providers or to some other group. Could you clarify  
15 a little bit?

16 DR. LUCIO: Absolutely. Thank you for the  
17 question. Yes, we -- that information has been very  
18 helpful. What has been available either directly from  
19 EMA or in some of the other clinical literature that  
20 has been published, helping them to understand the  
21 paradigm of originator biologic variability. That has  
22 kind of demystified some of the concern and made it not

1 quite as novel of an experience, but still even with  
2 the information that, you know, our organization  
3 provided, others have provided FDA, there's still a lot  
4 more education that could take place. And so making  
5 that easily accessible would be very helpful.

6 DR. SHERMAN: Dr. Kozlowski.

7 DR. KOZLOWSKI: So in terms of making  
8 manufacturing changes public, kind of, one assuming  
9 that there was a legal framework to do that, which  
10 there may not be, there are many, many, many  
11 manufacturing changes. Some of them are very small,  
12 right. Some of them are very, very large. Do you have  
13 any sense about what would be looked for to be public?

14 DR. LUCIO: I think even just the number of  
15 manufacturing changes and that gradation of whether  
16 they are more complex, whether simple, and even helping  
17 the public to understand what the differentiation of  
18 those types of changes happen to be, would be very  
19 instrumental, so even if the number could be per  
20 molecule of what has transpired, even that is  
21 informative and maybe even over a certain timeframe  
22 that would be very useful.

1 DR. KOZLOWSKI: Okay, thank you.

2 DR. LUCIO: Sure.

3 DR. SHERMAN: Other questions? Thank you for  
4 your comments.

5 DR. LUCIO: Thank you.

6 DR. SHERMAN: Our next speaker is Kathleen  
7 Arnsten from Lupus and Allied Diseases Association.

8 MS. ARNTSEN: I am Kathleen Arnsten,  
9 President, CEO, of Lupus and Allied Diseases  
10 Association. Good morning and thank you for the  
11 opportunity to provide my unique patient perspective.

12 Biosimilars hold tremendous promise and  
13 therapeutic advantages for people like me, just as  
14 biologics have revolutionized treatment for millions of  
15 individuals. As more biosimilars become available in  
16 the United States, we want to ensure they are safe,  
17 efficacious, accessible and affordable. We must remain  
18 vigilant in protecting patient safety while promoting  
19 unfettered access to vital treatments.

20 Lupus is an extremely complex, chronic,  
21 inflammatory autoimmune disease affecting virtually any  
22 organ system of the body, with few approved drugs, no

1 known cause or cure, and a challenge to live with and  
2 treat. Besides Lupus I struggle with several other  
3 autoimmune disorders and comorbid conditions. I take  
4 46 drugs a day and have a paralyzed GI tract and am  
5 blind in my right eye.

6 I have allergies and sensitivities to both  
7 active and inactive ingredients in drugs and I recently  
8 developed a cardiac complication after using an eyedrop  
9 for only four weeks.

10 There is no cookie-cutter approach to treat  
11 intricate patients like me. Our immune response to  
12 drugs is unique, contrary and at times adverse. Due to  
13 the heterogenous nature of autoimmune diseases, no two  
14 patients are alike and treatment is highly  
15 individualized. Effectively treating us requires  
16 thinking outside the box and media access to the entire  
17 arsenal of treatments and open and transparent  
18 communication between us and our providers. They know  
19 best what therapies to use.

20 In response to Question 3, it is essential  
21 that the intricacy and vulnerability of the patient  
22 populations is taken into consideration when dealing

1 with biosimilars, especially since the performance may  
2 not be equivalent in every population, resulting in  
3 unexpected effects.

4 Patients like me are so hypersensitive that  
5 even the slightest change in manufacturing dose or  
6 delivery method, as well as switching between drugs,  
7 can provoke immunogenicity.

8 In order to be designated as interchangeable,  
9 biosimilars must unequivocally produce the same  
10 clinical result in any given patient and each condition  
11 for which the biologic reference product was approved,  
12 rigorous criteria including sufficient proof of  
13 clinical efficacy, safety, purity, potency and  
14 tolerability must be provided for each population, even  
15 if they are small studies, not just projected clinical  
16 safety, and any product that is deemed as such must be  
17 shown to be safe and effective in a marketplace, where  
18 one originator will have multiple biosimilars and  
19 interchangeable products, which will lead to patients  
20 being switched multiple times.

21 We urge you to finalize guidance on  
22 interchangeability and keep in mind atypical patients

1 like me, who do not fit the norm, and the importance of  
2 safety as you consider ways to increase confidence in  
3 these products. We also ask that you include  
4 clarification on the potential substitution of two  
5 biosimilars that are deemed interchangeable with the  
6 same reference product but not considered  
7 interchangeable with each other.

8 We applaud you for instituting guidance for  
9 distinguishable suffixes, and support the establishment  
10 of a policy that includes unique nonproprietary names  
11 with meaningful suffixes, for future interchangeable  
12 biosimilars in order to assure patient safety and  
13 provide transparency and from collegians processes.

14 Utilizing discernable names is necessary to  
15 identify exactly which medicine was received, if an  
16 adverse event does occur, since all biologics will be  
17 administered to individuals suffering from serious  
18 diseases, who also take multiple medications and do not  
19 participate in a controlled study. This will increase  
20 patient provider confidence, which will foster market  
21 uptick, while enhancing industrial competitiveness.

22 The regulatory process must also evaluate

1 biosimilars through post-marketing surveillance in  
2 order to not diminish product efficacy and be  
3 detrimental to patient safety. Preapproval, non-  
4 clinical and clinical testing will establish that there  
5 are no meaningful differences in safety, efficacy or  
6 mechanism of action comparability. But only real world  
7 evidence will demonstrate this.

8 We suggest that you consider adopting  
9 innovative methods, such as apps on electronic devices  
10 and patient reported outcomes to monitor real world  
11 events. Pharmacovigilance is essential for all  
12 biologics, as they may produce immunogenic reactions in  
13 patients who may also be hypersensitive to changes in  
14 production methods or impurities. Adverse effects are  
15 difficult to predict and may only occur after many  
16 years of treatment. And due to the abbreviated review  
17 process, you must do more to implement comprehensive  
18 post-market tracking and reporting to detect safety  
19 problems. Developing an aggressive tracking system  
20 will also help to guarantee stakeholder confidence and  
21 facilitate market uptick while establishing a  
22 longitudinal electronic medical record.

1           In response to Question 9, one of the biggest  
2   impediments to the advancement of innovative therapies  
3   is the overabundance of egregious payer utilization  
4   management policies, such as step therapy and non-  
5   medical switching protocols. These cost containment  
6   measures pose an ethical dilemma for healthcare  
7   professionals by requiring the provider to follow a set  
8   course of care, regardless of their best personal  
9   judgment. They are not based on a person's specific  
10  medical profile or the physician's assessment of the  
11  best treatment option for an individual's condition and  
12  certainly do not apply to an atypical patient like me,  
13  who is excluded from the cited clinical studies the  
14  insurer uses as justification.

15           As an individual who is harmed by step therapy  
16  protocol, I am concerned that patients who are stable  
17  on a biologic will be switched for non-medical reasons  
18  to a biosimilar that has not been determined to be  
19  interchangeable. We urge you to establish robust  
20  patient safeguards by applying strong scientific safety  
21  standards, as stating the switching of stable patients  
22  should only be determined by the treating provider and

1 patient and facilitating dialogue among multi  
2 stakeholders, including payers.

3           These practices do not keep pace with  
4 biomedical innovation and nothing is being done to  
5 modernize the process. We must act now or payers will  
6 continue to manipulate research to their benefit in  
7 order to justify preferred treatments. You must reach  
8 out to other federal agencies and work with them to  
9 develop sound policies that address access issues. We  
10 feel that biosimilars have the potential to promote  
11 greater competition among biological products and hope  
12 that they are more affordable and accessible for  
13 individuals struggling to manage life-diminishing  
14 diseases. There are many Americans who struggle to get  
15 through each day with some semblance of dignity and  
16 tact, who have little or no treatments. It is the  
17 promise of research and development to discover better  
18 treatments and the belief that a regulatory system  
19 should deliver them, that motivates us to keep going,  
20 but it's time to finalize all biosimilars guidances and  
21 execute your action plan and get back to regulating and  
22 advancing all drugs and devices for those who

1 desperately need them. Regulatory policy must keep  
2 pace with innovation.

3 In closing I want to reiterate that I am  
4 unwavering in my belief in the sanctity of the doctor-  
5 patient relationship and that only providers who are  
6 familiar with an individual's personal medical history  
7 should be making treatment decisions. Patient's safety  
8 must be first and foremost in choosing the most  
9 appropriate therapies for any person with complex  
10 medical conditions.

11 I have faith that we can advance biosimilars  
12 while still allowing physicians to make decisions in  
13 the best interest of their patients. I believe in the  
14 FDA and our regulatory process. There are millions of  
15 people who could benefit from access to innovative  
16 therapies now and many more in the future who are yet  
17 to be diagnosed. United we can achieve the promise of  
18 biological medicines for them. We need to work  
19 together to make that happen.

20 I thank you for the opportunity to share my  
21 perspective and I applaud the FDA for continually  
22 recognizing the importance of the patient voice during

1 the regulatory process, and we will be submitting  
2 comprehensive written comments. Thank you.

3 DR. SHERMAN: Thank you for your comments.  
4 Questions from the panel? Ms. Maloney?

5 DR. MALONEY: Yes. Could you just, point of  
6 clarification, you spoke about post-market surveillance  
7 for biosimilars but were you suggesting it should be  
8 different than for the originator?

9 MS. ARNTSEN: No. I think that all drugs and  
10 devices should have robust pharmacovigilance. I  
11 believe that with the advent of electronic health  
12 records that it's very easy to track and trace through  
13 electronic systems. I recently had surgery and I have  
14 several devices planted in my body, and they all have  
15 serial numbers. They're all part of my EHR, and if  
16 anything was to happen, it would be very easy to track  
17 them and trace them.

18 DR. SHERMAN: Other questions? Thank you for  
19 your comments.

20 MS. ARNTSEN: Thank you.

21 DR. SHERMAN: Our next speaker is Dr. Richard  
22 Markus from Amgen.

1 DR. MARKUS: Thank you. My name is Richard  
2 Markus and I'm Vice President of Development at Amgen  
3 for Biosimilars Division, and as you know Amgen is a  
4 developer and manufacturer of both originator products,  
5 as well as biosimilars.

6 I will present thoughts on four of the  
7 questions asked, as listed here, as well as some  
8 additional recommendations.

9 The FDA has been effective in reviewing and  
10 approval of biosimilars, with the first approval in  
11 2015. FDA has approved a total of 12 different  
12 biosimilars to eight reference products, and they have  
13 been meeting the timelines as outlined in both PPCIA  
14 agreements. We can compare that to the EMA, which has  
15 also been effective, though they started six years  
16 earlier with a legal basis for approval, and hence it's  
17 understandable that more applications have been  
18 approved in that region.

19 But if comparing the eight years of the PPCIA  
20 pathway in the U.S. to the first eight years of having  
21 a pathway, the EU approved five unique biosimilars to  
22 two reference products compared to the FDA's 12

1 biosimilars to eight reference products. Our  
2 experience working with both agencies is that the  
3 requirements and expectations are generally consistent  
4 and the FDA has been very flexible while maintaining  
5 scientific integrity.

6 We hear a lot of discussion about the U.S.  
7 Market and questioning why it's different than Europe  
8 or elsewhere, and I suspect that's a major reason we  
9 are all here today. We believe the current U.S.  
10 landscape is set up for significant competition that  
11 will lower costs to healthcare systems.

12 In the U.S. there so far has been two  
13 originator biologics to face biosimilar competition,  
14 and two more just recently launched. The first  
15 approved biosimilar, which competes with Filgrastim,  
16 has rapidly obtained substantial market share and  
17 market uptick over the first three years was comparable  
18 to its uptick in Europe.

19 The second product with competition is  
20 infliximab and those biosimilars have struggled but  
21 there are multiple reasons as to why those may have  
22 struggled, and we don't believe this is indicative of

1 the market behavior as a whole.

2 A key aspect for evolving the biosimilar  
3 landscape is through education. We believe that the  
4 current FDA requirements are appropriate to ensure  
5 confidence in biosimilars and with that the  
6 requirements and scientific standards should be shared  
7 and understood by the stakeholders, so they are well  
8 informed, and this can facilitate their acceptance and  
9 confidence in this new type of biologic.

10 Amgen's caution with standardization in order  
11 to maintain regulatory flexibility within the  
12 scientific approach.

13 I will now address Question 4 with  
14 consideration for testing the reference product lots.  
15 First, based on our experience, developing biosimilars,  
16 the cost of procuring the reference product used for  
17 analytical characterization and analytical similarity  
18 testing is generally less than five percent of the  
19 process development and preapproval manufacturing  
20 costs. Therefore, limiting the number of reference  
21 product lots will only minimally decrease costs.  
22 However, it may add risk as the sampling of fewer lots

1 may not provide a true range of product attributes.

2           Additionally, if this approach is employed by  
3 multiple sponsors, this increases the likelihood of  
4 greater differences between two biosimilars or between  
5 two interchangeable products. This concept is  
6 illustrated in the figure on the right, where one  
7 sponsor may randomly acquire the lot circled in blue  
8 and a second sponsor may randomly acquire the lot  
9 circled in green.

10           Both sponsors would believe they have a  
11 representative sample of the reference product, as well  
12 as a good estimate of the mean for the attribute, when  
13 in fact they don't, and the two would differ in their  
14 product design targets.

15           Ultimately, the number of lots tested should  
16 be appropriate to characterize the variability of  
17 critical attributes in the reference product.

18           Question 5 is regarding the potential use of  
19 non-U.S. license comparator. We believe such an option  
20 may be appropriate and this includes potentially being  
21 appropriate for development of interchangeable  
22 biologics. However, bridging of non-U.S. product to

1 that of the U.S. product is still important and a  
2 flexible science-based approach to bridging is  
3 recommended.

4 Incentivizing innovation is clearly a key  
5 consideration in the ideal healthcare environment.  
6 Developing new medicines is high risk, where many  
7 programs ultimately do not show clinical benefit. So  
8 to make such risky investments worthwhile, there has to  
9 be confidence the intellectual property created will be  
10 maintained and supported, and that the appropriate  
11 patent protection and regulatory exclusivity will be  
12 awarded for biotechnology innovations.

13 Amgen believes that umbrella exclusivity  
14 preserves critical incentives for continued development  
15 and innovation that can improve patient outcomes.

16 I'd like to spend a moment addressing  
17 perspectives on interchangeability, since there's been  
18 some rhetoric about how critical this is for  
19 competition. First, the U.S. is the only highly  
20 regulated jurisdiction with a defined pathway for  
21 health agency determination that facilitates pharmacy  
22 substitution of biologics. For example, this doesn't

1 exist in Europe and that market is very competitive.

2 Another point is that only ten percent of  
3 biologics that are reported to lose exclusivity in the  
4 U.S. through 2023 are primarily distributed through a  
5 retail pharmacy, where substitution can occur. And,  
6 therefore, the function of pharmacy substitution likely  
7 will offer little contribution to the marketplace for  
8 90 percent of these products.

9 For the ten percent of products for which  
10 interchangeability could be relevant, Amgen feels that  
11 the FDA draft guidance on interchangeability outlined  
12 appropriate science-based standards and allowed the  
13 appropriate degree of regulatory flexibility.

14 We, therefore, urge the Agency to finalize the  
15 draft guidance without significant revision. However,  
16 it would be beneficial if the FDA clarifies in this or  
17 other guidance how proposed interchangeable products  
18 can address potential life cycle management by the  
19 reference product, including those listed on the slide,  
20 such as changes in formulation, updated devices and new  
21 indications.

22 In my last couple of minutes I'd like to make

1 a few suggestions to FDA, including circumstances when  
2 expedited review could be available, with some  
3 suggestions listed on the slide.

4           Regarding manufacturing plant inspections, the  
5 expectations of GMP manufacturing are and should be the  
6 same for originators and biosimilars, as there should  
7 only be one GMP standard of what is appropriate for  
8 biologic manufacturing. Therefore, these  
9 recommendations apply to both originator and biosimilar  
10 approvals. Conducting preapproval inspections earlier  
11 in the review process and more communication about  
12 potential findings could provide more time to address  
13 the concerns, potentially facilitating approvals.

14           With regard to labeling changes, we know there  
15 are many times a biosimilar will be licensed without  
16 all the indications of the reference product, when  
17 scientifically appropriate and when the patent or  
18 regulatory exclusivity ends, then an expeditor review  
19 to add the additional indications should be considered.

20           In conclusion, the FDA has been very effective  
21 with regard to meeting the review timelines outlined in  
22 both PPCIA agreements. And there are now two products

1 with biosimilar competition of more than a year and two  
2 more just launched, so it's early as there are many  
3 more expected to launch in the near future, and the  
4 market will likely evolve quickly.

5           What can FDA do? We have outlined some points  
6 that may be helpful. Importantly, the FDA can partner  
7 with medical societies and patient groups in outreach  
8 and education and we recommend maintaining flexibility  
9 and current regulatory standards that are consistent  
10 with other ICH agencies, as this will maintain  
11 confidence in this class of products.

12           Thank you.

13           DR. SHERMAN: Thank you for your comments.  
14 Questions from the panel? Dr. Kozlowski.

15           DR. KOZLOWSKI: So you mentioned the cost of  
16 acquiring reference product lots is not prohibitive but  
17 it may not just be the cost, it may be availability and  
18 access to them. You know, what actually is the  
19 challenge in terms of accessing reference product lots?

20           DR. MARKUS: Thanks. We have ten programs in  
21 development so this is a spanning experience of many  
22 different types of products, and we haven't actually

1 had great challenge, only in the case, I think, where  
2 there's restricted distribution, such through REMS  
3 would there be challenges with access to these  
4 products. The others we have not had challenges.

5 DR. KOZLOWSKI: And then you comment on  
6 reference product lots. Do you have any comments on  
7 the number of biosimilar product lots?

8 DR. MARKUS: Can you clarify what you're  
9 asking?

10 DR. KOZLOWSKI: Candidate product, how many  
11 lots need to be generated?

12 DR. MARKUS: So that's -- talking about  
13 sampling of the reference. I think that is an area  
14 that also the manufacturer having more experience with  
15 -- definitely provides more confidence with regards to  
16 control of their process, and I think importantly those  
17 have to be at scale and in the, you know, at full scale  
18 basically in the commercial -- to the commercial  
19 process as opposed to the process changes during the  
20 development.

21 DR. KOZLOWSKI: And one last other question.  
22 You made a recommendation about facility issues in a

1 more rapid timeline. Were you referring to all  
2 products? Were you referring to biosimilar products?  
3 What's the scope of that suggestion?

4 DR. MARKUS: Of which suggestion?

5 DR. KOZLOWSKI: You know, you suggested  
6 expedited manufacturing plant inspections.

7 DR. MARKUS: Uh-huh.

8 DR. KOZLOWSKI: Three-month clock instead of a  
9 six-month.

10 DR. MARKUS: So the scope of that suggestion?

11 DR. KOZLOWSKI: Yes, the scope of that  
12 suggestion.

13 DR. MARKUS: Yeah, I think the -- if there's  
14 potential challenges in the inspection, then -- and  
15 that's the only remaining element is in essence  
16 clarifying questions, are you going back and forth with  
17 questions and answers, then that circumstance and the  
18 rest of the file, for example, has been deemed  
19 acceptable, then that would be in general the scope,  
20 where --

21 DR. KOZLOWSKI: General scope, not just  
22 biosimilars?

1 DR. MARKUS: No, in general -- I think the  
2 scope is as I said for originator and biosimilars, that  
3 that should be an opportunity to facilitate approvals.

4 DR. KOZLOWSKI: Thank you.

5 DR. SHERMAN: Additional questions?

6 DR. UNLU: Your caution against  
7 standardization of requirements, can you explain a  
8 little more what kind of standardization did you have  
9 in mind?

10 DR. MARKUS: Yes. The aspect of maintaining  
11 flexibility, because each development program,  
12 including each from an analytical perspective as well  
13 as choices that the manufacturer may choose to make in  
14 clinical development, could be different, and I think  
15 from a development perspective I'd like the flexibility  
16 and not a one -- only one development pathway is what  
17 exists for each product, and so I think in many ways  
18 that flexibility with scientific backing and integrity  
19 is what is most appropriate and provides for the  
20 targeted approach and step-wise approach, so that again  
21 if there is -- where there is residual uncertainty, is  
22 where then the rest of the experiments would lie.

1 MS. ABRAM: Your presentation touches upon the  
2 number of products approved, and then those that have  
3 actually entered the market, and others today have  
4 touched upon that with the 12 approvals, and yet only a  
5 handful are actually in market. What do you see as  
6 kind of the driving factors for that difference between  
7 the number approved and the ones that are actually  
8 available to patients on market today?

9 DR. MARKUS: So I cannot speak for other  
10 companies that also have products approved and  
11 launched, but I can tell you from Amgen's view there is  
12 still intellectual property that's still standing. If  
13 we have two products approved in the U.S., neither have  
14 launched yet, due to intellectual property that still  
15 stands, but we respect the intellectual property. We  
16 think that's a key aspect of innovation, and so that's  
17 -- we by design would get the products approved and go  
18 through the intellectual property exchange, and then be  
19 available once the intellectual property is expired, if  
20 that's the right word.

21 DR. SHERMAN: Joe, do you have a quick  
22 question?

1 DR. FRANKLIN: We'll stop there.

2 DR. SHERMAN: Okay, great. We're at a time --  
3 if I could just ask in your comments, if you could  
4 address two things. One that caught my eye, hasty  
5 policy changes on Slide 4, if you could just let us  
6 know in your comments what you meant by that. And you  
7 talked about that only ten percent are at a retail  
8 pharmacy, but we've heard some discussion this morning  
9 about substitution, written substitution, whatever you  
10 want to call it, at the formulary level, if you could  
11 discuss that in your comments?

12 DR. MARKUS: Yes. I think interchangeability  
13 -- quick, I'm sure -- or you don't want me to --

14 DR. SHERMAN: No, if you could just address  
15 them in the written comments, that would be great.

16 DR. MARKUS: In the written comments, sure.

17 DR. SHERMAN: Thank you very much for your  
18 comments.

19 DR. MARKUS: Thank you.

20 DR. SHERMAN: If I get us late, then I'm in  
21 true trouble.

22 Our next speaker is Dr. Harry Gewanter.

1 DR. GEWANTER: Got.

2 DR. SHERMAN: Thank you. From Medical Home  
3 Plus.

4 DR. GEWANTER: Good morning and thank you for  
5 the opportunity to speak. My name is Harry Gewanter.  
6 I'm a pediatric rheumatologist, and Medical Director of  
7 Medical Home Plus. This is a nonprofit that works with  
8 families of children with any kind of chronic or  
9 disabling condition, and try to help them, provide them  
10 with information, support and resources.

11 I'm both a prescriber and someone who has  
12 benefitted from biologic therapies through members of  
13 my family, and I want to really thank the FDA for all  
14 they've done to get these wonderful, wonderful products  
15 on the market.

16 I do want to remind everybody that this is  
17 Rheumatic Disease Awareness Month, through the American  
18 College of Rheumatology and for everyone to take  
19 advantage of that.

20 I also want to, you know, sort of disclaimer  
21 in advance. I'm a very concrete pediatrician with  
22 ADHD, and so I'm going to go through questions

1 specifically as I go through these, with some comments  
2 for you, looking at it from really both a prescriber  
3 and patient/family perspective.

4 I think with respect to Question 1, how do we  
5 get more biosimilars out? I think you all need more  
6 help and more bodies to be able to expedite the  
7 processes, both in terms of valuation and as was  
8 mentioned, in terms of plant monitoring and so on. I  
9 think we really need to help have therapeutic choices  
10 for everybody, and my pie in the sky would be that we  
11 eliminate formularies.

12 If you want true market competition, let's let  
13 me have availability of all the products out there.  
14 Let me know what the costs are to the patient, as was  
15 mentioned earlier, the out-of-pocket costs, and let me  
16 and the patient decide what to do and not have these  
17 decisions made by anybody else.

18 With respect to the Purple Book, most folks  
19 don't even know it exists, and I think you've got, you  
20 know, some education to do with that. I think perhaps  
21 having a Cliff's Note version or something similar for  
22 prescribers to be able to access it when they launch

1 and perhaps have it in the electronic health records or  
2 so on, but I think other people have really addressed  
3 the question of other ways to improve the Purple Book.

4 With respect to the biosimilar marketplace,  
5 approval and interchangeability does not equal access,  
6 and we need to have an equal playing field for all  
7 options. The current systems of formularies and  
8 decisions made by someone other than a patient and the  
9 prescriber goes against what we're all supposed to do  
10 as physicians, and it goes against the patient's  
11 ability to make rationale and appropriate decisions for  
12 themselves.

13 Open formularies with transparent pricing  
14 would help make a true marketplace, and you know, I'm  
15 not sure that's under your legal purview, but I think  
16 it ought to be. I mean, if you are going to be in  
17 charge of ensuring that medications are safe,  
18 efficacious and available, then the post-approval  
19 process is an important aspect that needs to be  
20 addressed, because many of us view that as a current  
21 limiting factor.

22 In terms of Question 4 about biosimilar

1 development, keep up your scientific rigor. Even if it  
2 takes longer to get the drugs to the market, having any  
3 lack of confidence in your approval process, is going  
4 to be detrimental both in the short and the long term,  
5 and you know, I think that we need to maintain that at  
6 all cost.

7           It's already been mentioned, I think having  
8 adequate samples for biosimilar manufacturers, so that  
9 things that can be -- processes that can be created are  
10 the most flexible as possible but certainly be very  
11 helpful.

12           With respect to multi-national development, I  
13 think whatever the FDA can do to work with WHO and  
14 other nations to have a global harmonization of naming  
15 both -- of all biologics, both originators and  
16 references are absolutely crucial. I'll give a nod to  
17 Gail Attara, who is a Canadian involved with their  
18 Crohn's Agency, talked about having identical twins and  
19 they have the same genes, but they are different and  
20 you have to have two different names for the twins, and  
21 I think the same is true for these products. We need  
22 to have identifiable names so that we know everything

1 about which medicine is being given.

2 We need to harmonize our criteria so that  
3 products can be utilized both in the U.S. and  
4 elsewhere, and that we be able to use those comparators  
5 and again going back to Question 1, where how do we get  
6 biosimilars to market more quickly, if we can show that  
7 a non-U.S. comparator is sufficiently close, I think  
8 that that would be one way of improving access.

9 With regard to Question 7, Dr. Kozlowski keeps  
10 coming back to the analytics and I think it's an  
11 important thing that we have to, you know, teach all of  
12 us that it's about the molecules. As physicians we're  
13 trained that to look at clinical studies, and we're not  
14 as used to looking at analytics, but talking about this  
15 in terms of the molecules, I think would help with  
16 that.

17 I think the other thing has been mentioned  
18 before is using patient report outcomes, real world  
19 evidence and registries. I give a nod to the American  
20 College of Rheumatology's Rise Registry, where we now  
21 have over a million patients with rheumatoid arthritis  
22 being tabulated through physicians' offices and

1 extractions from the electronic records.

2           Those kinds of information would be  
3 extraordinarily helpful moving forward, so that we can  
4 know what is the real work effects. You know, we worry  
5 about the down side of biosimilars but we haven't  
6 thought much about the potential upsides, that there  
7 may be with genetic variabilities certain biosimilars  
8 or certain glycosylations or whatever that are going to  
9 work out better for some individuals than others, and  
10 unless we can monitor and track these changes, both  
11 good and bad, we're never going to know.

12           I'm fine with Question 9. The challenge is,  
13 again, from a practical standpoint, the administrative  
14 barriers and the pricing is just a huge problem, and I  
15 think that that is really one of the biggest issues you  
16 have right now. As was mentioned, I think having out-  
17 of-pocket costs are really what matter.

18           We are as patients the ultimate payers, not  
19 the insurers, not the PBM's. It's coming out of our  
20 checkbooks and those need to be addressed that way. I  
21 think as was mentioned, having testing of biosimilars  
22 against biosimilars and the active pharmacovigilance is

1 absolutely critical.

2 And thank you. Appreciate the time.

3 DR. SHERMAN: Thank you for your comments.

4 Questions from the panel? Dr. Kozlowski.

5 DR. KOZLOWSKI: So clarifying your comment  
6 about harmonizing criteria, so do you mean that there  
7 should be standards like the International Council of  
8 Harmonization has standards that many regions accept or  
9 are you talking about something more than that in terms  
10 of --

11 DR. GEWANTER: No, I think it would be, you  
12 know, as you've gone through biosimilar approvals, you  
13 know, saying you have to use an EMA approved lot versus  
14 a U.S. approved lot, I think if we can have some  
15 standards where those are sufficiently close, that that  
16 would allow us to be able to expand access a lot  
17 quicker.

18 DR. KOZLOWSKI: So currently we have bridging,  
19 scientific bridging, which allows use of the XUS  
20 material, so are you thinking about something broader  
21 than that? In other words, because that's an  
22 individual comparison for each product that's brought

1 as a candidate.

2 DR. GEWANTER: No. No, I think that really I  
3 was thinking about this thing how do we get more, you  
4 know, medications to market or if there's manufacturing  
5 problems or things like that, and we can show that a  
6 non-U.S. -- that the bridging standards have shown  
7 sufficiently that the medications are close, that we  
8 can use them that way.

9 DR. KOZLOWSKI: Oh, so you mean to actually  
10 bring them to market as opposed to use them in studies?

11 DR. GEWANTER: Yeah, or both.

12 DR. KOZLOWSKI: Okay, that's --

13 DR. GEWANTER: I look at life as an "and" not  
14 an "or."

15 DR. KOZLOWSKI: Okay. And in addressing  
16 Question 9, you talk about encourage testing of  
17 biosimilars versus biosimilars. So I wondered what  
18 sort of testing? Was that analytical testing? Was  
19 that clinical testing? What were you thinking of by  
20 that?

21 DR. GEWANTER: I was thinking about clinical  
22 testing. I think it has been, you know, talked about

1 before, the range of differences between two potential  
2 biosimilars could be sufficient that -- for patients  
3 there would be -- even though they are interchangeable  
4 with the originator, they may not be interchangeable  
5 with each other, and I mean, a personal experience with  
6 chemical medicines has been patients with duloxetine  
7 that went from brand to one of generics had significant  
8 problems, and another one went from one generic to  
9 another generic, and also had significant problems.

10           And if you're going to have those kinds of  
11 differences with chemical medications, you know, even  
12 though they're both within the range, you know, they're  
13 not -- you know, their ranges are apart from each  
14 other, so I think that that's something that we need to  
15 have that evidence. I'm not sure it's necessary to  
16 prevent them coming to market, but I think being --  
17 again, this perhaps where pharmacovigilance can come  
18 in, we need to be able to know as much as we can about  
19 these molecules, and how well they're going to work or  
20 not work for individuals.

21           DR. KOZLOWSKI: Thank you.

22           DR. SHERMAN: Thank you for your comments.

1 DR. GEWANTER: Sure.

2 DR. SHERMAN: Our next speaker is Bruce  
3 Leicher from Momenta.

4 MR. LEICHER: Good morning. I'm Bruce  
5 Leicher, Senior Vice President and General Counsel at  
6 Momenta Pharmaceuticals. Momenta is a biotechnology  
7 company engaged in the development of biosimilar and  
8 interchangeable biologics, as well as complex generics  
9 and novel products. We innovate to develop biosimilars  
10 and new cures for patients. Thank you from holding  
11 this important meeting.

12 The Biosimilars Action Plan evidences strong  
13 leadership by the Agency to support biosimilars. It  
14 recognizes the primary goals of the Biologics Price  
15 Competition and Innovation Act, to unleash competition  
16 and innovation to provide access to biosimilars and  
17 interchangeable biologics.

18 We offer seven steps the Agency can take to  
19 enhance competition and innovation, competition to  
20 drive affordability and access and innovation to reduce  
21 the cost to biosimilar development and accelerate  
22 biosimilar approval. Each are necessary to deliver

1 lifesaving biosimilar medicines to patients.

2 First, access to reference product for  
3 biosimilar development is necessary for competition.  
4 For over 30 years reference product access was  
5 unrestricted and considered a condition of originator  
6 product approval. It was available promptly on  
7 commercially reasonable terms for testing under the  
8 regulatory supervision of the Agency. When access to  
9 originator products is blocked or delayed, biosimilar  
10 development is not possible.

11 Similarly, the misuse of REMS programs to  
12 block access and approval of biosimilar compounds this  
13 problem. The Commissioner's decision to publish a list  
14 of restricted access abusers is a valuable first step  
15 but some brand companies still simply refuse to sell  
16 their products for biosimilar development.

17 The FDA should issue a policy confirming the  
18 commercially reasonable access to reference products as  
19 a condition of approval under Hatch Waxman and the  
20 BPCIA. FDA should also work with CMS to condition CMS  
21 reimbursement on compliance with these supply  
22 obligations.

1           In parallel, the Agency should provide  
2 assurance to Congress that a supervision of biosimilar  
3 development ensures patients are protected and assist  
4 Congress in ensuring any legislation actually fixes the  
5 problem as the CREATES Act would.

6           Second, the Agency should continue to lead the  
7 world in promoting innovative biosimilar regulatory  
8 science. Advances in the United States made it  
9 possible to develop highly complex generics without  
10 clinical studies. These advances in analytical science  
11 also paved the way for development of biosimilars with  
12 targeted clinical trials. We now need to continue to  
13 use innovation to develop more affordable  
14 interchangeable biologics. Continuing to hire  
15 scientists with analytical expertise and encouraging a  
16 science-driven flexible approach to biosimilar review  
17 is essential. Highly talented and engaged staff are  
18 key for industry to attract investment, take risk and  
19 use innovation to make medicine more affordable.

20           Federal characterization of biologics and  
21 biosimilars makes it possible to prove fingerprint-like  
22 similarity. This reduces residual uncertainty.

1 Further advances should enable targeting clinical  
2 trials for both biosimilars and interchangeable  
3 biologics. Receptivity and clear guidance that new  
4 ideas and innovation are desirable is necessary to  
5 encourage private investment.

6 Over-reliance on clinical data will discourage  
7 innovation and raise the cost of seeking  
8 interchangeability too high. Let's drive innovation,  
9 not limit its use.

10 Third, issue an explicit policy statement in  
11 the Purple Book that an interchangeable biologic is  
12 therapeutically equivalent to the reference product.  
13 This policy is present for interchangeable drugs in the  
14 Orange Book and necessary to enable substitution at the  
15 pharmacy, but currently absent from the Purple Book.  
16 CMS relies on this statement in the Orange Book to  
17 provide favorable reimbursement for drugs. CMS is  
18 awaiting guidance from the FDA for interchangeable  
19 biologics.

20 Pharmacy substitution drives savings and  
21 affordability by reducing the need for marketing and  
22 promotion. Without it, affordable interchangeable

1 biologics will be an unattractive investment.

2 Fourth, level the playing field for biologic  
3 naming, ensure biosimilars do not look different or  
4 inferior by requiring originator products to also have  
5 proper name suffixes. Today only some originator  
6 products have suffixes. This is very confusing to  
7 physicians and patients and creates an additional  
8 barrier to biosimilar competition. Pharmacy computer  
9 systems will not be reprogrammed to accommodate a  
10 suffix unless all biologics must comply.

11 In addition, provide that interchangeable  
12 biologics have the same proper name as the reference  
13 product to ensure pharmacy substitution is instead  
14 implemented, as it is with interchangeable generic  
15 drugs.

16 Fifth, publish a policy that states  
17 substitution laws not conflict with the substitution of  
18 interchangeable biologics authorized under the BPCIA.  
19 A patchwork of state substitution laws, some of which  
20 facilitate substitution and some of which might not,  
21 also deters investment in interchangeable biologics.  
22 An explicit policy will provide certainty and eliminate

1 this barrier by rendering conflicting laws  
2 unenforceable.

3 Sixth, allow scarce application -- I'm sorry,  
4 allocate scarce application resources toward truly  
5 novel cures and biosimilars. Reduce resources assigned  
6 to incremental life extension products. Routine  
7 formulation changes or convenience devices set the  
8 stage for abusive behaviors, such as product hopping,  
9 patent misuse and citizen petition abuse. Given their  
10 pricing they do not warrant the same research priority  
11 as new cures or affordable medicine that actually  
12 address urgent patient needs. Incremental changes can  
13 come later.

14 In addition, promptly deny citizen petitions  
15 that seek to delay or prevent biosimilar approvals. As  
16 noted by Carrier and Midea, citizen petitions are  
17 rarely granted, are mostly filed at the end of a  
18 product's life cycle and delay the approval of  
19 affordable medicine.

20 Seventh, continue to call our companies that  
21 game the system to block competition. Work with CMS to  
22 end rebate abuse and contracting practices that make it

1 economically infeasible to launch a more affordable  
2 biologic.

3           The rebate trap is but one example. As shown  
4 by Aaron Hakim, the rebate trap can undermine  
5 competition by making the cost of market entry so high  
6 for a biosimilar that sales are unprofitable. Even  
7 with a substantially less expensive biosimilar, the  
8 pair will spend more if it buys the less expensive  
9 biosimilar product than if it remains exclusively with  
10 the originator product. Unless these issues are  
11 addressed, the goal of competition, affordability and  
12 innovation will be thwarted.

13           We should ask why is it the 12 biosimilars  
14 have been approved but less than half that number have  
15 been launched? Why is it that biosimilar market access  
16 is slower than expected? Is it because federal policy  
17 inadvertently provides protection for incumbent  
18 products over new competitive entrance?

19           We believe these seven steps could help  
20 address these questions and thank you for the  
21 opportunity to address the panel today.

22           DR. SHERMAN: Thank you for your comments.

1 Questions from the panel? Dr. Franklin.

2 DR. FRANKLIN: You mentioned that there are a  
3 couple things FDA might do to encourage access to  
4 reference product samples by similar developers. And  
5 you mentioned I think specifically that FDA should  
6 issue a statement that it would be a condition of  
7 approval I guess for the reference product that samples  
8 be provided. From your perspective is this something  
9 FDA could do under its current statutory authorities or  
10 would additional authorities be needed?

11 MR. LEICHER: We believe it's authorized under  
12 the current law. I mean, the practice for years was  
13 the understanding that when you were approved, when the  
14 whole underlying premise of Hatch Waxman was that the  
15 reference product had to be available. So we believe  
16 it's implicit in the statute and you can read it into  
17 the existing authority in both statutes.

18 DR. SHERMAN: Dr. Kozlowski.

19 DR. KOZLOWSKI: So we heard from Amgen that  
20 accessing reference product was not necessarily that  
21 much of a challenge. So what do you think the  
22 difference is in the experience you had and that of

1 certain other companies?

2 MR. LEICHER: Well, it's interesting. We have  
3 both kinds of experiences, so when we're both a novel  
4 company as well as biosimilar company. We've been  
5 doing competitive studies in our novel product trials.  
6 Never an issue purchasing product from a manufacturer  
7 when we're doing the comparative study. But when we go  
8 to purchase product from a wholesaler for the  
9 biosimilar company for a biosimilar program, the first  
10 question we're asked is is it for biosimilar study and  
11 we're often told -- once we were told there's a REMS  
12 program in place, we looked it up. There was no REMS  
13 program in place. They then said well, we're not  
14 allowed to sell it to you.

15 So what happens is you go through a two to  
16 three, four month, delay. You may ultimately be able  
17 to purchase it, and there are products that we have not  
18 put into development because it was just too hard to  
19 buy.

20 DR. KOZLOWSKI: Thank you.

21 MS. ABRAM: I'm curious, going back to your  
22 remarks on the citizen petition process, if you have

1 anything to expand on those remarks or if you have  
2 specific suggestions that might be considered with  
3 respect to potential reforms in that area?

4 MR. LEICHER: Well, you know, looking at the  
5 article that was published, I think the risk is that  
6 you have to look at not just the citizen petition, but  
7 you have to look at examples of product hopping and  
8 examples of life extension, incremental changes to  
9 products. If there's an opportunity to delay the  
10 approval of a biosimilar or a generic through a citizen  
11 petition review process, and it slows down the review,  
12 it creates the setting in which minor changes can be  
13 introduced, you know, and planned as a way to switch  
14 the market to a new -- a question was raised earlier  
15 how is it going to affect interchangeability if there's  
16 a new presentation or a new convenience device, and all  
17 of those things are barriers to entry for biosimilars  
18 and potentially for interchangeable products in the  
19 future, and we ought to ask what is -- you know, what's  
20 in the interest of patients? Is it to get the new  
21 competitive product out or to get the new incremental  
22 improvement out?

1 DR. SHERMAN: Thank you for your comments.

2 Our next speaker is Dr. Lisa Skeens from Pfizer.

3 DR. SKEENS: Good morning. I'm Lisa Skeens,  
4 Vice President of Global Regulatory Affairs for Pfizer  
5 Essential Health.

6 I'm here today to share with you Pfizer's  
7 recommendations on the steps necessary to ensure a  
8 robust biosimilars marketplace in the United States  
9 that has the potential to provide patients with greater  
10 access to these important medicines while lowering  
11 healthcare costs.

12 Pfizer has a long heritage in developing both  
13 originator biologics and biosimilars. We have more  
14 than 30 years of expertise in the development of  
15 biologics and more than ten years in market experience  
16 of biosimilars in Europe.

17 We are the leading company worldwide by  
18 revenue. We market three biosimilars globally,  
19 Inflectra, infliximab, Retacrit, epoetin, and Nivestim,  
20 filgrastim.

21 We have a strong and exciting pipeline, which  
22 demonstrates our continued commitment to the success of

1 biosimilars worldwide.

2           Pfizer's experience shows that one of the  
3 greatest hurdles to biosimilar success is market  
4 access. Here is the example of the infliximab market.  
5 The originator molecule of Remicade in the green line  
6 has 95 percent market share, one-and-a-half years after  
7 the introduction of infliximab biosimilars. Even  
8 though the average sale price of Pfizer's biosimilar,  
9 Infectra, the orange line, is 24 percent less than that  
10 of Remicade as shown in the smaller graph.

11           There could be savings up to half a billion  
12 dollars a year for commercial payers and Medicare,  
13 according to one study, just by increasing the use of  
14 infliximab biosimilars to 50 percent. In order for  
15 patients to benefit for the U.S. healthcare system to  
16 realize cost savings, for the biosimilars pathway to be  
17 successful, and for companies to continue to commit to  
18 this important area of drug development, work needs to  
19 be done to ensure that all of these important  
20 biosimilar medicines have the potential to reach  
21 patients as quickly and efficiently as possible.

22           The biosimilars marketplace in the U.S. is at

1 a critical juncture and more needs to be done to ensure  
2 its success. Opportunities to further advance  
3 biosimilars go beyond FDA working alone. For a  
4 successful biosimilars marketplace that will expand  
5 access to patients, for these important medicines and  
6 bring lower costs to the healthcare system, it's  
7 important that multiple federal agencies and state  
8 agencies work both individually and collectively to  
9 implement policies that will remove barriers and  
10 support biosimilars uptick.

11 Today we will highlight several opportunities  
12 to take action now to support a successful biosimilars  
13 pathway and marketplace. There are three key areas  
14 that will take biosimilars to the next level and ensure  
15 continued commitment and success. They are  
16 optimization of biosimilar development, proactively  
17 combatting misinformation and instilling confidence in  
18 both prescribing and using biosimilars, and expediting  
19 market access to biosimilars.

20 Now I will share our recommendations for each  
21 of these in a little more detail.

22 Pfizer fully supports the rigorous evaluation

1 standards that FDA applies to all products, including  
2 biosimilars, so that patients can be assured of the  
3 quality, safety and efficacy of these products. There  
4 are opportunities to further optimize the development  
5 of biosimilars without compromising these scientific  
6 standards. Pfizer recommends several key actions the  
7 FDA can take to build efficiencies and to biosimilar  
8 development programs.

9 First, FDA should consider flexibility in  
10 bridging expectations and acceptance of non-U.S.  
11 licensed comparator data that would enable efficient  
12 development and minimize redundant work.

13 Second, FDA should be flexible in their  
14 willingness to consider alternative comparative  
15 clinical study and switching studies statistical  
16 approaches, study end points and overall study design,  
17 when sponsors have alternative approaches supported by  
18 scientific justification, that meet the standard for  
19 demonstrating there are not clinically meaningful  
20 differences between the proposed biosimilar and its  
21 reference product.

22 Third, FDA should maximize review efficiencies

1 by ensuring there is appropriate allocation of  
2 resources and timely implementation of the GDUFA  
3 INSPECTION goals, particularly hiring goals.

4 It's also essential that the FDA work to  
5 ensure there is clear and consistent communication of  
6 application expectations relating not only to  
7 demonstration of biosimilarity but also to  
8 biotherapeutic manufacturing standards in general.

9 Finally, FDA should develop a seamless process  
10 for biosimilar sponsors to add indications post-  
11 approval. Currently FDA is suggesting a prior approval  
12 supplement process to add indications. However, as  
13 sponsors have already scientifically justified  
14 extrapolation of the indication they propose to add,  
15 the Agency should consider a CBE-0 submission to  
16 prevent unnecessary delays in patient access to  
17 biosimilars.

18 In addition to optimization of development of  
19 a biosimilar through the regulatory pathway, it is of  
20 the utmost importance for multiple agencies and  
21 stakeholders to combat misinformation and instill  
22 confidence in biosimilars to support the development of

1 a robust and accessible biosimilar marketplace. More  
2 must be done to combat false and misleading marketing  
3 practices that create confusion and undermine efforts  
4 to enhance stakeholder confidence in biosimilars.

5 The FDA, FTC, as well as other agencies need  
6 to take an active role to ensure the information  
7 regarding biosimilars and interchangeable biologic  
8 products is represented in a way that is complete,  
9 truthful and non-misleading.

10 Pfizer has filed a citizens petition with FDA  
11 asking the Agency to issue guidance outlining the kind  
12 of reference product communication surrounding the  
13 safety and efficacy of biosimilars, including  
14 interchangeability and switching, that would be  
15 truthful and non-misleading. This is another step to  
16 combat the behavior by certain originator companies  
17 that could build barriers or block access to the use of  
18 biosimilars in the United States.

19 While not sufficient on its own, ongoing  
20 education is also necessary and it should be created in  
21 a manner to facilitate a conversation between a  
22 healthcare provider and their patient.

1           Pfizer appreciates the steps FDA has taken in  
2 this area and urges the Agency to expand in their  
3 efforts.

4           Finally, in our experience without market  
5 access, an approved lower cost biosimilar will not be  
6 successful in the U.S. We need to implement policies  
7 that will proactively remove barriers and advance the  
8 uptick of biosimilars. Support is needed from the FDA  
9 and other agencies, such as the FTC and CMS, as well as  
10 stakeholders such as commercial payers and purchasers.  
11 First and foremost the U.S. Government should enforce  
12 antitrust laws to prevent anti-competitive practices by  
13 reference biologic manufacturers that use exclusionary  
14 contracts to create access barriers.

15           Contracts that require patients to fail first  
16 on a reference biologic before they can access a  
17 biosimilar are preventing access to biosimilars. CMS  
18 should do more to proactively support uptick of  
19 biosimilars such as publicly track, update, uptick,  
20 expand balance incentives to drive uptick at the  
21 hospital and provider level, such as the 340b pass  
22 through and work with state and Medicaid agencies to

1 ensure biosimilars are available to Medicaid patients.

2 We call upon all stakeholders to engage in  
3 driving uptick of biosimilars and we thank the FDA for  
4 their support in hosting this important public meeting.

5 Thank you.

6 DR. SHERMAN: Thank you for your comments.

7 Any questions from the panel? Dr. Kozlowski.

8 DR. KOZLOWSKI: So you mentioned manufacturing  
9 guidance for biological products in general, so I would  
10 hope in comment to the docket you are a bit more  
11 specific about what would be particularly helpful.

12 DR. SKEENS: We do. We've seen additional  
13 requests in some of our biosimilar FDA's during review  
14 that are more typically handed through prior approval  
15 inspections or other means, and so if there is new  
16 expectations, then we really need to call that out in  
17 guidance instead of during review and it should be  
18 applicable to all BLA's, not just biosimilar BLA's.

19 DR. KOZLOWSKI: Okay. Well, clearly sharing  
20 that would be of use to us. Thank you.

21 DR. SKEENS: Thank you.

22 DR. SHERMAN: Other questions? Thank you for

1 your comments.

2 DR. SKEENS: Thank you.

3 DR. SHERMAN: Our last speaker before lunch is  
4 Dr. Richard Dolinar from the Heartland Institute.

5 DR. DOLINAR: You had to put in lunch to  
6 remind everybody they're hungry.

7 My name is Dr. Richard Dolinar. I am a  
8 clinical endocrinologist in private practice in  
9 Phoenix, Arizona. In our group we have 12  
10 endocrinologists. We see over 200 endocrine patients a  
11 day so it's quite a busy practice.

12 Let me get this organized here. I'm also a  
13 senior fellow on healthcare policy for the Heartland  
14 Institute and I was a member of the National  
15 Legislative and Regulatory Committee as listed there  
16 for 15 years, but since this slide was made, I've moved  
17 over to the Socioeconomics Committee, where we focus on  
18 healthcare economics.

19 I'm also a member of the Editorial Advisory  
20 Board of Endocrine Today and the Journal of American  
21 Physicians and Surgeons.

22 I was the first Chairman of the Alliance for

1 Safe Biologic Medicines, and I'm quite proud of what  
2 ASBM has one over the years in the world of biologics  
3 and biosimilars. I think it's been very helpful for  
4 everybody.

5 I should also add that in my experience when I  
6 was in the Air Force, I was able to travel to many  
7 parts of the world and see healthcare systems and see  
8 how other countries have their healthcare set up, so  
9 it's allowed me to compare and contrast our system with  
10 theirs. I'm also a retired Air Force Colonel.

11 The first item I'd like to get into today  
12 involves the transition products and as you know, those  
13 are the products that meet the FDA's definition of a  
14 biologic, but currently are approved under Section 505  
15 of the Food Drug and Cosmetic Act.

16 The Biologics Price Competition and Innovation  
17 Act of 2009 provides that on March 23rd, 2020, these  
18 products will transition and become deemed -- that's a  
19 legal term, not a medical term -- deemed as approved  
20 products under Section 351 of the Public Health Service  
21 Act, and potentially under Section 351(k) as a  
22 biosimilar.

1           This transition raises a number of regulatory  
2           and also process questions that impact the continued  
3           development of biologics and follow-on biologics. For  
4           example, Basaglar. Basaglar is a glargine insulin. In  
5           my practice I focus primarily on diabetes, and so I do  
6           use many of -- in fact, I use all of the diabetic  
7           drugs. But let me focus on Basaglar. It was approved  
8           by the FDA as a follow-on biologic under Section  
9           505(b)(2) of the Food Drug and Cosmetic Act.

10           It's been designated as a transition product  
11           and, therefore, will become a Public Health Service Act  
12           approved product as of March 23rd, 2020. The FDA has  
13           not yet decided how Basaglar and similarly situated  
14           products will be classified, whether as a standalone  
15           biologic under Section 351(a) of the Public Health  
16           Service Act, or a biosimilar under Section 351(k).

17           In March of 2016 the FDA issued a draft  
18           guidance on this topic entitled Implementation of the  
19           Deemed to be a Licensed Provision of the Biologic Price  
20           Competition and Innovation Act of 2009. However, key  
21           questions, including how products such as Basaglar will  
22           be classified have not yet been addressed.

1 I urge the FDA to finalize its guidance on  
2 this transition and these transition products in order  
3 to offer more clarity and promote a robust biosimilar  
4 and biologic market.

5 Naming. Let me go on to naming. Naming is  
6 absolutely critical and I think the FDA is correct in  
7 using a suffix to differentiate these products. But  
8 the current names used in the suffixes -- the suffixes  
9 are non-sensical. They're difficult to pronounce, if  
10 you can pronounce them at all, and these suffixes are  
11 untethered to anything. So they're difficult to  
12 remember. So we have a situation where we have a name  
13 that a doctor can't pronounce or is very difficult to  
14 pronounce, and if you have words that you can't  
15 pronounce, you're not going to remember them. And if  
16 you don't remember the name of that drug, you won't  
17 order it, and if you don't order the drug, the patient  
18 won't have access to that drug.

19 So our recommendation is that we allow for  
20 more memorable and meaningful names in brand names, and  
21 especially in the design of the suffixes that are being  
22 used. And I encourage the FDA to work with WHO to

1 advance the use of distinct naming systems worldwide.

2 More education. It's been touched upon by  
3 others. Doctors need to be educated on biologics and  
4 biosimilars and follow-on biologics. That's a major  
5 issue. That could potentially block bringing these  
6 drugs to their patients, so I'd strongly encourage  
7 education for the physicians. Most doctors don't even  
8 know a Purple Book exists. We've got to get word out  
9 to them and got to get them educated.

10 We need to educate the public too about  
11 biologics and biosimilars. I think there's a role for  
12 direct to consumer advertising. I think the FDA could  
13 advertise and alert the public to this issue, and I  
14 think the companies could also do that.

15 Remember, the purpose of advertising is not  
16 only to inform and educate but to persuade, educate the  
17 public regarding biologics and follow-on biologics and  
18 biosimilars, and persuade them that these are safe,  
19 effective, they're cheap, they're beneficial, so I  
20 think that that word needs to get out.

21 Data over time builds confidence. As the  
22 others here have said, I thank the FDA for maintaining

1 their high standards. I think that's critically  
2 important. Recommend that clinical studies should be  
3 done in every indication. Switching studies will help  
4 physicians feel comfortable switching their patients.  
5 This will all help to have a robust active market.

6 Extrapolation will be a problem with treating  
7 physicians. They'll be reluctant to accept that and  
8 that's why I encourage the clinical studies. We  
9 practice evidence-based medicine, so that's what we'll  
10 want to see, the evidence, rather than the  
11 extrapolation.

12 Analytical studies are needed, as the others  
13 have stated. I won't spend time on that.

14 PBM's. This is a real problem. On Mondays I  
15 see the patients. I make my decisions. I use my best  
16 medical judgment, and then on Tuesday I'm back peddling  
17 because I'm being told the formulary no longer covers  
18 this, although it covered it maybe the month before,  
19 and now I'm in a situation where I'm using my second,  
20 third or fourth best medical judgment. PBM's in  
21 certain cases set up obstacles to me giving my best  
22 medication for my patient.

1           They call it a walk-away rate. Walk-away  
2 rates can be as high as 65 percent, meaning only 35  
3 percent of the time is the patient getting the drug  
4 that we ordered, the drug that we thought was best for  
5 them. So I think there's a lot needs to be done  
6 regarding PBM's. I think the incentives are  
7 misaligned. They're paid on a basis of a percent of  
8 the initial list price, and I think that's problematic.

9           I will just finish by reiterating that the  
10 importance of naming -- if the doc cannot remember the  
11 name because he can't pronounce it, he won't be using  
12 that drug. And if he doesn't use that drug, not  
13 ordering it, the patient won't have access to it, so  
14 all these hurdles that we talked about today, you may  
15 surmount all of them, but the final one with the  
16 physician, we've got a problem.

17           So thank you. Thank you for this morning.

18           DR. SHERMAN: Thank you for your remarks. Any  
19 questions from the panel? I guess everybody is hungry.  
20 Thank you for your remarks. Well, for the speakers  
21 this morning, we heard a lot about the Purple Book, but  
22 I think very differing ideas of the intended audience,

1 so anything you can do to elaborate in your comments  
2 would be much appreciated.

3 And on that note, we'll -- it's lunch, and  
4 we'll be back. We'll start promptly at 12:45. Thank  
5 you.

6 (Lunch break from 11:41 a.m. until 12:45 p.m.)

7 DR. SHERMAN: Hi. I think we're going to get  
8 started. Good afternoon. It's my pleasure to announce  
9 the first speaker of the afternoon is Commissioner  
10 Gottlieb.

11 COMMISSIONER GOTTLIEB: Thanks, Rachel, for  
12 that warm and detailed introduction.

13 DR. SHERMAN: Should I try a do-over?

14 COMMISSIONER GOTTLIEB: Moving. I want to  
15 thank you all for being here today and I want to thank  
16 you for the opportunity to join you for a short period  
17 of time.

18 This meeting is really important to us. The  
19 information that we gather here today that's submitted  
20 to us is part of the docket. It's going to help FDA as  
21 we continue to work to foster the competitive  
22 marketplace for safe and effective biologic products.

1           We're committed to this work at FDA. We have  
2 a vital role to play in supporting innovation and  
3 ingenuity that provides patients with novel therapeutic  
4 options, while also helping encourage a competitive  
5 marketplace that can make these therapies more  
6 affordable and more accessible to patients. And while  
7 FDA isn't directly involved in the pricing of drugs or  
8 biologics, we know that we play an important role to  
9 play in these issues, applying science-based policies  
10 to help facilitate greater access to affordable new  
11 drugs.

12           Biologics, as all of you I'm sure share, have  
13 become crucial in the treatment of many serious and  
14 life-threatening diseases. But the high costs of  
15 biologics are likely familiar to you, as well. Almost  
16 40 percent of total prescription drug spending is on  
17 biologics and biologics represents 70 percent of the  
18 growth in drug spending between 2010 and 2015.

19           We know it's going to take more work to  
20 achieve a vibrant and competitive marketplace for  
21 biologics, and today's public dialogue is an important  
22 part of that process for us.

1 Congress, through the Biologics Price  
2 Competition and Innovation Act gave FDA the authority  
3 to implement a pathway for approval of biosimilars and  
4 interchangeable products, and to balance innovation and  
5 competition when it came to this category of drugs.

6 In the past several years there has been  
7 substantial efforts vested to make this pathway  
8 successful by many people here at FDA, many of whom are  
9 with us today. FDA has developed the scientific and  
10 regulatory framework for the review, marketing  
11 applications for biosimilars products, incorporating  
12 feedback from many diverse stakeholders, some of whom  
13 are also here with us today.

14 Manufacturers have also invested a lot of  
15 money in developing biosimilar products and the  
16 information needed to support approval, and this work  
17 has yielded some concrete results. We've seen 12  
18 biosimilar products approved, including six approvals  
19 in the last year alone.

20 But as I've said before, I'm not satisfied  
21 with the current state of the biologics market, and  
22 biosimilars in particular. Even as we meet to discuss

1 these important issues today, not even half of the  
2 biosimilars approved by the FDA have entered the  
3 market.

4 Each approved biosimilar product that is not  
5 yet marketed means a lot of loss, potential cost  
6 savings, from a biosimilar that meets FDA's rigorous  
7 standards but is not yet available to patients and not  
8 yet available to increased competition with the  
9 referenced product.

10 I have expressed concerns in the past that  
11 biosimilars are not being developed or submitted for  
12 approval because of marketplace dynamics that are  
13 viewed as unfavorable to biosimilars, and I know you've  
14 discussed some of these here today, including the  
15 challenges that biosimilar manufacturers face in  
16 getting access to the doses that they need in order to  
17 run their studies.

18 Another one that I've talked about is the  
19 consolidation of supply chain that can work in favor of  
20 incumbent reference biologics and discourage adoption  
21 of biosimilar competitors.

22 We know there is more work to do at FDA to

1 advance the science and policies to make the  
2 development of biosimilars more efficient, to increase  
3 the acceptance of biosimilars and to avoid the  
4 regulatory gaming that can deter competition in this  
5 space. That's why earlier this year we announced the  
6 Biosimilars Action Plan, working with the staff of the  
7 group in CEDR that's charged in reviewing and approving  
8 these products, and we announced that a little over a  
9 month ago now.

10 To formulate this plan FDA looked at how we  
11 could adapt the lessons learned from our regulation of  
12 generic drugs. We looked to what we had already  
13 learned from our interactions with biosimilar sponsors,  
14 as well, during the product development and application  
15 review process.

16 And we looked to how we could modernize our  
17 policies on the development of biosimilars to improve  
18 the efficiency and increase regulatory certainty,  
19 without compromising safety and effectiveness and we  
20 evaluated input from various stakeholders such as  
21 professional societies and patient organizations.

22 Under that plan not only are we making the

1 biosimilar development and review process more  
2 efficient and predictable, we're also taking new steps  
3 to communicate with patients and payers and providers  
4 to improve the understanding of biosimilars and  
5 interchangeable products. And we'll act, where  
6 appropriate, to deter the gaming of FDA requirements  
7 that unfairly delay competition among biologics.

8           The Federal Trade Commission is a vital part  
9 in this work, and we look forward to continue  
10 coordination with them to address anti-competitive  
11 behavior in drugs and biologics marketplace, and we'll  
12 be taking some steps in conjunction with them in the  
13 coming months to work more closely with them in all of  
14 these efforts.

15           Our action plan is dynamic, and we continue to  
16 evaluate additional FDA actions that are needed to  
17 strike the appropriate balance between encouraging  
18 ongoing innovation and biologics, while also  
19 facilitating the robust competition that we know can  
20 reduce costs and help increase access for patients.

21           And so a key element of FDA's Biosimilars  
22 Action Plan is to learn from stakeholders in today's

1 public hearing. It's encouraging to see such a diverse  
2 group of perspectives here. And in announcing today's  
3 hearing FDA solicited input from the public on a broad  
4 set of questions about how we should address complex  
5 and challenging issues related to the biosimilars  
6 marketplace, including interchangeable products, taking  
7 steps to try to encourage competition, while also  
8 supporting innovation and striking other important  
9 balances.

10 We asked about other areas where we see real  
11 potential to make the development and review of  
12 biosimilars more efficient, and where we can clarify  
13 regulatory requirements for stakeholders. And so I'd  
14 like to thank you all for joining us here today. The  
15 feedback from today's meeting is very important to us.  
16 We learn a lot from these Part 15 hearings, but also  
17 the information that we get submitted to the docket is  
18 equally important. So I hope you all take the  
19 opportunity to not just share comments today but also  
20 think about information that you can submit to our  
21 docket to help us, as we think about how to improve  
22 this marketplace going forward.

1                   Thanks a lot. Thanks for having me here  
2 today.

3                   DR. SHERMAN: Thank you, and I appreciate that  
4 you stayed on time. Does the panel have any questions  
5 for Dr. Gottlieb? All right.

6                   Our second speaker of the afternoon will be  
7 Dr. Mariana Social from the Johns Hopkins Bloomberg  
8 School of Public Health.

9                   DR. SOCIAL: Good afternoon. My name is  
10 Mariana Social. I'm a medical doctor and I have a Ph.D.  
11 in health systems from Johns Hopkins and a master's in  
12 public policy from Princeton University.

13                   I currently work as an assistant scientist at  
14 Johns Hopkins School for Public Health. My research  
15 focuses on ways to provide the best appropriate  
16 pharmaceutical coverage for people who need drugs in  
17 order to improve their health and their quality of  
18 life.

19                   I would like to thank today the Laura and John  
20 Arnold Foundation, who support my research in Johns  
21 Hopkins. However, I'm speaking here today on my own  
22 behalf and neither of the institutions have had any

1 role in preparing my remarks today.

2 So I would like to provide commentary on how  
3 the FDA could improve information availability and  
4 accessibility in the Purple Book. And I'm going to be  
5 focusing on competition. I already understood that  
6 there's also interest in hearing about other  
7 stakeholders use of Purple Book, and I'm going to  
8 address that in the written remarks.

9 So the information currently available in the  
10 Purple Book is limited to drug proprietary and non-  
11 proprietary name, biologic license application number,  
12 BLA, and licensing date. Reference products may also  
13 have information on date of first licensure and  
14 exclusivity expire date. Although this information is  
15 available for a small number of products, any potential  
16 351(k) applicant who wishes to obtain more information  
17 on a particular product must spend considerable time  
18 and financial resources running independent search.

19 These searches may add cost and delay  
20 biosimilar development. The uncertainty generated by  
21 the lack of readily available information may also  
22 prevent investors and manufacturers from considering

1 becoming 351(k) applicants in the first place.

2           Improving information availability and  
3 accessibility in the Purple Book would increase  
4 transparency and decrease uncertainty in the market,  
5 contributing to decreasing barriers to entry and  
6 increasing competition.

7           So three pieces of information should be added  
8 to the Purple Book. First, drug identification  
9 information should be expanded to include information  
10 such as manufacturer's name, the drug's route of  
11 administration, dosage form, strength and others, so  
12 drug identification is key to allow potential 351(k)  
13 applicants to easily identify products that exists in  
14 the marketplace corresponding to each of the FDA  
15 licensed biologics.

16           Also the biosimilars should be identified by  
17 the name of their main active ingredient, and the four  
18 letter suffix should be presented in a separate field  
19 to increase clarity.

20           Okay. Second, all unexpired exclusivity  
21 periods should be published in the Purple Book.  
22 Potential 351(k) applicants and the investors gain

1 greater clarity when exclusivity information is  
2 transparent and readily available. This means that  
3 first the FDA should make a determination on the date  
4 of first licensure for all licensed biologics. And for  
5 those found to be eligible to the 12-year reference  
6 product exclusivity under the BPCIA, the exclusivity  
7 expiration date should also be determined and made  
8 available in the Purple Book.

9           Currently the policy appears to be that the  
10 FDA determines first licensure dates only in cases of  
11 regulatory necessity or on the wishes of the reference  
12 product license holder. This policy is in my view  
13 misguided.

14           A better policy where the FDA would  
15 automatically make and publish determinations for all  
16 drugs would significantly promote competition.

17           The FDA has issued guidance on reference  
18 product exclusivity and in particularly the limitations  
19 on exclusivity set forth by the Public Health Service  
20 Act. With this guidance document in hand, FDA should  
21 be in a position to modify its policy and make  
22 determinations on date of first licensure and reference

1 product exclusivity on all drugs.

2 In addition, many biologics also have other  
3 FDA granted market exclusivities, such as pediatric use  
4 or orphan status. All biologics with unexpired FDA  
5 granted exclusivities should have the exclusivity  
6 description and the expiration date listed in the  
7 Purple Book.

8 The FDA already makes this information  
9 publicly available through the orphan drug database in  
10 the pediatric exclusivity list, for example.

11 Third, the Purple Book should contain  
12 information on all unexpired patents that the BLA  
13 licensee reasonably believes protect their biologic  
14 product. Licensees should be requires to submit patent  
15 information as part of a BLA, and to update this  
16 information in keeping current after licensing.  
17 Including patent information in the Purple Book is  
18 critical to increased competition in the biologics  
19 marketplace.

20 Absent readily available information, a  
21 potential new market entrant must engage a scientific  
22 expert or a patent attorney or both to sift through

1 hundreds and hundreds of complex pharmaceutical  
2 patents. Also, even in this case, it's easy to miss a  
3 key patent.

4 Patents are public information. If a BLA  
5 applicant or licensee reasonably believes that its  
6 product is protected by one or more patents, then it  
7 should be required to provide the FDA within  
8 information on those patents and the FDA should list  
9 those patents in the Purple Book.

10 Requiring BLA's to include relevant  
11 information on patents would require the FDA to amend  
12 its existing regulation, which the FDA is authorized to  
13 do under the Public Health Service Act. The amended  
14 regulation should apply to all BLA licensees current  
15 and future. The FDA should adopt some reasonable  
16 timeframe for BLA licensees to comply with this new  
17 requirement.

18 A final note is that the ideal format of the  
19 Purple Book would combine the CDER and CBER lists,  
20 would be searchable online, and potential link to the  
21 products' corresponding indices. The FDA has expressed  
22 their commitment to helping facilitate competition in

1 the biosimilar marketplace. Increasing transparency  
2 and reducing uncertainty are important to building  
3 blocks of this effort.

4 Thank you so much.

5 DR. SHERMAN: Thank you for your comments.  
6 Any questions from the panel?

7 DR. UNLU: So let's say we had the regulation  
8 that said you need to list all patents you believe  
9 reasonably protect your product, and then it turns out  
10 that the manufacturer made a mistake or forgot to list  
11 a patent and they wanted to assert that in litigation  
12 against the biosimilars applicants, what would the  
13 remedy be?

14 DR. SOCAL: So it would depend on how exactly  
15 the new amended regulation would frame it, because if  
16 it frames it as a requirement for the FDA to approve  
17 the biosimilar, only for those patents that are listed  
18 in the Purple Book, then litigation could be a  
19 questionable pathway. It depends on what the actual  
20 language would be.

21 DR. UNLU: But we don't approve biosimilars  
22 for uses listed in patents. I mean, that doesn't have

1 anything to do with our approval.

2 DR. SOCAL: I agree. But if that -- it  
3 depends on what the language of the regulation would  
4 be. If you made one thing a requirement to the other,  
5 then it might change the remedies that are available  
6 from a legal perspective.

7 DR. SHERMAN: Dr. Franklin.

8 DR. FRANKLIN: Right. I guess to follow up a  
9 little bit more specifically, have you looked at the  
10 potential interaction between this proposal to provide  
11 -- to require that 351(a) applicants provide patent  
12 information, if I'm characterizing that accurately,  
13 interaction between that and the patent exchange  
14 provisions under Section 351(l) of the --

15 DR. SOCAL: So let me first make a  
16 clarification about my previous answer, and I just  
17 assume -- I'm assuming we're thinking the same, we are  
18 seeing things from the same perspective. And what I  
19 was referring to is in the small molecule space in the  
20 Orange Book, if a patent is unexpired and it's  
21 published in the Orange Book, then the FDA should not  
22 approve a generic, if that information is there. And

1 I'm thinking that if the same language would be  
2 available for biologics and biosimilars, then we would  
3 incur the same provisions. That's just clarifying my  
4 thought before.

5 And so in response to your current question  
6 about how would that change patent exchange  
7 information, that wouldn't necessarily change but it  
8 wouldn't necessarily change the implications of it, but  
9 given that most patents will become publicly available,  
10 then it might not be even necessary.

11 DR. KOZLOWSKI: So clarification, because as  
12 now other than the patent exchange, a patent doesn't  
13 really withhold the Agency from making a decision, so  
14 you're referring to something that would actually have  
15 the Agency not approve something based on the existence  
16 of a patent. So is that what you're suggesting?

17 DR. SOCAL: It would be an option, yes. It  
18 depend on the willingness of the Agency to update its  
19 regulations. In my opinion, my main suggestion is  
20 publishing the patents and that's important for  
21 transparency.

22 DR. KOZLOWSKI: So publishing the patents

1 helps transparency but limiting the Agency's ability to  
2 approve is different than transparency.

3 DR. SOCAL: Correct.

4 DR. KOZLOWSKI: So you think the only way to  
5 have one is to have both?

6 DR. SOCAL: No, not necessarily. Yeah, that's  
7 why I mentioned the Orange Book, so it's an option.  
8 That's not necessarily what I'm proposing today. I'm  
9 proposing effort for transparency first and foremost.

10 DR. KOZLOWSKI: Just as a comment I would  
11 encourage you to provide even more detail about these  
12 recommendations, because I think as a lot of folks have  
13 recognized today, we're looking at ways to increase the  
14 utility of the information in the Purple Book and so  
15 the more detailed the proposals we can receive on that,  
16 the better.

17 DR. SOCAL: Perfect. Thank you.

18 DR. SHERMAN: Thank you for your comments.  
19 The next speaker is Michelle Cope from National  
20 Association of Chain Drug Stores.

21 MS. COPE: Thank you for the opportunity to  
22 share the perspectives of chain pharmacy on ways to

1 promote biosimilars uptick and facilitate competition  
2 and innovation in the biological products market.

3 I'm Michelle Cope, Director of Federal and  
4 State Public Policy for the National Association of  
5 Chain Drug Stores. And ACDS represents traditional  
6 drug stores, supermarkets and mass merchants with  
7 pharmacies. Chains operate over 40,000 pharmacies and  
8 our members operate nearly 100 chain member companies,  
9 including regional chains with a minimum of four stores  
10 and national companies.

11 And ACDS strongly supports policies that will  
12 lead to growth in the biosimilars market and promote  
13 use of a more affordable biological medications. In  
14 that vein I am here today to speak to the following  
15 issues and questions that FDA raised in the Federal  
16 Register.

17 Number one, improving the utility of the  
18 Purple Book. Number two, cultivating a robust  
19 biosimilar market and promoting stakeholder confidence  
20 in these products. And finally, increasing healthcare  
21 provider and patient understanding of biological  
22 products, including biosimilar and interchangeable

1 products.

2 We thank FDA for the chance to speak to these  
3 issues today. Regarding ways to improve the utility of  
4 the Purple Book, to enable pharmacists to substitute  
5 more affordable therapeutic alternative biological  
6 products, it is critical that FDA provide tools and  
7 resources like the Purple Book to support such  
8 dispensing. To this end we recommend the following  
9 revisions to the Purple Book to facilitate this.

10 The format of the Purple Book should be  
11 designed to clearly group and identify both therapeutic  
12 alternative biosimilars and interchangeable biological  
13 products with their respective reference products.  
14 This is especially important given that there are  
15 unlikely to be a significant number of interchangeables  
16 on the market for years due to various market  
17 disincentives.

18 Accordingly, pharmacists will need to know  
19 which products relate to a specific reference product  
20 and may, therefore, be appropriate for therapeutic  
21 interchange. Additionally, we believe that the terms  
22 describing biosimilars in the Purple Book and elsewhere

1 are confusing to most laypersons.

2 To address this we recommend that FDA use the  
3 simplified term "clinically equivalent" to mean no  
4 clinically meaningful differences.

5 Number two, regarding cultivating a robust  
6 biosimilars market and promoting confidence in these  
7 products. With respect to the question of what more  
8 FDA can do to facilitate the evolution of the  
9 biosimilar and interchangeable product market, we  
10 encourage the Agency to prioritize efforts to expedite  
11 the availability of interchangeable biosimilars,  
12 recognizing that it may not be cost effective for many  
13 biosimilar manufacturers to perform the studies  
14 necessary to demonstrate interchangeability, we  
15 encourage FDA to work with Congress and AHRQ to explore  
16 new approaches to facilitate the performance of the  
17 required interchangeability studies.

18 FDA could achieve this by securing federal  
19 funding for interchangeability studies of approved  
20 biosimilars, or by accepting studies performed by  
21 health systems or other private entities that  
22 demonstrate interchangeability.

1           Additionally, in the meantime, we urge the  
2 Agency to encourage federal and private programs to  
3 recognize the benefit of therapeutic interchange for  
4 biosimilars as a cost-savings measure.

5           With respect to what more the Agency can do to  
6 ensure patients and healthcare providers' competence in  
7 biosimilar products, we urge the Agency to update its  
8 recent naming policies for biological products to align  
9 with the naming practices for small molecule drugs.  
10 FDA's new naming practice for biosimilars that tacks on  
11 a non-sensical four-letter suffix deviates from  
12 historical naming conventions. We have ongoing  
13 concerns that this nomenclature can lead to general  
14 confusion relative to the appropriate use, safety and  
15 efficacy of these medications, as well as therapeutic  
16 duplication that would be detrimental to patients'  
17 health.

18           Moreover, naming practices for biological and  
19 biosimilar products that are different from other  
20 medications undermines healthcare provider and patient  
21 confidence in these medications and perpetuates the  
22 notions that biosimilars are not comparable to the

1 innovator product. This must be remedied.

2 All biological medications regardless of  
3 whether the product is an innovator, a biosimilar, or a  
4 biosimilar that has been deemed interchangeable, should  
5 be assigned the same non-proprietary name. This naming  
6 paradigm is familiar to healthcare providers and  
7 patients alike, and promotes confidence in use of these  
8 products.

9 Finally, relating to healthcare provider and  
10 patient education opportunities, physician and patient  
11 confidence in biosimilar and interchangeable products  
12 is critical to increased market acceptance of these  
13 products. NACDS supports the education and outreach  
14 efforts to physicians, patients and other healthcare  
15 providers to facilitate awareness, understanding and  
16 adoption of biosimilars. We encourage FDA to continue  
17 efforts to educate healthcare providers and the public  
18 about biosimilar mediations.

19 Initiatives such as CE programs designed to  
20 familiarize healthcare providers with biosimilar  
21 mediations and multi-media public awareness campaigns  
22 can be useful to promote further understanding and

1 adoption of biosimilar medications. Specifically  
2 biosimilar education should stress that biosimilars are  
3 designed to match the structure and function of the  
4 reference biological product.

5 Patients should be assured that FDA approved  
6 biosimilars have the same safety and efficacy as their  
7 reference products. Moreover, FDA should convey that  
8 the Agency approves biosimilars utilizing the same high  
9 standards for manufacturing and quality that apply to  
10 all biological products.

11 The Administration should educate that the  
12 availability of biosimilars is anticipated to lower  
13 cost burdens for the U.S. healthcare system.

14 We thank you again for the opportunity to  
15 speak and I will be submitting our statement to the  
16 public docket, so thanks.

17 DR. SHERMAN: Thank you for your comments.  
18 Questions from the panel? Dr. Kozlowski?

19 DR. KOZLOWSKI: So you referred to third party  
20 or outside groups helping smaller entities meet  
21 interchangeability expectations. So you mentioned  
22 health system studies, so were you thinking of real

1 world evidence? What type of evidence were you  
2 thinking about?

3 MS. COPE: Well, currently, I mean, where in  
4 the United States you're seeing any sort of switching  
5 from one to another, it would be formulary driven. So  
6 that being the case, this is just one potential avenue  
7 to pursue where you have patients that have been  
8 potentially been switched from the innovator to a  
9 biosimilar, and that's when -- you know, as times goes  
10 on, you may compile the data. We were just trying to  
11 kind of think outside of the box so --

12 DR. KOZLOWSKI: Okay, thank you.

13 MS. COPE: mm-hmm.

14 DR. SHERMAN: Other questions? Thank you for  
15 your comments.

16 MS. COPE: Thank you.

17 DR. SHERMAN: Our next speaker is Christine  
18 Simmon, Biosimilars Council, Division of the  
19 Association for Accessible Medicine.

20 MS. SIMMON: Thank you. On behalf of AAM and  
21 its Biosimilars Council, we want to thank the Agency  
22 for its tremendous leadership on biosimilars.

1           As policy makers from the President on down to  
2           State Governors, grapple with high drug prices,  
3           biosimilars represent new savings and access for  
4           patients and payers. Unfortunately, the biosimilars  
5           face marketplace challenges, as we just heard  
6           Commissioner Gottlieb reinforce.

7           And Dr. Gottlieb has previously remarked that  
8           had all of the FDA biosimilars that were approved in  
9           2017, FDA approved in 2017, been successfully marketed,  
10          Americans could have saved more than \$4.5 billion last  
11          year alone.

12          This illustrates the unfortunate truth that  
13          FDA approval of a more affordable medicine does not  
14          guarantee the medicines get into the hands of patients,  
15          and it doesn't guarantee that the savings accrue to the  
16          health system. So what's standing in the way?

17          Three of the biggest obstacles are  
18          reimbursement issues in Medicare, patent tactics to  
19          extend monopolies, and unwarranted restricted access to  
20          reference products. So you might believe I just named  
21          three things that the Agency can't do anything about.  
22          But we would disagree.

1           The Agency is more than the regulator of  
2 biosimilars. FDA is the most credible federal resource  
3 on biosimilars. It makes you all a key influencer.  
4 You're well positioned to collaborate within HHS with  
5 CMS, and with other agencies, such as USTR and PTO, as  
6 well as Congress, to advance biosimilar competition,  
7 and we applaud that you are having an ongoing  
8 collaboration with the FTC, and that's fantastic to  
9 hear.

10           So clearly much of what is holding back  
11 biosimilars from patients requires policy makers to  
12 build on actions the FDA already has taken or will be  
13 taking under the Biosimilars Action Plan. As the  
14 Administration continues to implement its blueprint on  
15 lowering drug prices, FDA is the engine that can drive  
16 policy makers on biosimilars opportunities.

17           Let's start with those issues where FDA's  
18 credibility and influence can drive policy wins for  
19 patients.

20           Reimbursement. A sustainable biosimilars  
21 market depends on well-designed FDA regulations  
22 combined with market incentives, created by CMS payment

1 and formulary review policies. Predictable  
2 reimbursement and market access is critically  
3 important. Would-be biosimilar manufacturers can't  
4 justify allocating significant capital into development  
5 programs without a reasonable potential for commercial  
6 success.

7 CMS has taken important steps to support  
8 biosimilars, but rebate traps, exclusionary contracting  
9 and a lack of reimbursement incentives remain barriers.  
10 We encourage FDA to work with HHS and CMS to ensure  
11 that Medicare reimbursement and formulary design  
12 prioritize utilization of these lower cost lifesaving  
13 medicines.

14 Patent tactics or shenanigans. AAM and the  
15 Biosimilars Council strongly support innovation. That  
16 said, efforts by some brand new pharmaceutical  
17 manufacturers to manipulate the patent system through  
18 patent thickets that extend their market exclusivity  
19 beyond Congressional intent are a primary reason FDA  
20 biosimilars cannot timely enter the marketplace and get  
21 into the hands of patients.

22 These patent thickets not only delay entry,

1 they chill competition overall because of the  
2 exorbitant cost of litigating meritless patents. We  
3 urge FDA to work with the patent trademark office to  
4 stem the issuance of non-innovative patents and support  
5 the use of inter partes review or IPR. IPR provides  
6 biosimilars manufacturers an earlier and more accurate  
7 picture of the patent landscape in a timely and less  
8 expensive manner.

9 We are also deeply concerned that the recently  
10 announced U.S. Mexico trade understanding to extend  
11 brand name biologic data protection to ten years will  
12 harm patients and the biosimilar industry. We believe  
13 USTR's efforts actually undermine both the President's  
14 blueprint and the biosimilar action plan. We encourage  
15 FDA to work with USTR, advocate for rejection of these  
16 provisions.

17 Finally, we appreciate the FDA's commitment to  
18 naming the companies seeking to block competitor  
19 acquisition of reference product samples via restricted  
20 distribution schemes to try to deter such conduct.  
21 However, a study released today by Matrix Global  
22 Advisors reveals the growing cost of these abuses, with

1 annual loss savings exceeding \$13 billion. This is  
2 nearly triple the annual loss savings number of just  
3 four years ago.

4 The bipartisan CREATES Act would prohibit  
5 brand pharmaceutical companies from restricting access  
6 to samples to delay biosimilar competition. We are not  
7 aware of any companies who have changed their practices  
8 as a result of FDA's naming and shaming. Congress  
9 needs to act, and we urge FDA to work with Congress and  
10 help it pass this important legislation.

11 I will now touch on some of the questions in  
12 the hearing notice or the topics.

13 Education. We applaud FDA's introduction of  
14 provider education materials about biosimilars. As I  
15 say, you're the single-most credible resource for  
16 stakeholders, especially patients and healthcare  
17 providers, seeking information about biosimilars. We  
18 urge you to expand your efforts to promote and instill  
19 confidence in biosimilar safety, efficacy and quality.  
20 This should include using understandable terminology  
21 and prioritizing efforts toward those stakeholders who  
22 stand to benefit most.

1           We also agree with those urging the FDA via  
2           the citizen petition process to address misinformation  
3           campaigns that are damaging marketing confidence in  
4           biosimilars. We believe this includes statements  
5           around so-called non-medical switching. In fact,  
6           patients are routinely switched from one biologic to  
7           another, if the treating physician deems such a change  
8           as the appropriate course of treatment.

9           In Europe physician-led switching from a brand  
10          biologic to a biosimilar is common, and extensive data  
11          shows that a one-time switch for a brand biologic to a  
12          biosimilar does not carry increased risk of an adverse  
13          event. This is one way false and misleading  
14          information undermines public confidence in the safety  
15          and efficacy of biosimilars.

16          Also, it's important for the FDA to continue  
17          to make clear that an interchangeability designation  
18          does not indicate a better biosimilar than one approved  
19          absent that designation. It's not a superiority  
20          designation.

21          We believe this misperception is gaining  
22          traction among payers and delaying biosimilar update.

1           You've heard a lot about the Purple Book  
2           today, so I'm going to kind of skip over some of that,  
3           except to say we agree with many of the stakeholders  
4           here today, we want the Purple Book to list which  
5           products have been determined not to have exclusivity  
6           and those that are still subject to pending decisions.

7           We also applaud FDA allowing biosimilar  
8           manufacturers to carve out specific indications  
9           protected by patents from their label, and we would  
10          like you to continue your current policy around that.

11          In terms of facilitating development, AAM  
12          strongly supports eliminating the requirement for  
13          sponsors to conduct expensive and unnecessary bridging  
14          studies when using non-U.S. licensed reference product.  
15          We are concerned that some aspects of the draft  
16          guidance on interchangeability impose unnecessarily  
17          burdensome scientific standards on interchangeability  
18          determinations or may be inconsistent with statutory  
19          requirements.

20          If finalized, these requirements not only will  
21          create significant disincentives for sponsors to  
22          develop interchangeable biologics, but more importantly

1 will also significantly affect patient access.

2 We look forward to submitting our written  
3 comments and am happy to take your questions. Thank  
4 you.

5 DR. SHERMAN: Thank you for your comments.  
6 Questions from the panel? Dr. Franklin.

7 DR. FRANKLIN: You mentioned some of these  
8 very important but -- very important concerns that may  
9 be in some ways or in many ways peripheral to FDA  
10 authorities, but when it comes to one -- when it comes  
11 to intellectual property and some of -- and the patent  
12 thickets as you described them, are there actions FDA  
13 can take? You mentioned patent carve-outs from  
14 labeling. Are there other actions FDA can take to help  
15 out from your perspective in this area?

16 MS. SIMMON: Well, we appreciate what you have  
17 done. We appreciate Dr. Gottlieb, you know, that term  
18 patent thicket is his. He's called this out himself  
19 using that exact language, and so we do understand that  
20 PTO and FDA are separate agencies. But we do think  
21 that first of all some of the Purple Book that I kind  
22 of glossed over, but some Purple Book improvements

1 would also help alleviate this by clarifying, you know,  
2 which products have been determined not to have  
3 exclusivity. That way -- and maybe allowing  
4 exclusivity determination requests, you know, to come  
5 from biosimilar applicants and not just the BLA holder.

6 So those are some ways of getting at it. But  
7 again, we really encourage you to continue to use your  
8 bully pull pit, that the Commission has, to influence  
9 other agencies, because you've taken us all very far in  
10 biosimilars, but you need the assistance of your  
11 compadres in the Federal Government to get us across  
12 the finish line.

13 DR. SHERMAN: Dr. Kozlowski.

14 DR. KOZLOWSKI: So you mentioned that we  
15 should work on making scientific bridging less  
16 burdensome. So were you focused on PK, BPK aspect of  
17 bridging or the analytical part of bridging?

18 MS. SIMMON: I will be focused on asking our  
19 Senior Vice President of Science and Regulatory to  
20 embellish on that in our written submission.

21 DR. KOZLOWSKI: Okay, thank you.

22 DR. SHERMAN: Any other questions? I have

1 one. We saw this morning the difference in update from  
2 (indiscernible). Do you have any thoughts on why that  
3 might be?

4 MS. SIMMON: Well, some of what I mentioned,  
5 but a lot of it too is these rebate traps that happen  
6 in the commercial payer side of the equation. I think  
7 several speakers have touched on this today and that is  
8 a lot of it. I was fascinated by the new data that  
9 Pfizer and that the Pacific Research Institute will be  
10 highlighting today, and I think that's really very  
11 telling. That charge is very telling, and it just  
12 shows that, again, FDA approval is super important  
13 obviously. It's critical, but it's insufficient.

14 DR. SHERMAN: Great. Thank you very much for  
15 your comments.

16 MS. SIMMON: Thank you.

17 DR. SHERMAN: Our next speaker is Dr. Meni  
18 Melek from Novartis.

19 DR. MELEK: Thank you and good afternoon. My  
20 name is Meni Melek and I'm the Global Head of  
21 Regulatory Affairs at Sandoz Biopharmaceutical.

22 Sandoz is a division of Novartis and today I'm

1 representing Novartis. We think FDA for organizing  
2 this hearing and for their recent actions to improve  
3 biosimilar development and ultimately access for U.S.  
4 patients.

5 We believe that the Agency has adequately  
6 identified a number of important topics in the  
7 biosimilar action plan, that if addressed have the  
8 potential for substantial positive impact on  
9 biosimilars.

10 We, therefore, urge the Agency to continue its  
11 efforts and identify actionable solutions to these  
12 topics. Novartis will comment to the questions raised  
13 by the Agency in writing.

14 For today's hearing we'll focus on selecting  
15 topics listed here, where we believe the FDA can either  
16 take rapid action or those which could have a longer-  
17 term significant impact on biosimilar development.

18 So Novartis is in a unique position, where for  
19 decades we've been the global leader, serving patients  
20 with treatment options across a full spectrum, from  
21 generics to breakthrough innovative biologics, to  
22 biosimilars and others.

1           We have the fortune to recognize the value  
2           that each of these can bring to the U.S. healthcare  
3           system. At Novartis we've been a biosimilar pioneer  
4           launching the first biosimilar, Omnitrope, in Europe in  
5           2006, and in receiving the first U.S. FDA biosimilar  
6           approval with Zarxio in 2015.

7           Through our multiple sources and projections  
8           supporting the value of biosimilar, not only to the  
9           individual patient but also to the healthcare system  
10          more broadly, Novartis would like to reaffirm its  
11          conviction that biosimilars can play a critical role to  
12          the U.S. healthcare system to ensure sustainability of  
13          the system and to expand access to these important  
14          medicines.

15          As such, we support FDA's renewed efforts to  
16          foster biosimilar approvals and uptick in the U.S.,  
17          while at the same time ensuring the balance in order to  
18          support continued innovation in diseases and sub-  
19          populations that remain underserved.

20          The first item we'd like to address is  
21          staffing in the Agency. FDA has made a number of  
22          commitments as part of the BsUFA II process as well as

1 in the biosimilar action plan with identified priority  
2 deliverables. At the same time the Agency has had  
3 continued difficulties to deliver guidance documents  
4 and/or meet some of its BsUFA goals. We, therefore,  
5 strongly support the continued efforts from the Agency  
6 on its organization, including the establishment of the  
7 Office of Therapeutic Biologics and Biosimilars and  
8 full recruitment of open positions through their  
9 recently announced streamlined hiring program.

10 Adequate staffing is a cornerstone of the  
11 Agency's ability to deliver effectively on its  
12 commitments.

13 Within the biosimilar action plan FDA has  
14 taken the action to explore the potential for increased  
15 use of non-U.S. licensed comparator product for certain  
16 biosimilar studies. And thereby streamlining related  
17 bridging requirements.

18 Novartis fully supports the Agency efforts and  
19 also acknowledges that challenges need to be addressed  
20 before implementation could occur. We look forward to  
21 continued dialogue to define the framework for  
22 implementation and believe this could provide

1 significant benefit, not only to biosimilar development  
2 but also for innovative biologics where comparative  
3 studies may be needed.

4 Analytical similarity assessment is at the  
5 foundation of biosimilar development, and the key focus  
6 during review and registration. However, as the Agency  
7 noted in the biosimilar action plan, this can represent  
8 a hurdle for efficient development of biosimilars for  
9 two reasons.

10 The first one is when defining the reference  
11 product range, which is typically established quite  
12 early in development, and is then set for the duration  
13 of development.

14 The second hurdle is in regards to aiming the  
15 biosimilar at a moving target. During the life cycle  
16 of biologics, changes to analytical characteristics may  
17 occur, changes that are detectable with newer advanced  
18 analytic tools, but they have also been shown by the  
19 sponsor not to impact efficacy or safety.

20 To address these issues we do look forward to  
21 continued engagement with the Agency on the new  
22 statistical guidance and any other guidance documents

1 or tools which FDA has referenced in the biosimilar  
2 action plan. We hope these actions will put more  
3 emphasis on the totality of evidence over statistical  
4 analyses of single attributes.

5 As recognized by the Agency and the biosimilar  
6 action plan, a sponsor may need to revise a product  
7 label to remove indications or related information  
8 protected by IP rights, before an approved product can  
9 be launched. A biosimilar label is always based on the  
10 reference product's label, and in these instances  
11 changes are a result of either removing and/or  
12 anonymizing information related to information covered  
13 by patent.

14 Alternatively the biosimilar sponsor may re-  
15 introduce the approved wording contained in the  
16 reference product. In this context we recommend that  
17 FDA develop streamlined and pragmatic review processes  
18 to allow for simplified and timely implementation of  
19 these changes.

20 We have included some suggestions on this  
21 slide as an example. We believe that this topic which  
22 is one which the Agency could address relatively

1 rapidly.

2 Education is an important consideration for  
3 the efficient uptake of biosimilars in the U.S. An  
4 understanding of biosimilars, what they are, what they  
5 can bring to the U.S. healthcare system, not only to  
6 patients but also to providers, and to payers is  
7 paramount to the acceptance of their use.

8 The FDA, as a trusted government agency, has a  
9 key role to play in this regard. We welcome the  
10 Agency's initiatives here and encourage continued  
11 outreach. We believe it could be useful for the Agency  
12 to more actively monitor information in the public  
13 domain to target education efforts on topics that  
14 remain misunderstood, to address misinformation and to  
15 engage in an educational campaign on the basics of  
16 biosimilars.

17 The last topic we would like to address is  
18 FDA's biologic's naming policy. At the July Brookings  
19 event the Commissioner emphasized the Agency's belief  
20 in the value of this naming approach for biologics.  
21 Novartis respectfully disagrees and believes that  
22 experience gathered to date, especially in regions

1 where biosimilars have been accessible for over a  
2 decade, does not support the hypothetical concerns that  
3 the naming policy was intended to address.

4           Novartis has a sizeable pharmacovigilance  
5 database with Zarzio in the U.S. Our experience shows  
6 that the suffix is not being used in PV reporting. But  
7 more importantly, that it has not impacted the  
8 reporting of these cases. In fact, the naming policy  
9 has created a distortion in the marketplace, where  
10 reference products do not have suffixes, where  
11 biosimilars do.

12           Connected to the previous slide on education  
13 efforts, we would like to draw attention to the fact  
14 that some FDA decision and actions, such as this one,  
15 may indirectly contribute to misperceptions about  
16 biosimilars in the community and consequently hamper  
17 uptick in access.

18           And with that I'd like to close and open for  
19 questions.

20           DR. SHERMAN: Thank you for your remarks.

21           Questions from the panel? Dr. Christl.

22           DR. CHRISTL: Just a point of clarification.

1 In terms of the biosimilar labeling, question seven,  
2 you had given some points initially about enabling  
3 scientific review for all indications that are not  
4 covered by regulatory exclusivity, but then talk about  
5 re-introduction of an indication that was left out  
6 initially. Do you envision from your perspective some  
7 difference maybe in regulatory approach between, again  
8 distinguishing initial review of things that weren't  
9 covered by exclusivity, if you made a decision to leave  
10 something out for, you know, non-exclusivity reasons,  
11 if the Agency had already reviewed that information  
12 from a scientific standpoint versus adding in  
13 indications that weren't previously reviewed?

14 DR. MELEK: So we had considered all different  
15 scenarios and we'll go into detail in our written  
16 response, but I think we can all agree that if you have  
17 seen and reviewed something previously and were pulling  
18 something in or pulling out, that could be -- I think  
19 that would be a foundation for something streamlined  
20 and pragmatic, where if there, for example, if there's  
21 a new indication from the innovator and you're  
22 reviewing something de novo, it would likely have a

1 different type of pathway, but we'll provide this in  
2 more detail.

3 DR. CHRISTL: Yeah, it would be very helpful  
4 to sort of parse that out in terms of what you think  
5 the approach should look like. And also in your  
6 comments if you could give some more meat around this  
7 connection between streamlining bridging requirements  
8 versus circumstances where maybe bridging studies could  
9 be waived or not needed, you acknowledge the challenges  
10 that might exist, it would be helpful to us to have  
11 your approach about how to address those challenges,  
12 versus just pointing out that there could be  
13 challenges, so that the more information you can give  
14 us in the comments, the more helpful that will be.

15 DR. MELEK: Yeah, we'll do our best to provide  
16 as much detail and direction as we can.

17 DR. SHERMAN: Dr. Kozlowski.

18 DR. KOZLOWSKI: So you referred to a global  
19 reference standard, sort of continuing this lack of  
20 need for bridging. So what do you envision that means?  
21 Does that just mean a set of material from different  
22 regions all could be equally used as reference product?

1 Do you mean a third party holding, for instance, some  
2 sort of reference material? What is your intent by  
3 global reference product?

4 DR. MELEK: So just to clarify, when non-U.S.  
5 approved product -- and I think it depends. It's on a  
6 case-by-case basis, depending on the publicly available  
7 information. In some cases it's quite transparent  
8 based on EPAR's in Europe or summary based approval in  
9 the U.S. that you indeed have the same product in the  
10 U.S. and in Europe, and so that's one extreme case.

11 We could also imagine a scenario where there  
12 is analytical data and maybe that would suffice to show  
13 that the products are the same, but what we're looking  
14 to is to find scientific and credible ways to provide  
15 what's needed, no more, no less.

16 DR. KOZLOWSKI: Thank you.

17 DR. SHERMAN: Any other questions? Thank you  
18 for your comments.

19 DR. MELEK: Sure.

20 DR. SHERMAN: Our next speaker is Andrew  
21 Spiegel from the Global Colon Cancer Association.

22 MR. SPIEGEL: Good afternoon and thank you for

1 allowing me to speak on behalf of the patient community  
2 today. My name is Andrew Spiegel, representing the  
3 Global Colon Cancer Association. I've been a patient  
4 advocate for nearly 20 years now, having founded the  
5 U.S. based Colon Cancer Alliance back in the late 90's,  
6 and now I run an international colon cancer  
7 organization called the Global Colon Cancer  
8 Association.

9 I think I've seen all of your in the past from  
10 earlier testimony that I have given on biosimilars and  
11 so I won't spend much more time getting involved with  
12 why I'm here. I lost both of my parents back in the  
13 late 90's to cancer, two days apart, and since then  
14 have been full time a patient advocate.

15 I'm immediate past chair of the Digestive  
16 Disease National Coalition and I was just elected as  
17 incoming Chair Elect of the International Alliance of  
18 Patient Organizations, but most relevant for today is  
19 that as many of you know, almost a decade ago we  
20 started the Alliance for Safe Biologic Medicines, which  
21 is a patient and physician led group to put together to  
22 ensure that biosimilar regulatory policy benefits

1 patients.

2           So colon cancer affects a lot of people in  
3 this world. Actually this is old data. It's now over  
4 1.4 million people who are diagnosed with colon cancer.  
5 That number is expected to double over the next 17  
6 years, so it is a rapidly growing cancer worldwide, and  
7 we have been advocating now for six years on a regional  
8 and international basis for a number of policies to  
9 help colon cancer and regular patients.

10           And like I said, in late 2010 we co-founded  
11 ASBM, the Alliance for Safe Biologic Medicines, to  
12 bring our perspective to this exact discussion.

13           We know that about 800 million patients  
14 worldwide have benefitted from biosimilar medicines and  
15 we often know that patients like Kathleen, who  
16 testified earlier, sometimes may take years to find the  
17 right medicine or the right cocktail, I would say, for  
18 them and as a result we don't want to expose patients  
19 like Kathleen to serious or more serious concerns,  
20 because we've messed with her cocktail.

21           But biologic medicines have had a tremendous  
22 impact in the colorectal cancer community. I remember

1 the days when there was only one drug, when my mom was  
2 diagnosed with colon cancer in the late 90's, which was  
3 highly ineffective and now we're knocking on the door  
4 of almost 15 approved drugs and more than half of those  
5 are biologics. And the data that's come from that is  
6 that the average life expectancy of the metastatic  
7 patient has tripled from less than a year to now  
8 knocking on the door of three years, and there's very  
9 other few cancers that can say they have measured  
10 success like that in such a short time.

11 So the colon cancer community does have a  
12 vested interest in biologics, and has a great interest  
13 in getting biosimilar medicines to market. We're  
14 excited about biosimilars. We want them to come to the  
15 market. We understand the many benefits that  
16 biosimilars promise, which is greater access. And this  
17 is especially true worldwide, where I do most of my  
18 work, where other countries -- they simply cannot  
19 afford the expense of originator biologics and  
20 biosimilars really do hold promise to not only provide  
21 for cheaper medicines for the payers but an increased  
22 pool of patients who will then benefit from that

1 treatment because of the lower price.

2 But we want to make sure that policies like  
3 the FDA and the WHO put forward, put patients first  
4 and, therefore, we've developed about six  
5 recommendations that I'll run through quickly.

6 So obviously patients have to be the focal  
7 point of all biosimilar regulatory policies, not  
8 potential cost savings. We would ask that the  
9 regulators do not consider costs when determining  
10 biosimilar policy considerations and always keep the  
11 patient as the forefront of their objectives, because  
12 we're all going to be patients some day.

13 Number two, there should be no sacrifice on  
14 quality, safety or efficacy. Patients have the right  
15 to expect access to biosimilars and assurances that  
16 they are approved based upon the same high standards  
17 the FDA has always had for other types of reference  
18 medicines.

19 And third, we want robust data collection. We  
20 want data that shows that if a patient like Kathleen  
21 who has autoimmune disease is switching between a  
22 product time after time again, that that switch is

1 going to be safe, and that that drug is going to remain  
2 effective and she's not going to be made worse, and the  
3 only way we could really know that is with data, and so  
4 we know that Europe has biosimilars now for ten to 12  
5 years, and just a couple of years with monoclonal  
6 antibodies but I would say and I have said that I  
7 believe that the experience in Europe has been a missed  
8 opportunity rather than an opportunity which is helping  
9 patients, and that missed opportunity is the failure to  
10 collect post-marketing data once these biosimilars have  
11 put to market.

12           And I think the real proof of that is the  
13 uptick that has not happened in Europe. You would  
14 think 12 years after biosimilars have taken over, they  
15 would do like the generics did and own most of the  
16 market, and that simply has not been the case and when  
17 you look at the survey data as to why that is, it's a  
18 lack of confidence from the physicians and the patients  
19 because of the lack of data.

20           Treatment choices should be made. This is  
21 number four, by the patient and the patient's  
22 healthcare team, not by third party such as payers and

1 governments, who are looking to save money. The  
2 decision between whether to switch a patient to an --  
3 from an originator product to a biosimilar has to be  
4 made by the patient and by the healthcare provider, not  
5 by the payer.

6           And fifth, we want robust pharmacovigilance.  
7 The biosimilars that have been approved, we expect good  
8 tracking, good pharmacovigilance. We want to make sure  
9 that the FDA continues its use of non-proprietary  
10 names, unique but nonproprietary names on all  
11 biologics, not just biosimilars, but all biologics.  
12 Contrary to what an earlier speaker said, I feel that  
13 the nonproprietary names is a critical, critical  
14 element to continuing post-market data collection and  
15 pharmacovigilance, and I know that the FDA already  
16 agrees with me, because I've attended meetings in the  
17 recent months where FDA has absolutely credibly  
18 defended its use of unique nonproprietary names in  
19 biosimilars, and we would ask that all biologics have  
20 those unique names.

21           So the last thing I want to focus on is  
22 probably something you won't hear from other speakers

1 today. I literally came here from the ICDRA meeting in  
2 Dublin, which is the International Conference of Drug  
3 Regulators, which takes place every two years, and I've  
4 participated in a pre-ICDRA panel yesterday, with  
5 senior leadership from the WHO and other patient  
6 groups, and the issue that -- one of the issues that we  
7 discussed with senior leadership of WHO, and this is  
8 leadership within the naming division, were a global  
9 system for pharmacovigilance, such as unique naming,  
10 like the FDA has here in America.

11 And what I'm asking of the FDA, because the  
12 FDA is truly respected all over the world, when I meet  
13 with other regulators and I don't mean Health Canada  
14 and the TGA. I'm talking about other smaller  
15 regulators from around the world. They truly look to  
16 the FDA for guidance on how to conduct themselves and  
17 how to approve drugs, and the FDA has to use its  
18 leadership position to push the WHO and to get other  
19 regulators together to push the WHO on a universal,  
20 global naming policy, and that's my ask of the WHO  
21 today, to use its gravitas as perhaps the leading  
22 regulator in the world, to help all of the other

1 regulators by combining efforts and pressuring the WHO  
2 to move forward with the unique naming proposal.

3 With that I will close and take any questions  
4 you all may have.

5 DR. SHERMAN: Thank you for your comments.  
6 Questions from the panel? Dr. Kozlowski.

7 DR. KOZLOWSKI: So you mentioned there was a  
8 missed opportunity in all the years of biosimilar use  
9 in Europe, so what sorts of data were you thinking  
10 could have been collected that were not?

11 MR. SPIEGEL: Well, because of the lack of  
12 mandatory post-data marketing collection or post-  
13 marketing data collection, we don't have data that says  
14 multiple switches from one biologic to a biosimilar to  
15 another biosimilar, which we certainly will be -- we  
16 will see happening soon enough, is safe and is  
17 effective. And as I've said before and other  
18 regulators have said before, lack of data is not data.  
19 So for you to say there hasn't been any major safety  
20 concerns, there hasn't been any major things that have  
21 happened from biosimilars to date, that's great, so we  
22 know that they're not going to kill all of us, but if

1 we had data that we could present to the physician  
2 community and the patient community to say look, we  
3 switched thousands of patients from this drug to this  
4 drug, and then this drug to this drug, and this drug to  
5 this drug, and there's been no adverse events, and the  
6 drugs are still safe and effective, then I think  
7 physicians would be much more apt to prescribe  
8 biosimilars, and the patient community would be much  
9 more apt to take biosimilars. And I think it's that  
10 missed opportunity with the lack of data that's been  
11 collected from drug manufacturers that has led to the  
12 lack of confidence and I believe has led to the lack of  
13 uptick.

14 DR. KOZLOWSKI: So there is adverse event  
15 reporting. So you're talking about something beyond  
16 that, in terms of claims data, if there's national  
17 healthcare, that sort of data, because it would seem  
18 that data probably exists for a lot of this.

19 MR. SPIEGEL: I'm talking about real world  
20 data. I'm talking about the fact that when prescribed  
21 a medicine in Europe, there may -- I'm sorry. What was  
22 the first part of your question?

1 DR. KOZLOWSKI: So in other words, that there  
2 is adverse event reporting. So you're asking for more  
3 than that. And so there are in different countries in  
4 Europe, national healthcare, other things where  
5 presumably there are data sets, so is the question that  
6 that data exists and nobody is actually mining it?

7 MR. SPIEGEL: Well, if the data existed and  
8 I've asked for it for almost a decade now, I think it  
9 would have come forward. I think if the EMA has data,  
10 that they've been collecting, post-marketing -- post-  
11 marketing data, they would have shared it by now. With  
12 the number of people that have expressed concerns about  
13 the lack of post-marketing data, wouldn't you think  
14 they'd say sure, we have the data, here it is. Well,  
15 they don't have the data and they don't have it because  
16 they haven't mandated collecting it.

17 And if we look at real world, what percentage  
18 of European physicians do you think actually do adverse  
19 event reporting and take that a little step further, is  
20 loss of efficacy. We did a survey of -- from 11  
21 countries and asked physicians is loss of efficacy an  
22 adverse event? Would you report that? And the vast

1 majority said no. So the fact is there's no  
2 international standards. There's no European standards  
3 for when these physicians should be reporting, and I've  
4 heard data that says physician reporting of adverse  
5 events is actually under five percent in Europe.

6 So I think that's not the kind of data the FDA  
7 relies upon. It's not the kind of data that WHO should  
8 rely upon. And again, we would ask that the FDA take  
9 that leadership position to push the rest of the world  
10 to have these high safety standards, just like we have  
11 here in America.

12 Thank you.

13 DR. KOZLOWSKI: Thank you.

14 DR. SHERMAN: Any other questions? Thank you  
15 for your comments.

16 MR. SPIEGEL: Thank you.

17 DR. SHERMAN: Our next speaker is Dr. Soumi  
18 Saha from the Premier Health Alliance.

19 DR. SAHA: Thank you. Premier Healthcare  
20 Alliance thanks the FDA for the opportunity to provide  
21 comments on the FDA's approach to enhancing competition  
22 and innovation in the biological products marketplace,

1 including by facilitating greater availability of  
2 biosimilar interchangeable products.

3 My name is Soumi Saha and I am the Senior  
4 Director of Advocacy at Premier.

5 Premier is a leading healthcare improvement  
6 company uniting an alliance of more than 4,000 U.S.  
7 hospitals and health systems and approximately 165,000  
8 other providers and organizations to transform  
9 healthcare through integrated data and analytics,  
10 collaboratives, supply chain solutions and consulting  
11 and other services.

12 Premier plays a critical role in the rapidly  
13 evolving healthcare industry, collaborating with  
14 members to co-develop long-term innovations that  
15 reinvent and improve the way care is delivered to  
16 patients nationwide.

17 A key component of our alliance is the Premier  
18 pharmacy program, which combines essential clinical  
19 data with purchasing power to deliver reduced costs,  
20 improve quality and safety, and increase knowledge  
21 sharing with other healthcare providers.

22 Premier views the accessibility of biosimilars

1 as a key element in creating a more competitive drug  
2 marketplace in the United States, and has been a leader  
3 in promoting a competitive biosimilars marketplace  
4 through our supply chain, clinical support, education,  
5 advocacy and thought leadership efforts. Premier  
6 currently has all marketed biosimilars on contract, and  
7 employees dedicated biosimilars team, that works with  
8 biosimilars manufacturers through a products life cycle  
9 from pre to post-launch, to ensure continued access to  
10 biosimilars.

11 Clinically Premier develops value analysis  
12 toolkits, provides product-specific information,  
13 including clinical and financial considerations, and  
14 supports its members with reimbursement considerations  
15 for biosimilars within the Medicare and 340(b)  
16 programs.

17 In regard to education, Premier maintains a  
18 dedicated website on biosimilars for health system  
19 pharmacy members that provides factual and unbiased  
20 information on biologics and biosimilars. In addition,  
21 Premier has developed several continuing education  
22 programs for healthcare providers and biosimilars and

1        outreaches to health system stakeholders to educate and  
2        promote the adoption of biosimilars.

3                From an advocacy perspective, Premier has been  
4        actively engaged in ongoing effort to Congress, FDA,  
5        CMS, and other stakeholders to ensure that the pathway  
6        to market for biosimilars prioritizes patient access  
7        and safety and encourages the development of these  
8        cost-saving medications.

9                And finally, Premier has authored several  
10       pier-reviewed journal articles, white papers and blog  
11       posts discussing the current biosimilars landscapes and  
12       encouraging adoption, as well as serving on the  
13       Advisory Board for the Center of Biosimilars.

14                So the Biosimilars Action Plan. Premier  
15       applauds the FDA for recognizing the value of  
16       biosimilars and its important role in minimizing the  
17       time and cost to develop biosimilars and in promoting  
18       effective communication. We further applaud the FDA  
19       for releasing the Biosimilars Action Plan to outline  
20       the Agency's approach to striking the appropriate  
21       balance between innovation, access and competition.

22                Premier offers the following comments on

1 elements of the action plan that it believes can be  
2 enhanced to further promote a robust biosimilars  
3 marketplace.

4           So one, to improve the efficiency of  
5 biosimilar interchangeability product development and  
6 approval, as an over-arching principle, FDA should  
7 permit a designation of biosimilarity parallel to  
8 granting an interchangeability designation, if the  
9 applicant seeks both. The FDA has previously advised  
10 that applicant should seek designation of biosimilars  
11 first and then subsequently seek interchangeability  
12 designation. A bifurcated process that creates  
13 procedural inefficiency and potentially delays the  
14 introduction of interchangeable biosimilars to the  
15 marketplace.

16           Therefore, Premier recommends that FDA create  
17 a parallel review process to permit applicants to seek  
18 a simultaneous designation of biosimilarity and  
19 interchangeability to create procedural efficiencies  
20 and improve access to interchangeable biosimilars.

21           Two, to maximize scientific and regulatory  
22 clarity for biosimilar manufacturers, Premier supports

1 FDA's intent to improve regulatory predictability,  
2 harmonize international regulation of biosimilars, and  
3 the acceptance of non-U.S. comparator products, and the  
4 use of real world evidence in supporting regulatory  
5 decision making.

6 One area to note, however, regarding  
7 harmonization and the acceptance of non-U.S. comparator  
8 products, is that the FDA's draft interchangeability  
9 guidance released in January, 2017, states that the use  
10 of a U.S. license reference product is required.  
11 Therefore, Premier urges the FDA to revise this  
12 requirement when issuing final interchangeability  
13 guidance to permit the use of non-U.S. comparators when  
14 seeking interchangeability designation.

15 Three, to improve the understanding of  
16 biosimilars, Premier agrees that it's critical to  
17 educate healthcare professionals and other stakeholders  
18 and applauds the FDA on their efforts thus far with the  
19 biosimilar education outreach campaign, and the FDA's  
20 commitment to creating additional innovative  
21 educational materials.

22 As the FDA looks to develop these innovative

1 educational materials, Premier suggests that FDA work  
2 with private partners who have already created these  
3 type of materials to adapt existing factual and  
4 unbiased educational materials to help speed the  
5 availability of these educational materials.

6 And four, to support market competition  
7 Premier agrees that it is necessary to reduce the  
8 gaming of FDA requirements, other attempts to unfairly  
9 delay competition. Premier offers two specific  
10 recommendations to help improve market competition.

11 First, some manufacturers restrict access to  
12 samples for biosimilar manufacturers by setting  
13 compliance with limited distribution or REM's  
14 requirements. This practice inhibits the ability of  
15 biosimilar manufacturers to demonstrate bioequivalence  
16 and thereby delays the ability -- I'm sorry, and  
17 thereby delays the availability of biosimilars in the  
18 marketplace.

19 Now, the FDA has acted in this regard and has  
20 begun on their website listing manufacturers that the  
21 FDA is aware of that is abusing these requirements;  
22 however, more needs to be done to actually prevent

1 these practices. And, therefore, Premier recommends  
2 that FDA work with Congress to prevent access  
3 restrictions to product samples needed for  
4 bioequivalence testing for biosimilar development.

5 Second, there's been an increase in patent  
6 disputes and settlements between biologic and  
7 biosimilar manufacturers, delaying the availability of  
8 biosimilar in the marketplace beyond market exclusivity  
9 granted under the BPCIA.

10 Currently this process is not transparent, as  
11 biological and biosimilar manufacturers do not have to  
12 report patent settlements to the Federal Trade  
13 Commission in the same manner that brand and generic  
14 manufacturers must. A process that is considered a  
15 deterrent for brand manufacturers to enter into patent  
16 settlements.

17 Therefore, Premier recommends that FDA work  
18 with Congress and the FTC to require biological and  
19 biosimilar manufacturers to report patent settlements  
20 to the FTC.

21 Finally, one additional area not included in  
22 the action plan that Premier would like to raise is the

1 naming convention for biosimilars. Current naming  
2 convention finalized by the FDA in January of 2017 adds  
3 complexity to the healthcare system, which could lead  
4 to errors in prescribing medications and pose a risk to  
5 patient safety, hampers clinical decision making and  
6 the ability to identify lower cost therapeutic  
7 alternatives, and causes unnecessary confusion amongst  
8 patients and providers, all issues that do not lend  
9 themselves to increasing the adoption of biosimilars.

10 Therefore, Premier urges the FDA to rescind  
11 the current naming guidance and reissue guidance that  
12 uses the same international non-proprietary name for  
13 biosimilars as the reference product.

14 So in summary, Premier encourages the FDA to  
15 permit a parallel designation of biosimilarity to  
16 interchangeability, harmonize international regulation  
17 of biosimilars and the acceptance of non-U.S.  
18 comparitors to demonstrate interchangeability, work  
19 with private partners to adopt existing factual and  
20 unbiased educational materials, work with Congress and  
21 the FTC to address anti-competitive practices and  
22 revise the naming guidance to use the same INN for

1 biosimilars as the reference product.

2           Again, I'd like to thank the FDA for the  
3 opportunity and I'm happy to take any questions that  
4 you may have.

5           DR. SHERMAN: Thank you for your remarks.  
6 Questions? Dr. Franklin.

7           DR. FRANKLIN: Thank you. I think many of  
8 your comments focus on interchangeability. We  
9 obviously agree that interchangeability is a very  
10 important concept and I think one of the questions that  
11 I had is for an organization entity like Premier, can  
12 you give some examples of how interchangeability is --  
13 do you think is going to play an important role in the  
14 uptick of these products?

15           DR. SAHA: Absolutely. So you know, our  
16 health systems and hospitals are frequently using  
17 biosimilars and biologics, and what we think is  
18 happening right now is the more interchangeable  
19 products that we can get to market, the easier it will  
20 be to substitute an interchangeable product for a  
21 biologic, thereby reducing healthcare costs to the  
22 overall health systems. And that's one of our utmost

1 goals.

2 DR. FRANKLIN: Okay. And so you're primarily  
3 looking at pharmacy substitution?

4 DR. SAHA: Correct.

5 DR. FRANKLIN: I just wanted to clarify one  
6 thing, which is that you stated that the draft  
7 interchangeability guidance describes a requirement to  
8 use the U.S. license product as a comparator. I  
9 believe it just states that that is strongly  
10 recommended. Again, that's just draft guidance, but I  
11 just want to make that clarification.

12 DR. SAHA: I will double check but I believe  
13 it was a requirement and not a strong suggestion, but  
14 we will absolutely double check.

15 DR. SHERMAN: Ms. Abram, Anna.

16 MS. ABRAM: Not so much a question but more a  
17 request for when you submit comments in to the docket.

18 DR. SAHA: Absolutely.

19 MS. ABRAM: Under your bucket that denotes  
20 supporting market competition by reducing gaming, and  
21 you touched upon restrictions in the distribution and  
22 access to the samples, to the extent that you think

1 that there are other actions the Agency might consider  
2 under its existing authorities, I would just encourage  
3 you to denote that in your comments.

4 DR. SAHA: Absolutely.

5 DR. SHERMAN: Dr. Kozlowski.

6 DR. KOZLOWSKI: So you mention real world  
7 evidence as something that should be used more. So  
8 from your Alliance, based on your description of the  
9 breadth of this organization, clearly has access to a  
10 lot of information on patients and patient records, so  
11 are you taking on an attempt to at least explore the  
12 idea of real world evidence and what it can show you  
13 about these products?

14 DR. SAHA: Absolutely. So Premier currently  
15 has access to over one-third of hospital discharge  
16 patients and we are looking at an opportunity to  
17 utilize our robust data infrastructure to look at  
18 biosimilar safety and efficacy in the marketplace in  
19 the real world.

20 DR. KOZLOWSKI: Thank you.

21 DR. SAHA: You're welcome.

22 DR. SHERMAN: Diane.

1 DR. MALONEY: Just a request that you clarify  
2 or provide more explanation of your comment that we  
3 should improve regulatory predictability. You know, if  
4 you have examples. Thanks.

5 DR. SAHA: Right. And I think the goal there  
6 is we support everything that's in the Biosimilars  
7 Action Plan in regards to improving predictability for  
8 a biosimilar manufacturer coming into the marketplace  
9 and we are continuously happy to work with the FDA to  
10 come up with any additional solutions that may bridge  
11 beyond the action plan, but it is a concept that we are  
12 extremely supportive of.

13 DR. SHERMAN: Any other questions? Thank you  
14 for your remarks.

15 DR. SAHA: Thank you.

16 DR. SHERMAN: Our next speaker is Dr.  
17 Madelaine Feldman from the Alliance for Safe Biologic  
18 Medicines.

19 DR. FELDMAN: Well, I too thank the FDA for  
20 holding this public forum on promoting biosimilar  
21 development uptick and access.

22 I'm Dr. Madelaine Feldman and I've been in

1 practice in rheumatology for 30 years now, and have a  
2 pretty good idea of what encourages physicians to write  
3 prescriptions and what sort of engenders confidence in  
4 new drugs that come to market.

5 I wear a lot of hats. Today I'm here as the  
6 Chair of the Alliance for Safe Biologic Medicine.

7 So a little bit about it. We've had a few  
8 speakers that talked to the beginnings of ASBM about  
9 ten years ago, and we have over 135 members. And as  
10 you can see, our steering committee is comprised only  
11 of physician and patient groups.

12 We've participated in the past ten WHO INN  
13 consultations and on July 12th we had a second in a  
14 series of meetings with various regulators from around  
15 the world, including the FDA. Oh, another thing that  
16 we're pretty active in is in education, particularly  
17 with pharmacists. We have CE programs that we offer  
18 around the states, as well as patient organization  
19 education.

20 And we also conduct surveys around the world  
21 in terms of adverse event reporting and how physicians  
22 view biologic naming, et cetera. So we have sort of a

1 wide breadth of what we do.

2           You know, we look at access and uptick.  
3 Uptick I think is based on access and confidence, but  
4 access is actually based on availability and  
5 affordability. So all of these attributes go into what  
6 makes a biosimilar available, what gives the confidence  
7 and thus leading to update, and I think the FDA is on  
8 the right track, certainly in terms of availability and  
9 providing rapid approval and getting them out there.

10           As you can see, we're really not far behind  
11 Europe. It was only two-and-a-half years after the EMA  
12 that we approved the first monoclonal antibody, so  
13 we're not really slow in our ability to approve these  
14 drugs, and I think they're getting out on the fast  
15 track and perhaps we may actually even overtake Europe  
16 in terms of approvals.

17           So the speed with which it's -- I don't think  
18 we should try to enhance the speed by reducing safety  
19 and lowering standards. I think we're on the right  
20 track with that, because we do have the biosimilars out  
21 there, so I don't think we necessarily have to increase  
22 the speed.

1           But one of the things we have to do is build  
2 confidence so that the drugs that are out there will be  
3 prescribed, and as you know there's two different  
4 pathways for the originator and the biosimilars, and  
5 with the reduction of regulatory emphasis on clinical  
6 studies, I think physicians would like to see real  
7 world evidence, and we're talking about RWE over and  
8 over again, and organizations like Premier perhaps can  
9 help us with real world evidence to engender this  
10 confidence to see that analytics are applicable and  
11 enough to demonstrate biosimilarity and efficacy and  
12 safety.

13           But convincing physicians of that is something  
14 else, and that's where education is going to come in,  
15 and we do need to have increased pharmacovigilance  
16 because that also will increase confidence from  
17 physicians.

18           So building this confidence. Education, as  
19 we've stated, is extremely important and ASBM is very  
20 active in that, particularly with pharmacists,  
21 physicians and patient groups.

22           So some of the thing that have been mentioned

1 in terms of whether it's naming or the ability to  
2 increase the rapidity of approvals, I think those --  
3 some of those comments actually -- I would submit that  
4 not having unique naming decreases confidence. It  
5 doesn't increase confidence.

6 As a physician, I would like to know in terms  
7 of adverse reporting the exact drug that we're using.  
8 Unfortunately, in some of the surveys that we've done,  
9 up to a third of physicians worldwide and in the United  
10 States use only the non-proprietary name, when  
11 reporting adverse events. So, of course, that can lead  
12 to mis-attributing adverse events to the wrong or  
13 perhaps to the reference product or do a biosimilar  
14 that it really shouldn't be attributed to.

15 So I think we really need to continue with  
16 educating physicians and patients and that will  
17 increase confidence.

18 Of course, I have to bring this up. We keep  
19 talking about the transitive property with  
20 interchangeability of biosimilar A's. Interchangeable  
21 with reference product and biosimilar B, but they're  
22 not interchangeable to each other. And we feel that

1 that is an important guidance that the FDA needs to  
2 emphasize in their final guidance.

3           Okay, getting back to naming. Here is where  
4 we talk about nearly 70 percent of physicians and  
5 pharmacists in the United States support the FDA in  
6 terms of distinct, non-proprietary names. And we've  
7 held a number of meetings with regulators from around  
8 the world in terms of supporting distinct naming and  
9 international harmonization as with what Andy Spiegel  
10 had talked about, and I think that as much as the FDA  
11 can encourage regulators from around the world to  
12 harmonize a global system, particularly for  
13 pharmacovigilance, I think it would be a good thing.

14           So I'm going to get to the part that everyone  
15 else has been talking about. The bottleneck in access  
16 is really happening after the FDA approval, and that is  
17 why despite 12 approvals, we only have four that are  
18 available to patients. Dr. Gottlieb has observed this  
19 in terms of barriers to access are not scientific but  
20 commercial. Yes, there is patent litigation but I  
21 think one of the main things is formulary access,  
22 because competition alone does not lower price.

1           And if you look at the list price of the  
2 reference products, even if they were offered at 40  
3 percent off, patients could not afford them if they're  
4 not on the formulary. And I mean, the first question  
5 that I ask after I go through diagnosing a patient and  
6 we come to what the patient can take is what's your  
7 insurance.

8           So how do they determine what is on the  
9 preferred? We'd like to think that the more  
10 competition there is, the lower the price goes. So  
11 there's two different ways that competition can drive  
12 price.

13           When you're building a house, the more  
14 competition, the lower the price. When you're selling  
15 your house, competition actually drives up the price,  
16 and unfortunately that's the -- our drug distribution  
17 system as it stands. So it does create a perverse  
18 incentive for a higher priced medicine. Rebates based  
19 on the list price, present discount and market share.  
20 Biosimilars have no market share and a lower price so  
21 they're behind the eight ball to begin with.

22           So we really need to penetrate the formulary

1 wall and whatever the FDA can do, whether it is joining  
2 up with the Federal Trade Commission, whether it is  
3 CMS, Congress, and even the Department of Justice has  
4 taken over looking at vertical integration with PBM's  
5 and plans. So I think this has to be sort of a global  
6 approach. PhRMA, PCMA, everyone has to get in here to  
7 turn around this formulary wall, so biosimilars can  
8 actually be prescribed and taken by patients.

9 So overall we encourage the FDA to continue  
10 with its rigorous standards and because of the way  
11 biosimilars are approved, real world evidence is  
12 important, and the approach to distinct naming, we  
13 support you on that, and in general doing the right  
14 thing.

15 So thank you. I'll take any questions.

16 DR. SHERMAN: thank you for your comments.

17 Questions from the panel? Joe.

18 DR. FRANKLIN: Thank you. I have a question  
19 about your slide four, and this a point that's been  
20 reiterated by a few commenters, but you point out that  
21 FDA may make a designation of interchangeability  
22 between a reference product and product A and --

1 interchangeably product A and interchangeable product  
2 B. This is something we pointed out in our notice we  
3 wanted to ask about, ask for comments on, this kind of  
4 scenario, because we expect there would be different  
5 perspectives on it.

6           And you have lines connecting the reference  
7 product with the two interchangeables that are both  
8 green and then a big red line, not interchangeable,  
9 between biosimilar A and biosimilar B or  
10 interchangeable A and interchangeable B. And say that  
11 this is an important policy point which FDA should  
12 emphasize in guidance. I just want to clarify. When  
13 you say that we should clarify that point or the non-  
14 interchangeability between those products and guidance,  
15 are you talking about doing so without specific  
16 information about safety or efficacy problems, so this  
17 would be something proactive, it would be general, and  
18 would not be based on any kind of specific information  
19 that would demonstrate a lack of interchangeability  
20 between those products?

21           DR. FELDMAN: I think in terms of education,  
22 what interchangeability means, whether it's to the

1 pharmacies, to physicians, so that they understand that  
2 when a product is interchangeable and they write the  
3 prescription, that they don't -- that it doesn't fall  
4 into the trap of what was spoke to earlier, I believe  
5 by the AbbVie representative. So I think it's more of  
6 an educational thing and in listening to Dr. Christl at  
7 the DIA meeting recently, she reiterated that this is  
8 the way it's going to be.

9 Now, I don't know if there's going to be a  
10 change in that, but if that is the final guidance, I  
11 think it needs to have a little bit more PR behind it.

12 DR. FRANKLIN: Okay. So just to clarify,  
13 you're proposing that we would just clarify the -- what  
14 FDA's policy is with respect to the alternating or  
15 switching between products.

16 DR. FELDMAN: Yes. The biosimilar A and B  
17 would not be interchangeable with each other, even  
18 though they're both interchangeable with the reference  
19 product.

20 DR. FRANKLIN: Okay. Thanks.

21 DR. SHERMAN: Other questions?

22 DR. CHRISTL: Just possibly a point of

1 clarification, maybe for written comment if it's too  
2 much to get into, but there's been a lot of  
3 conversation about the value of real world evidence  
4 that, you know, could help to, you know, give  
5 confidence to prescribers and inpatients about  
6 scenarios that might come in opposed to approval  
7 setting, where patients are switched, things like that,  
8 and I'm struck a little bit that the more that I listen  
9 to it during the day about the chicken and egg scenario  
10 maybe here, you know, that in order to collect that  
11 information you have to have uptick and use of these  
12 products, and there's a little bit of conversation I  
13 think about sort of validating the pathway and  
14 validating the data asks through this real world  
15 evidence of showing, you know, there's not issues or  
16 problems.

17           And so I don't know if you have thoughts of  
18 perspectives about how to balance that in terms of the  
19 ability to collect that information versus having the  
20 products, you know, be approved based on the FDA  
21 standards and the statutory standards and then this  
22 requirement for this data to be collected to sort of

1 support uptick in use, but again, as I said, to get  
2 that data you have to have uptick in use.

3 DR. FELDMAN: It's difficult. So in the  
4 United States with 80 percent of the patients having  
5 their formularies controlled by three entities, it's  
6 going to be difficult to get real world evidence if the  
7 patients can't get the biosimilars to begin with, but  
8 as I look back over the years, there are I would say a  
9 good 30 to 40 percent of physicians that I know would  
10 wait until a drug was out three or four years, you  
11 know. They would talk to their peers about how the  
12 drug worked, and then that would give them the  
13 confidence.

14 So I think we have to break that wall to allow  
15 biosimilars to be used in order to get the real world  
16 evidence or from companies like Premier that have  
17 perhaps more evidence because they have a better  
18 controlled formulary that is allowing biosimilars or  
19 Europe.

20 DR. SHERMAN: Any other questions? Maybe in  
21 your comments if you could also address the uptick  
22 issue for (indiscernible) versus infliximab and I guess

1 for all the speakers, when we talk about RWE, it can be  
2 lots of different things. Are we talking about rear  
3 adverse events? Are we talking about outcomes? What  
4 is it that you're all thinking that we might be able to  
5 get?

6 DR. FELDMAN: Thank you.

7 DR. SHERMAN: All right. As I mentioned, we  
8 are running ahead in large part thanks to Dr. Gottlieb.  
9 Someone should tell him I said something nice about  
10 him, please. So we're going to take our break on time,  
11 which means we're ready for our next speaker, Dr. Wayne  
12 Winegarden. Great, you're here. Thank you. From  
13 Pacific Research Institute.

14 DR. WINEGARDEN: Good afternoon and thank you  
15 very much for giving me the opportunity to present to  
16 you here today. I'm Wayne Winegarden, a senior fellow  
17 with the Pacific Research Institute. One of my areas I  
18 concentrate on is pharmaceutical economics.

19 And we've spent some time trying to evaluate  
20 kind of what's the dollar value of the savings and try  
21 to put that into the context of what you're doing here.  
22 I should apologize up front, being an economist, there

1 are many numbers and I apologize up front for all of  
2 those.

3           What we had found that in effect the savings  
4 do exist. I'll kind of just flip to the conclusion and  
5 start with that, that there are significant savings.  
6 We examined one specific originator of biologic versus  
7 the biosimilars and infliximab. We wanted to evaluate  
8 -- are the savings that we believe existing, do they  
9 exist, and then if they do, then kind of how can we  
10 connect that to the obstacles that we've been talking  
11 about over and over here today?

12           When we were looking at the savings, we found  
13 that in a commercial market you could save about 50  
14 percent market share, you could save \$278 million if  
15 you had 50 percent biosimilar market share, and almost  
16 \$150 million in savings for Medicare. So the savings  
17 are very significant and so the obstacles that we've  
18 been talking about today, buy and bill, fail first, the  
19 PBM's that Dr. Feldman just mentioned, all of these are  
20 very, very important to kind of obstructions that need  
21 to be addressed, and I think it's important to state  
22 right up front that some of these are outside of your

1 control.

2 But the regulatory clarity and especially the  
3 interchangeability designation, that is within your  
4 control. And while that may not be sufficient in terms  
5 of getting a biosimilars market similar to generics  
6 here, at 90 percent, it is necessary, and so we need to  
7 see these types of reforms if we're going to actually  
8 get the savings that we've estimated here.

9 So I wanted to just very quickly kind of walk  
10 you through what we did so you can kind of see where  
11 these savings are coming from and the importance of the  
12 regulatory clarity.

13 Again, we looked at infliximab, because  
14 there's a well-developed market. We have one  
15 originator, a biologic, two biosimilars. We based the  
16 analysis on the CMS Medicare payment data that was  
17 effective between April and June, annualizing that, so  
18 we're trying to use the most kind of -- most recent  
19 data available. And then we broke the markets into our  
20 employer sponsored market and the Medicare market.

21 And so we broke out the average sales price,  
22 the ASP, from the Medicare payments data, and then we

1 said okay, at the kind of commercial kind of price,  
2 you're going to have different markups. Zero to six  
3 percent, ten, 15 and 20, kind of based on that kind of  
4 cost plus pricing scenario.

5 And then Medicare was, in fact, statutory with  
6 the current sequester, you're talking about 4.3 percent  
7 increase over ASP's are the prices that are being paid.  
8 And so we wanted to see what the potential savings are  
9 on both a per patient and an aggregate savings basis.

10 This is diverse of -- far too many numbers.  
11 But on a per patient basis what we looked at is what  
12 would be the prescribed maintenance dosage for  
13 infliximab for the five common kind of autoimmune  
14 disorders that it treats. You can see across the  
15 board.

16 And then based on that we looked at what would  
17 be kind of the annual cost of administering infliximab  
18 versus Renflexis versus Remicade. And then obviously  
19 on a per patient basis the savings is simply just the  
20 difference between -- I think the most important one is  
21 the average biosimilar price compared to the biologic  
22 price. And what you can see, and this is with respect

1 to the Medicare market, you can see that there is about  
2 \$2100 to \$3600 per patient of savings that's possible  
3 if we can actually increase our use of the biosimilar  
4 versions of infliximab.

5 In the commercial market -- I skipped one --  
6 we'll just leave this one up. In the commercial  
7 market, again, it was the same process but what you saw  
8 was -- oh, here it is. One more. One more down. It  
9 should be slide five. Perfect, thank you. Sorry about  
10 that.

11 We look at a per patient basis for the  
12 commercial market. You can see again it's a savings of  
13 \$2100 all the way up to \$4400, with a potential  
14 savings, depending upon the condition that's being  
15 treated, and of course depending upon the markup.  
16 Obviously, simple arithmetic, the markup savings  
17 increase as the percentage markup rises, as well.

18 If we then look at it from an aggregate basis,  
19 and we say okay, we can see there's large per patient  
20 savings that are available, what about for the entire  
21 market? And so what we did is we created a scenario.  
22 We said imagine the entire market was based on the

1 biologic. Right, the originated biologic is the entire  
2 market, and that's that first number in the top row,  
3 the \$1.9 billion.

4           How much savings can we get under alternative  
5 scenarios? Kind of going by tens, all the way up to  
6 the current generic market share, how much potential  
7 savings are out there? And this is for the Medicare  
8 program. You can see, taking about a 50 percent market  
9 share, you're talking about eight percent cut in costs  
10 or about \$150 million in savings, just from infliximab.

11           Now, I don't think it can be the same share as  
12 the generics because they're fundamentally different,  
13 but using that as a benchmark, you're talking about  
14 almost a 15 percent savings to Medicare in its  
15 expenditures on infliximab that biosimilars can create.  
16 And the savings are very similar if you look at the  
17 employer sponsor market.

18           Again, depending upon the markup, the savings  
19 are going to vary, but at a 50 percent market share,  
20 you have somewhere between 260 and 300 million dollars  
21 in annual savings that's available from greater use of  
22 biosimilars.

1           And so kind of the whole point in presenting  
2 terms -- you're talking a bit over eight percent, and  
3 so the whole point of kind of going through this  
4 exercise and why we went through it is, you know, one  
5 possible explanation in terms of why biosimilars  
6 haven't developed is that the savings are a ruse,  
7 right? The savings aren't really available. We only  
8 think they are.

9           But when you look at the actual pricing data  
10 that's out there, in one of the more developed markets,  
11 that's not the case, right. The savings are there and  
12 so both the market barriers, right, the fail first  
13 policies, which required it to fail first and the  
14 originator, before you can go to a biosimilar, or the  
15 whole buy and bill, networks off of the PBM problem,  
16 right, where all of a sudden there's an incentive to  
17 use higher prices.

18           And one of the things that's kind of very  
19 important in terms of just economics, particularly  
20 healthcare economics, is that you've got to get the  
21 incentives correct, and so we need to address those  
22 market disincentives to biosimilars in order to get to

1 the market shares that we're talking about, but from an  
2 FDA perspective the interchangeability guidelines is  
3 very important, and ideas such as kind of having the  
4 dual efficiencies so that we don't have to have  
5 separate tracks to speed up the cost. That's going to  
6 reduce your cost of development, reduced cost is going  
7 to increase the outcome.

8 So I think it's that kind of combination of  
9 market changes, as well as regulatory changes which is  
10 what we need to work toward to kind of get the savings  
11 that are potentially out there.

12 So thank you for the opportunity and I'm  
13 certainly happy to take any questions.

14 DR. SHERMAN: Thank you for your remarks. Any  
15 questions from the panel?

16 DR. UNLU: So your study was based on  
17 reference product and two biosimilars that are not  
18 interchangeable. From your last slide can we  
19 understand that if they were designated  
20 interchangeable, they would be prescribed more? Is  
21 that what your first bullet point, is that what that's  
22 supposed to mean?

1 DR. WINEGARDEN: I don't think you should take  
2 it that cause and effect, because -- and that's what I  
3 was trying to very carefully talk about other factors  
4 that are involved, as well, and I think it's -- they  
5 work with each other, right, the lack of  
6 interchangeability works with the BPM's, works with  
7 the, you know, the other obstructions and so just  
8 pulling on one isn't going to solve it. But you need  
9 to address all of them to get the environment kind of -  
10 - in effect you want to properly incent the  
11 biosimilars, right. We don't want to over-incent, so  
12 the patient that should be on the originator are not  
13 able to get that medicine, but the incentives shouldn't  
14 be discriminating against the biosimilar, and kind of  
15 the whole environment that they can kind of exist in,  
16 that's a discriminatory environment, and that's the  
17 problem.

18 DR. UNLU: So as a follow-up, on your second  
19 bullet you're saying that current regulations need to  
20 be clearer. Can you be more specific, either here or  
21 in your written comments, about what kind of  
22 uncertainties you're detecting and how they can be made

1 more clear?

2 DR. WINEGARDEN: In the written comments I'll  
3 be much more explicit about that.

4 DR. FRANKLIN: Yes. Following on my  
5 colleagues comments, you know, I think it would be  
6 useful from an economics perspective to look at --  
7 undoubtedly the role of guidance is importance enough  
8 to stress the importance of finalizing the  
9 interchangeability guidance, but we've also heard from  
10 at least one other commenter today that overly  
11 prescriptive recommendations from FDA can limit the  
12 flexibility in the context of particular development  
13 programs. It would be useful to look at whether  
14 there's any way to kind of model the benefit versus  
15 cost of different levels of detail in FDA  
16 recommendations when it comes to product development,  
17 if there's any possibility. That's -- I guess that's  
18 more of a comment.

19 But the question I have is infliximab a useful  
20 case study? Is it representative of other product  
21 classes that may have different pricing considerations  
22 or pricing results?

1 DR. WINEGARDEN: I think so. Part of the  
2 problem is we don't have enough data out there to know  
3 for sure, so I think it's an important case because of  
4 the lack of data that's out there and it's something we  
5 can kind of plan to flag, and I think it warrants a lot  
6 more research to be sure.

7 DR. SHERMAN: Steve.

8 DR. KOZLOWSKI: Following up on the  
9 interchangeability comment and bullet you have, so you  
10 note that interchangeability can be used as an excuse  
11 not to prescribe.

12 DR. WINEGARDEN: Right.

13 DR. KOZLOWSKI: Is that actually saying that  
14 just the existence of the standard of  
15 interchangeability discourages biosimilarity or  
16 discourages biosimilar use?

17 DR. WINEGARDEN: Again, I don't think it's  
18 just the existence. I think it's the existence in the  
19 current environment. Right. So when you have -- and  
20 you have to be very careful, because I don't mean to  
21 assign any adverse kind of intentions on anyone's part,  
22 but what you're looking at is a very complex issue, and

1 then at the same time when you're saying this is very  
2 complex, you're not sure which is the right way to go,  
3 but hey, you're going to make more money if you go on  
4 this side, which is the safer side. You're now biasing  
5 the environment towards one versus the other, as  
6 opposed to having a neutral environment.

7           And so when you're establishing the  
8 incentives, in terms of between the different products,  
9 you need to make sure that that's neutral. I mean,  
10 that's not what we have now, so I wouldn't say by  
11 itself, no. And I wouldn't want to comment -- I think  
12 I'd be out over my skies to say whether or not it's  
13 medically viable. That's not my area. I wouldn't want  
14 to comment on that, but from an incentive perspective,  
15 how do we get the right system? It's interacting  
16 inappropriately.

17           DR. KOZLOWSKI: Thank you.

18           DR. SHERMAN: Okay. We'll now take a ten-  
19 minute break. Thank you for your comments. And we'll  
20 resume at 2:31.

21           (Off the record from 2:21 p.m. until 2:33  
22 p.m.)

1 DR. SHERMAN: All right, our panel is  
2 assembled. And we're going to move forward with our  
3 next speaker, Molly Burich, Boehringer Ingelheim  
4 Pharmaceuticals. Thank you.

5 MS. BURICH: Well, thank you on behalf of  
6 Boehringer Ingelheim. My name is Molly Burich and we,  
7 of course, as all other speakers have echoed, want to  
8 thank the FDA for allowing for this hearing and  
9 listening to our feedback and comments.

10 Boehringer Ingelheim is a global innovative  
11 biopharmaceutical manufacturer, and one of the largest  
12 producers of biological medicines in the world.

13 As a pioneer in the production of biologics  
14 with more than 35 years of experience, Boehringer  
15 Ingelheim is developing its own and has manufactured  
16 more than 25 biologics for 15 of the top 20 global  
17 pharmaceutical companies. We've also strongly invested  
18 in the development of biosimilars, which as you know  
19 represent an opportunity to help improve patient access  
20 and drive down costs of biologics by introducing high  
21 quality, lower cost options.

22 Boehringer Ingelheim currently has one

1 approved biosimilar, Cyltezo, a biosimilar to Humira.

2 It was FDA approved in August of 2017, but has yet to  
3 commercially launch due to ongoing litigation.

4 Noteably, Humira biosimilars are anticipated to launch  
5 outside of the U.S. market later this year.

6 We are committed to bringing such a biosimilar  
7 to U.S. patients as soon as possible and certainly  
8 before 2023, when companies that settled their lawsuits  
9 will be able to launch their biosimilars.

10 Our presentation today is going to focus on  
11 questions one, two, three and nine.

12 So question one. As I go throughout, we  
13 strongly support and appreciate the continued advocacy  
14 and commentary by Commissioner Gottlieb and others  
15 sitting up here, highlighting the existing challenges  
16 in commercially launching a biosimilar.

17 A new white paper called Steps to Reducing  
18 Barriers to Biosimilars in the U.S. by Matrix Global  
19 Advisors echoes the challenges recognized by  
20 Commissioner Gottlieb and your Agency's recent report.

21 In particular the white paper cites  
22 unjustified late stage patents acquired by reference

1 product companies with a goal of obstructing or  
2 delaying competition. To be clear, we strongly support  
3 legitimate exclusivity for true innovation as  
4 contemplated by the patent system, but we also believe  
5 that when exclusivity is up, the system must allow for  
6 prompt market-based competition.

7           Current many biosimilars are facing multiple  
8 year litigation based delays before we can launch.  
9 With the average cost to develop a biosimilar at two  
10 hundred to three hundred million, it's untenable to  
11 have multiple years of delays before being able to  
12 launch a product after clinical development.

13           If this pattern continues, this may have a  
14 significant impact on investment in future biosimilar  
15 development, if not addressed, and could have a  
16 negative impact on patient access and affordability to  
17 all biologics in the future.

18           Question two, improvements to the Purple Book.  
19 We, like many others, consider the Purple Book a  
20 valuable tool for all stakeholders, not just  
21 pharmacists, but also other healthcare providers,  
22 patients and others. As such, we are concerned that

1 other stakeholders may request changes to the Purple  
2 Book to describe what biosimilars are, but also what  
3 they are not, or more accurately, what listed products  
4 have not applied to be, which is inconsistent with the  
5 Purple Book's purpose.

6 For example, any addition to the Purple Book  
7 that would list all biosimilars as quote, "not  
8 interchangeable," end quote, is grossly misleading,  
9 that it implies the biosimilar has asked the FDA for an  
10 interchangeable designation and failed to obtain one.  
11 Hence, it is only appropriate to list approved  
12 interchangeables and remain silent on those that have  
13 not pursued or been reviewed for interchangeability.  
14 Anything else we believe risks the perception of less  
15 quality, efficacy or other concerns, and could  
16 certainly generate stakeholder confusion.

17 In a time when the Agency recognized the  
18 myriad of misunderstandings surrounding biosimilars,  
19 and interchangeables, and is taking action to educate  
20 the public, we urge the Agency to be ever vigilant  
21 regarding additions to the Purple Book that would serve  
22 to undermine the proven safety, efficacy and quality of

1 biosimilars.

2 We would also ask the Agency to -- that a  
3 statement of interchangeability is equivalent to a  
4 description of suitable generics, namely, therapeutic  
5 equivalence and A rating. This will help build  
6 physician confidence and understanding and follow the  
7 themes of what we've seen in generic medicine.

8 Lastly, as previously outlined, the number of  
9 pens held by reference product companies pose numerous  
10 challenges for biosimilar companies, and we feel  
11 there's an opportunity for improvement via the Purple  
12 Book. Therefore, we would suggest that all process and  
13 product patents for a given reference product be listed  
14 in a manner already established by the Orange Book.  
15 This would help improve the ability of potential  
16 biosimilar manufacturers to identify which patents are  
17 relevant to a particular product.

18 Question three, interchangeability. As the  
19 only company to have publicly announced the initiation  
20 of an interchangeability clinical trial for an approved  
21 biosimilar, we believe the FDA outlined an  
22 appropriately high bar to establish interchangeability.

1 This high bar builds confidence in the interchangeable  
2 biologic pathway and is important to ensure these  
3 products will enjoy significant uptick in the market  
4 once they are available. We firmly believe the FDA  
5 should finalize the guidance and not lower the  
6 requirements, as this could have a negative effect on  
7 the value of interchangeability to providers and  
8 patients.

9 We would, however, encourage the Agency to  
10 consider some flexibility based on the nuances of a  
11 given product, and the most appropriate requirements  
12 for that specific situation. However, as I said, in  
13 general we support the draft guidance and would like to  
14 see it finalized.

15 We would also encourage the Agency to be aware  
16 of reference company tactics to undermine the  
17 designation by developing alternate formulations or  
18 other product variations that do not impact the  
19 fundamental components of the product. We implore the  
20 Agency to support the durability of the designation and  
21 grant interchangeability to products as appropriately  
22 outlined in your guidance and sustain that designation

1 against tactics that would seek to thwart competition.

2 Interchangeability should be a designation  
3 that a given biosimilar should only need to obtain one  
4 time in their development. It is not something that  
5 should have to be chased based on anti-competitive  
6 action by the reference product manufacturer.

7 Question nine, continued FDA activity to  
8 address market challenges. We are very supportive of  
9 the excellent education materials the Agency has  
10 developed for biosimilars. The marketplace is  
11 unfortunately overflowing with misinformation and  
12 misleading messaging surrounding biosimilar and  
13 interchangeable biologics which has generated the  
14 perception of risk for switching to a bio. This is  
15 unwarranted and notably does not apply to reference  
16 products undergoing manufacturing changes as those are  
17 de facto invisible to patients and providers in the  
18 U.S.

19 We greatly appreciate the FDA's efforts to  
20 combat misinformation with its education initiatives.  
21 Such primary resources are invaluable to a multiple of  
22 stakeholders interested in insuring biosimilars and

1 interchangeables biologics can compete and provide  
2 increased access and affordability to these medicines.  
3 As such, we encourage the continued development of more  
4 materials aimed at healthcare professionals and would  
5 recommend the Agency consider the development of  
6 materials specifically aimed at switching and  
7 transitioning patients to biosimilars and  
8 interchangeables. There continued to be the  
9 proliferation of misleading terms across the landscape,  
10 like non-medical switching, which we believe  
11 scientifically does not apply to biosimilars, because  
12 clinically biosimilars are the same therapeutic protein  
13 as the originator, and does not constitute a  
14 therapeutic switch to the patient.

15 Non-medical switching is being used to  
16 dissuade the use of biosimilars via state legislation  
17 designed to block and materials being developed by  
18 those wishing to thwart biosimilar competition. As  
19 such, we would ask the Agency to specifically develop  
20 materials that can provide appropriate education and  
21 tools on patient transition to biosimilars and  
22 interchangeables for both healthcare professionals and

1 patients alike.

2 Boehringer Ingelheim appreciates the  
3 opportunity to present to you today and the continued  
4 support by the Agency on the biosimilar pathway. We  
5 look forward to continued engagement on creating  
6 competition to allow for a vibrant and sustainable U.S.  
7 biosimilar market. We will also be submitting our  
8 comments in further detail via comment letter. I'm  
9 happy to take any questions.

10 DR. SHERMAN: Thank you for your comments.  
11 Questions?

12 DR. FRANKLIN: I'd just ask you about  
13 something that other have also commented on today,  
14 which is the idea of listing patents in the -- or  
15 listing information about certain patents in the Purple  
16 Book, and would just encourage you to provide more  
17 detail about this. I think previously today we talked  
18 about the -- whether or not this is something FDA has  
19 within its current authorities.

20 MS. BURICH: Mm-hmm.

21 DR. FRANKLIN: Also I think, you know, it  
22 would be useful for any commenters to consider the

1 relative benefits of this information from the  
2 biosimilar products development perspective, in  
3 addition to the cost of providing that information. So  
4 I think more of a comment to provide more clarity on  
5 that in your comments, if possible.

6 MS. BURICH: Happy to do that, absolutely.

7 DR. SHERMAN: Steve.

8 DR. KOZLOWSKI: So you mentioned strategies  
9 like formulation changes and other things meant to  
10 serve as barriers. So obviously improving products and  
11 innovating originator products over time is an  
12 important thing. So do you have thoughts about how you  
13 could separate out, you know, improvements that are  
14 meant to say a convenience and increase compliance,  
15 versus those that are potentially blocking in some way,  
16 and not really a benefit to patients?

17 MS. BURICH: Yeah, it's a great point and I  
18 think that from our perspective, that's particularly  
19 important from an interchangeability standpoint, so if  
20 the fundamental components of the product don't change,  
21 e.g., don't warrant a brand new BLA, then we feel like  
22 if a company is pursuing or has pursued

1 interchangeability and obtained that designation, then  
2 there shouldn't be a need to continue to chase that  
3 because of improvements that don't warrant a brand new  
4 BLA.

5 DR. KOZLOWSKI: Okay, thank you.

6 MS. BURICH: Yeah.

7 DR. SHERMAN: Other questions? This would  
8 also be for your written comments, if you could expand  
9 a little bit and all speakers on we talked about the  
10 flexibility and interchangeability. Dr. Kozlowski  
11 earlier had asked if we have let's say five or six or  
12 seven -- pick your number, of products, biosimilars,  
13 demonstrated to be interchangeable with the reference  
14 product, do we have more confidence about that  
15 universe?

16 MS. BURICH: Great, thanks, will do.

17 DR. SHERMAN: Thank you again. Our next  
18 speaker is David Korn from PhRMA.

19 Mr. KORN: Thank you for holding this hearing  
20 and inviting the views of the public. I am David Korn,  
21 Vice President, Intellectual Property and Law at  
22 Pharmaceutical Research and Manufacturers of America.

1 PhRMA represents leading innovative biopharmaceutical  
2 companies who research and develop new and improved  
3 medicines for patients and includes companies making  
4 biosimilar products, as well as reference products.

5 We appreciate the Administration and FDA's  
6 effort to maintain the intended balance between  
7 innovation and competition in America's healthcare  
8 system, and specifically the marketplace for biological  
9 products. PhRMA supported the enactment of the BPCIA,  
10 has actively participated in FDA's implementation  
11 activities and supports continued development of the  
12 biosimilar pathway.

13 As America's healthcare system evolves,  
14 biosimilars are anticipated to play a critical role in  
15 constraining prescription drug costs by reducing  
16 spending on biologics. This is on top of the cost  
17 savings from generics, which now represent 90 percent  
18 of all medicines given to patients.

19 PhRMA urges FDA to do what it can under the  
20 law to foster a scientifically rigorous regulatory  
21 policy for biosimilar products that can bring these  
22 important medications to patients and maintain

1 incentives for innovation, and we look forward to  
2 working with the Administration and FDA as additional  
3 guidance documents are released.

4 While there have been many proposals discussed  
5 today and included in the Biosimilars Action Plan and  
6 FDA's meeting notice, today I will focus on five key  
7 areas. We also plan to submit written comments to the  
8 docket.

9 First, we strongly support FDA's application  
10 of an umbrella exclusivity policy for biologics, as FDA  
11 already does for small molecule products. With an  
12 umbrella policy the approval of a supplement or new  
13 application that does not receive its own period of  
14 reference product exclusivity, would not compromise  
15 already earned exclusivity for the first license  
16 product. Instead, the period of remaining exclusivity  
17 would cover the innovation reflected in the new  
18 application. Importantly, an umbrella policy would not  
19 extend exclusivity beyond the original period.

20 An umbrella policy is central to preserve the  
21 value of reference product exclusivity and encourage  
22 the R&D investments needed to support the development

1 of continued improvements to biologics to meet patient  
2 needs. Without an umbrella policy, a product change  
3 that doesn't result in new reference product  
4 exclusivity, for example, a new indication or route of  
5 administration, would have no exclusivity. A  
6 biosimilar applicant could immediately obtain approval  
7 for that changed product or new use even before it  
8 could obtain approval of a biosimilar of the original  
9 product.

10 This would effectively eviscerate the  
11 exclusivity for the first license product, as the  
12 biosimilar would be relying on the original approval.  
13 Failure to apply an umbrella policy would serve to  
14 disincentivize additional R&D investments that lead to  
15 the development of new indications and otherwise  
16 improve biologics and expand treatment options for  
17 patients.

18 Second, PhRMA supports FDA's use of  
19 appropriate data sharing agreements to expedite  
20 biosimilar development by facilitating harmonized  
21 development advice. Further, we support the adoption  
22 of analogous bridging study standards when non-U.S.

1 license comparators are used in innovator and  
2 biosimilar development programs.

3           PhRMA is concerned, however, with proposals to  
4 waive bridging study requirements based on non-public  
5 information where a non-U.S. comparator is produced at  
6 the same facility as the reference product. PhRMA does  
7 not object to waiving bridging study requirements if  
8 the biosimilar applicant can demonstrate through  
9 publicly available information that the non-U.S.  
10 product has the same drug substance, dosage form and  
11 route of administration as the U.S. reference product  
12 and is produced by the same manufacturer in the same  
13 plant, using the same sell line.

14           But in cases where this information is trade  
15 secret, FDA reliance on these trade secrets or  
16 disclosure of them to the biosimilar developer, either  
17 explicitly or implicitly through waiver of a bridging  
18 study requirement, would raise serious issues under  
19 federal law, and the takings clause.

20           Third, PhRMA seeks clarification of the plans  
21 for implementing the transition provisions of the BPCIA  
22 under which approved NDA's for biological products will

1 be deemed BLA's in March, 2020.

2 In comments on FDA's draft guidance we  
3 expressed concern with the proposal to extinguish  
4 unexpired Hatch Waxman and pediatric exclusivity for  
5 transitioning NDA's and deny them any reference product  
6 exclusivity. This proposal is inconsistent with the  
7 BPCIA, raises serious issues under the takings clause,  
8 and would significantly harm incentives for innovation.

9 We noted that the statute allows FDA to adopt  
10 an alternative approach in which granted exclusivity  
11 would remain in place and the Hatch Waxman patent  
12 provisions would apply through the term of the last  
13 expiring Orange Book listed patent.

14 This approach would be consistent with the  
15 statutory provision allowing sponsors of innovative  
16 transition products to choose between the NDA and BLA  
17 pathways, and their corresponding rights until the  
18 transition date.

19 Further, to increase efficiency and reduce  
20 regulatory burden, rather than requiring pending  
21 transitional applications be withdrawn and resubmitted  
22 as BLA's, FDA should allow these applications to retain

1 their status until final approval, when they will be  
2 deemed to be BLA's.

3 The transition date is just 18 months away and  
4 we urge FDA to provide prompt clarity on these issues  
5 so sponsors can prepare.

6 Fourth, PhRMA urges FDA to state in the Purple  
7 Book the Agency's commitment to publish prompt  
8 reference product exclusivity decisions at the time of  
9 BLA approval. This approach will give both innovators  
10 and biosimilar developers information they need to  
11 inform investment decisions.

12 We also recommend that the Purple Book state  
13 that an interchangeable determination reflects the  
14 Agency's judgment that an interchangeable biosimilar  
15 product may be substituted for the reference product,  
16 not another biosimilar product.

17 It's important for FDA to convey clear meaning  
18 of an interchangeability determination to avoid  
19 inadvertent substitution of products not demonstrated  
20 to be interchangeable with one another, and to promote  
21 prescriber confidence in interchangeable products.  
22 Individual interchangeable biosimilar products could

1 have differences and the potential immunogenetic  
2 effects of alternating or switching between them will  
3 not have been evaluated by FDA.

4           Finally, FDA's notice asked for input  
5 regarding a situation where a biosimilar applicant did  
6 not initially seek approval of a reference product  
7 condition of use due to patent or exclusivity  
8 protection, that protection expires and the applicant  
9 subsequently desires to seek approval for the condition  
10 of use. In such cases PhRMA supports approval of the  
11 conditions of use for the biosimilar based on clinical  
12 data or scientifically justified extrapolation.

13           We also support adoption of a clear process  
14 that enables the biosimilar applicant to obtain the  
15 approval of the new condition of use promptly upon  
16 expiration of the protection. Before the protection  
17 expires, however, FDA should not publicly discuss  
18 whether the product is biosimilar to the reference  
19 product with respect to the protected conditions of  
20 use, particularly for orphan protected uses, as this  
21 could undermine incentives to develop biologics for new  
22 indications.

1           In conclusion, we agree with FDA on the  
2           importance of fostering greater competition in the  
3           healthcare marketplace. As noted in the Biosimilars  
4           Action Plan, biosimilars have a crucial role to play in  
5           delivering new options to patients and in constraining  
6           prescription drug cost growth.

7           PhRMA looks forward to working with FDA on the  
8           continued implementation of the BPCIA in a way that  
9           encourages additional biosimilar competition, while  
10          protecting incentives for innovation.

11          DR. SHERMAN: Thank you for your comments.  
12          Questions? Joe.

13          DR. FRANKLIN: Thank you for the comments on  
14          these various issues. In our hearing notice we -- in  
15          our question about umbrella exclusivity, I'll just read  
16          it. We asked, "What is the relevance and significance,  
17          if any, of the patent scheme in considering this  
18          issue?" And I'm wondering if either today or in your  
19          written comments you can provide some insight to the  
20          significance in relationship of patents to the  
21          exclusivity questions that we highlighted in that  
22          notice.

1           Mr. KORN: We can address that in our written  
2 comments, but they are separate issues.

3           DR. FRANKLIN: Thanks.

4           DR. CHRISTL: Just a point of clarification,  
5 you had talked about FDA shouldn't be discussing in the  
6 review prior to exclusivity expiring, you know, where  
7 there's something that may be covered. Is it PhRMA's  
8 position that in an original 321 KBLA an applicant  
9 could submit data and information to support approval  
10 of conditions of use that would be covered by  
11 exclusivity for the reference product and just somehow  
12 redact that from the reviews, or are you talking about  
13 a process where it couldn't be included in the original  
14 321 KBLA and it would just have to be addressed once  
15 that exclusivity expired?

16           Mr. KORN: Well, for example, on orphan,  
17 people do submit before the time is up, but if someone  
18 is not currently seeking approval for an indication,  
19 then the process shouldn't be the public process about  
20 whether it's biosimilar for that indication, and we can  
21 address that further.

22           DR. CHRISTL: Thanks.

1 DR. SHERMAN: Other questions? Thank you.  
2 Our last scheduled speaker is Chrys Kokino from Mylan.

3 MR. KOKINO: Good afternoon, everyone. My  
4 name is Chrys Kokino. I'm the head of Biologics for  
5 North America. But that's not the most important thing  
6 today. The most important thing today is that some of  
7 you, I've been told, this is the first day of school  
8 for your preschoolers and your other kids. So  
9 congratulations, big moment for all of you. Now, I do  
10 have to ask the question, at least my kids in New  
11 Jersey, look forward to snow days to get off of school.  
12 So are we going to have scorch days where kids don't go  
13 to school anymore? Just a thought.

14 So some of you may already know that Mylan has  
15 a very robust portfolio of about 20 biosimilars in our  
16 pipeline. We have now launched and commercialized a  
17 number of those products in rest of world markets, and  
18 here specifically in the United States we have two  
19 biosimilars that have already been approved by the FDA,  
20 so thank you for that.

21 The first, of course, is our tras 2 bara give  
22 (phonetic) product. The second product most recently

1 was our pegfilgrastim molecule Fulphila, which was just  
2 approved recently and is being commercialized as we  
3 speak today.

4           So with that, Mylan appreciates the FDA's  
5 continued efforts to foster biosimilar competition with  
6 the objective of building a sustainable biosimilars  
7 market. Now, more importantly, we applaud the FDA for  
8 recognizing that U.S. patients needs always, always  
9 come first. Mylan has previously submitted comment to  
10 the docket on several points related to questions posed  
11 by the FDA.

12           In the interest of time and for purposes of  
13 this public hearing, I'll focus on select topics  
14 impacting the viability of the U.S. biosimilars market.  
15 Further detail will be provided in written submission  
16 to the docket.

17           Now, the FDA has immediate opportunities  
18 within its existing authority to foster biosimilar  
19 competition without compromising biologics innovation.  
20 Some commercial and contracting approaches taken by  
21 originator manufacturers have created market barriers  
22 to biosimilar utilization. These barriers may and in

1 some cases do have a direct impact on patients and  
2 patient access to these important biosimilar treatment  
3 options.

4 As an example, formulary restrictions on  
5 biosimilar medicines, as you all know, have the  
6 potential to block access to FDA approved biosimilar  
7 medicines.

8 Now, we've identified several recommendations  
9 for rectifying the situation, which are outlined in our  
10 response to the HSS blueprint. While we recognize that  
11 most market barriers are not within FDA's mandate to  
12 fix, all of us, all of us, including the FDA, share a  
13 responsibility to foster a sustainable biosimilar  
14 market for the benefit of American patients.

15 If the current tactics continue, competition  
16 may become highly limited and has the potential in some  
17 cases to completely halt any future investment in  
18 biosimilars development. The consequence of limited  
19 competitions that biosimilars will never realize their  
20 full potential.

21 FDA should be cognizant of the impact its  
22 actions have on commercial competition, as well as the

1 impact to patients. FDA plays a unique role as a  
2 trusted -- and I'm going to say that again, a trusted  
3 voice to increase confidence and trust in biosimilar  
4 medicines.

5 The FDA biosimilars education campaign is an  
6 excellent beginning, amplifying -- amplifying these  
7 educational activities is an immediate step that FDA  
8 could take to improve acceptance of biosimilars and  
9 increased competition.

10 Bold statements on the FDA website or via  
11 social media to underscore key facts could have and  
12 will have a huge impact. For example, an  
13 interchangeable biologic is not a better biosimilar.  
14 Reinforcing this message has the effect of building  
15 confidence in biosimilars, as well as removing doubt  
16 about the safety, the quality and efficacy of these  
17 products.

18 FDA could also take a stronger stance in  
19 tackling misinformation about biosimilars. As an  
20 example, some clinical guidelines today exclude  
21 biosimilars due to a perceived lack of sufficient data  
22 to justify use and extrapolated indications.

1           As another example, some formularies require  
2 patients to fail first on a reference product prior to  
3 being able to utilize a biosimilar.

4           We're always asked about data. As we know,  
5 there's a robust data set from the European unit as  
6 well as around the world, 700 million patient days of  
7 clinical experience. I perhaps wonder if I told you  
8 there's 701 million days, would that convince you?

9           Finally, such falsehoods are not only contrary  
10 to science but they truly create unsubstantiated doubt  
11 and are potentially harmful for both healthcare  
12 providers and patients.

13           From a market perspective the use of suffixes  
14 for biosimilars and not for reference biologics, it's  
15 just confusing, can be misinterpreted as it is with  
16 some of the back office staff, and may apply meaningful  
17 differences between the biosimilar and the reference  
18 product. If meaningless suffixes are to continue, they  
19 should immediately be applied to reference biologics,  
20 as was outline in the final guidance.

21           Some originator life cycle management  
22 approaches, such as product switches, product

1 reformulations or device changes are used by  
2 manufacturers with the intent that patients will remain  
3 on the originator medicine when the competition from  
4 biosimilars is eminent. FDA should be aware that this  
5 is a market barrier tactic to prevent obviously  
6 biosimilar competition.

7 True product innovation should always be  
8 encouraged but should not be used as a competition  
9 prior to biosimilar market entry. Life cycle product  
10 switches should not be used to gain the exclusivity  
11 system through multiple staggered or non-coinciding  
12 exclusivities. As we know, umbrella exclusivity is  
13 ruled out by the language of the BPCIA and was not  
14 appropriate in the context of biologic medicines.

15 As FDA works to draft and finalize biosimilar  
16 guidance, this Agency should recognize the tremendous  
17 potential for streamlining development approval for  
18 biosimilar medicines by increasing flexibility in use  
19 of non-U.S. reference products, as well as to refer to  
20 previous submission from the global biosimilars  
21 industry.

22 So in conclusion, with at Mylan not only thank

1 you but on behalf of the many biosimilar stakeholders,  
2 we all thank you for the opportunity to participate in  
3 this very important public hearing. We look forward to  
4 the impact the FDA can have with these immediate  
5 actions, which ultimately will serve most importantly,  
6 most importantly, to patients here in the U.S.

7 Thank you.

8 DR. SHERMAN: Thank you for your comments.  
9 Questions from the panel? Mustafa.

10 DR. UNLU: Can I echo the question asked to  
11 the last presenter about umbrella exclusivity? In your  
12 written comments if you haven't already done so, we're  
13 more interested in why it's not appropriate in your  
14 case or why it is appropriate, if you have that view.

15 MR. KOKINO: Sure.

16 DR. UNLU: Especially in light of the patent -  
17 -

18 MR. KOKINO: Yeah. I'm going to purposely  
19 withhold my answer on that question, provide written  
20 comment for that.

21 DR. UNLU: Thank you.

22 MR. KOKINO: Yeah, but thanks for the

1 question.

2 DR. SHERMAN: Other questions? Thank you.

3 MR. KOKINO: Thank you.

4 DR. SHERMAN: So we will now start our open  
5 public hearing. Speakers, please remember that the  
6 time slot is three minutes and Dr. Hoffman is standing  
7 at the microphone that you should use. So our first  
8 speaker is Ms. Mary Jo Carden from Academy of Managed  
9 Care Pharmacy.

10 MS. CARDEN: Good afternoon. I'm Mary Jo  
11 Carden, Vice President of Government and Pharmacy  
12 Affairs at the Academy of Managed Care Pharmacy. AMCP  
13 is the leading organization representing pharmacists  
14 and other healthcare professionals who provide  
15 healthcare services and health plans, pharmacy benefit  
16 management firms and emerging care models for 270  
17 million Americans covered by a prescription drug  
18 benefit.

19 AMCP appreciates the Food and Drug  
20 Administration's initiatives, including the Biosimilars  
21 Action Plan to support the implementation of a robust  
22 biosimilars pathway to ensure Americans receive access

1 to safe, effective and affordable biologics and  
2 biosimilars. AMCP believes that releasing a revised or  
3 new interchangeability guidance is critical to  
4 promoting a robust biosimilars pathway.

5 AMCP also encourages FDA to reconsider its  
6 naming conventions to allow for a shared non-  
7 proprietary name with biologics and biosimilars and use  
8 national drug codes to track use and dispensing.

9 Like FDA AMCP has also made biosimilars  
10 education for healthcare providers a key priority and  
11 looks forward to potential opportunities to partner.  
12 AMCP encourages FDA to focus educational efforts on  
13 providing resources to help healthcare providers and  
14 consumers understand that biosimilars are safe and  
15 effective alternatives to reference products and to  
16 provide resources on interchangeability standards.

17 Work to ensure biosimilar safety and  
18 effectiveness is already taking place through AMCP's  
19 biologics and biosimilars collective intelligence  
20 consortium or BBCIC. This was establish in 2015 to use  
21 real world evidence to address the active post-  
22 marketing surveillance evidence for biosimilars and

1 biologics. BBCIC is not directly associated with FDA,  
2 but leverages significant scientific investment by the  
3 Agency and in the sentinel initiative. BBCIC will help  
4 to generate evidence that is not available from  
5 clinical studies with restricted populations and  
6 restricted duration.

7 AMCP and FDA's focus on the need for  
8 interchangeability standards and education for  
9 healthcare providers is also shown here in a study of  
10 57 health systems published in the December, 2017  
11 Journal of Managed Care and Specialty Pharmacy.

12 The study identifies the key challenges and  
13 the use of adopting a biosimilar for infliximab.  
14 Payment and reimbursement are identified as primary  
15 reason for challenges associated with the adoption of a  
16 biosimilar, but the need for interchangeability and  
17 education to shift patient and provider preferences are  
18 also critical factors that have been identified.

19 To this end AMCP offers several suggestions.  
20 AMCP welcomes the opportunity to partner with FDA using  
21 its biosimilars resource center platform as a way to  
22 educate healthcare providers about biosimilars and

1 interchangeably products.

2 AMCP also encourages the use of FDA's social  
3 network platforms and other channels to provide  
4 education about biosimilars, particularly  
5 interchangeability standards that do not require  
6 physician consultation by a pharmacist prior to  
7 dispensing. AMCP also supports the release of a new or  
8 revised guidance with reasonable standards for  
9 interchangeability to encourage the designation when  
10 possible. AMCP supports the ability of applicant  
11 seeking interchangeability designation to use switching  
12 studies for non-U.S. licensed reference products.

13 AMCP also urges the FDA to consider the  
14 following issues in regard to --

15 DR. SHERMAN: Ms. Carden, can I ask you to  
16 wrap up your comments?

17 MS. CARDEN: Sure.

18 DR. SHERMAN: Thank you.

19 MS. CARDEN: Whether new or expanded  
20 indications would be used, naming interchangeability  
21 from biosimilar to biosimilar, dispensing standards for  
22 interchangeability, and whether follow-on products

1 approved under the 505 pathway, will be considered  
2 interchangeable or biosimilar, when incorporated.

3 Thank you very much and we will submit  
4 comments to the record.

5 DR. SHERMAN: Terrific. Thank you very much.  
6 Our next speaker is Professor Peter Pitts from Center  
7 for Medicine and Public Interest.

8 MR. PITTS: Good afternoon. It's been a real  
9 biosimilars bar mitzva today. My name is Peter Pitts  
10 and I'm President of the Center for Medicine and the  
11 Public Interest.

12 There are many issues surrounding the  
13 introduction of biosimilars into the American  
14 healthcare eco system, but biosimilars are here. They  
15 are safe and effective. They are less costly and they  
16 deserve a seat at the therapeutic table.

17 How can the FDA drive biosimilar innovation  
18 and competition? By being aggressive, creative,  
19 predictable and practicable. Aggressive, because we  
20 are already behind our European counterparts in both  
21 regulatory and marketplace experience. If we do not  
22 prioritize both, we will achieve neither, and that is

1 not an acceptable public policy outcome.

2 We must learn from Europe's mistakes and  
3 create better regulatory standards that instill  
4 confidence in patients, providers and payers.

5 Creative, because we needn't just copy the  
6 experience of others. We must learn from their  
7 successes and mistakes and then improve on the process.  
8 Through more 21st Century pharmacovigilance strategies  
9 and tactics, validated real world evidence collection  
10 and analysis, helpful labeling information, patient and  
11 physician education and more regular and intense  
12 collaboration with developers, FDA can, must and will  
13 become the global standard for innovative biosimilar  
14 regulatory science.

15 Issues related to the particularities of  
16 biologics, sources, process, quality requirements and  
17 evolving safety profiles, require sophisticated new  
18 thinking.

19 The Agency must work towards validated  
20 predictive models of potential hotspot products, base  
21 ingredients and suppliers. Consequently biosimilar  
22 pharmacovigilance will have to evolve at the same time

1 as new medicines are launched into this space.

2 Predictable, because it's regulatory  
3 predictability that drives a developer's desire to  
4 invest and compete, and it must be rhetorical prophecy,  
5 but practiced policy. Predictability is power in  
6 pursuit of the public health and nowhere is that more  
7 acutely felt than the evolving regulation of  
8 biosimilars.

9 Without regulatory predictability investment  
10 in a still evolving commercial marketplace will remain  
11 quiescent. A predictable FDA process facilitates  
12 speedier marketplace competition.

13 When it comes to healthcare, clarity is better  
14 than confusion, especially when it comes to drug  
15 safety, the sine qua non of medicine's regulation, and  
16 that means clarity in biosimilar nomenclature.

17 Practicable, because that's where the rubber  
18 meets the road. We don't need more biosimilar theory.  
19 We need more biosimilars. Biosimilars need earlier,  
20 regular and swifter access to good advice. The Agency  
21 must be both regulator and partner in advancing the  
22 development and review of biosimilars. Minus that,

1 nothing happens. This is not an academic exercise.

2 As Scott Gottlieb surmises, there is no silver  
3 bullet here that will make the biosimilar market go  
4 gangbusters. It's going to be a slow build, but build  
5 we must.

6 If the process is the product, we're  
7 interchangeability. We're label extrapolation. We're  
8 reference products in a world with multiple biosimilars  
9 in the same class. These are key regulatory issues  
10 that will directly and powerfully impact marketplace  
11 behavior in investment and contracting formulary  
12 development physician confidence, patient access and  
13 cost. And they must be addressed by FDA aggressively,  
14 creatively, predictably and in a practical manner now.

15 When it comes to biosimilars, the USA isn't  
16 behind Europe. We're learning from their mistakes and  
17 doing it better. It's not about lowering standards.  
18 It's about creating better standards. The stakes are  
19 too high, both in policy and patient outcomes, to cut  
20 corners or cave in to outside pressure. Steve Jobs  
21 said innovation distinguishes between a leader and a  
22 follower. FDA is a leader and must remain so. The

1 world is watching and patients are waiting.

2 Thank you.

3 DR. SHERMAN: Thank you. Our next speaker is  
4 Dr. Angus Worthing from the American College of  
5 Rheumatology. Oh, I goofed. Sorry. Our next speaker  
6 is Ms. Stacey Worthy from the Aimerd Alliance. Sorry.

7 MS. WORTHY: No problem. Thank you. Good  
8 afternoon. I'm Stacey Worthy, counsel to Aimerd  
9 Alliance. We're a nonprofit that works to improve  
10 access to quality healthcare. Thank you for this  
11 opportunity.

12 We commend the FDA on its efforts to preserve  
13 safety while also speeding up the approval process for  
14 new biologic products. The Agency should be proud of  
15 its work in creating competition in the drug  
16 marketplace and helping patients to access effective  
17 and affordable treatments. To ensure confidence  
18 amongst stakeholders we encourage the FDA to preserve  
19 safety over speed.

20 Although there is urgency to bring about cost  
21 savings, we must prioritize scientific rigor, given the  
22 complexity of large molecule drugs. In particular the

1 FDA should not lower the standards for  
2 interchangeability. The U.S. is the only country with  
3 a formal interchangeability designation, making us a  
4 leader among other nations. In that role safety must  
5 be top priority.

6           Additionally, as others have already said, the  
7 FDA should consider how cross interchangeability may  
8 impact patients. In the near future patients could be  
9 switched from an initial reference product to an  
10 interchangeable biosimilars and again to a second  
11 interchangeable biosimilars. While the two biosimilar  
12 products may be deemed interchangeable with the  
13 reference product, they may not be interchangeable with  
14 each other. These switches could result in an immune  
15 response.

16           We need data or at minimum educational  
17 awareness about the implications of these cross  
18 switching between biosimilars that are not  
19 interchangeable with each other to ensure that there is  
20 no harm.

21           Building on the FDA's biosimilar education and  
22 outreach campaign, the FDA should also take steps to

1 improve awareness of interchangeability designation by  
2 creating educational materials for various audiences,  
3 including insurers, health systems, pharmacies and  
4 practitioners. The Agency should provide practitioners  
5 with data on the safety of switching a patient from a  
6 biologic to biosimilar so they can make educated  
7 decisions.

8           However, it is important to discourage  
9 insurers and health systems from forcing practitioners  
10 to switch stable patients from one product to another  
11 for non-medical reasons.

12           Additionally, some health systems, pharmacy  
13 and therapeutic committees or P&T committees have been  
14 deeming products interchangeable for the purposes of  
15 setting up their formularies. Given that only the FDA  
16 has the authority to make a formal interchangeability  
17 designation, this -- it can be confusing and misleading  
18 for a P&T committee to use the same verbiage.

19           Moreover, as a result of some pharmacies have  
20 stocking reference biologics, and health systems are  
21 mandating that practitioners witch their stable  
22 patients from their current medications to different

1 products regardless of whether their practitioner deems  
2 such a switch medically appropriate. This type of non-  
3 medical switching should be discouraged.

4           Finally, as an evolution in the marketplace  
5 will require -- an evolution in the marketplace  
6 requires reform among payers. Insurers are currently  
7 restricting access to life saving biologics and  
8 biosimilars alike. We were encouraged to hear  
9 Commissioner Gottlieb's recent comments, in which he  
10 noted that rebates should be applied directly to lower  
11 out-of-pocket costs for patients who need biologics and  
12 biosimilars, rather than allowing pharmacy benefit  
13 managers and insurers to pocket rebates, as additional  
14 profits or spreading the benefits of rebates across all  
15 plan members. As he noted, high co-pays are not going  
16 to discourage overutilization among individuals with  
17 cancer, who have limited treatment options.

18           Therefore, rebate reform can have a meaningful  
19 impact on the increased use of both biologics and  
20 biosimilar medications.

21           Thank you, and we'll submit comments.

22           DR. SHERMAN: Thank you for your comments.

1 And our next speaker is Dr. Angus Worthing from the  
2 American College of Rheumatology.

3 DR. WORTHING: Thank you. We're going from  
4 Worthy to Worthing. Appreciate that. I'm Angus  
5 Worthing. I'm a practicing rheumatologist in the D.C.  
6 Metro Area and very grateful to represent the 9,500  
7 rheumatologists and rheumatology professionals of the  
8 American College of Rheumatology as their volunteer  
9 Chair of Government Affairs.

10 ACR strongly believes that safe and effective  
11 treatment should be available to our patients at the  
12 lowest possible cost, and in the absence of other large  
13 scale levers to control U.S. biologic drug prices, FDA  
14 approvals of biosimilars may be the only tool to keep  
15 costs within reason.

16 Unfortunately many of our patients struggle to  
17 afford these complex therapies, due to their high costs  
18 and the coverage restrictions, like step therapy, cost  
19 sharing and tiering that result from their high prices.

20 I'm going to focus briefly on the  
21 interchangeability pathway and refer you to our  
22 statement in the record about clarifications to the

1 prescriber information, PBM transparency, importance of  
2 careful extrapolation and pharmacovigilance and non-  
3 medical switching.

4           About interchangeability, we strongly support  
5 the FDA's proposal to require manufacturers to use  
6 robust switching studies to determine whether  
7 alternating between the biosimilar and its reference  
8 product impacts the safety and efficacy of the drug.  
9 Exposing patients in the experimental arm to each drug  
10 twice, a protocol that requires three switches at a  
11 minimum, is a reasonable attempt to simulate what our  
12 patients are likely to experience with the changing  
13 formularies in a multi-payer, multi-state, ever  
14 changing market.

15           The requirement for multiple switch studies to  
16 demonstrate the safety of interchangeability is  
17 particularly vital in light of the fact that providers  
18 will often not know that their patient's prescription  
19 has been switched or substituted.

20           The ACR was very pleased to see the FDA issue  
21 draft guidance on biosimilar interchangeability. The  
22 guidance brings us one step closer to the shared goal

1 of lowering prices in the biologics marketplace. We  
2 believe that the draft guidance strikes a good balance  
3 between insuring safety and efficacy, while also  
4 getting biosimilar products to market as efficiently as  
5 possible, while also providing prescribers with the  
6 confidence about robust data from three switched  
7 studies. And we, therefore, encourage the FDA to  
8 finalize the guidance with all due haste.

9 Thank you again for the opportunity to share  
10 the views of the American College of Rheumatology.

11 DR. SHERMAN: Thank you for your comments.  
12 You get a prize. Two-and-a-half minutes. Our next  
13 speaker is Mr. Thair Phillips from RetireSafe.

14 MR. PHILLIPS: Good afternoon. My name is  
15 Thair Phillips. I'm the President and CEO of  
16 RetireSafe, a nationwide, nonprofit advocacy  
17 organization for older Americans. I'm here today  
18 representing over 100,000 supporters and activists,  
19 many of which are patients receiving these new life-  
20 extending and life-enhancing medicines being discussed  
21 today.

22 Today we have listened to a wide range of

1 approaches to not only the question of facilitating  
2 price competition and innovation, but also on virtually  
3 all approaches to the use of biologics, biosimilars and  
4 interchangeables. While there are forces that pull in  
5 many different directions, I find comfort in the  
6 knowledge that the FDA's longstanding goal for medical  
7 care is to ensure that the right drug or device is  
8 delivered to the right patient at the right time.  
9 RetireSafe's hope is that we will see some day soon a  
10 marketplace where doctors and patients will have an  
11 unencumbered access to the right reference biologic,  
12 biosimilar and interchangeable, unencumbered meaning  
13 that the doctors have the information they need to make  
14 an informed decision on which of these medicines is  
15 right for their patient, that the cost isn't a barrier,  
16 and most importantly that they feel the medicines are  
17 safe.

18           There is work to be done in all of these  
19 areas. The mere fact that we heard the term  
20 "interchangeables" to describe different aspects of  
21 today's marketplace underscores the wild west nature of  
22 our current environment. Some biosimilars are being

1 treated like they are interchangeable, before there is  
2 even a final definition of what an interchangeable  
3 biosimilar is.

4 Through placement negotiations, formulary  
5 manipulation and step therapy requirements insurance  
6 companies and PBM's are deciding today which drugs are  
7 interchangeable. This type of environment does not  
8 build confidence and biosimilars will not be successful  
9 if doctors are subjected to this type of manipulation.

10 Doctors can't feel safe about switching from  
11 one biosimilar to another, when there's no information  
12 or testing on this type of switch. Doctors can't feel  
13 safe when a change in the formulary necessitates a  
14 switch away from an effective medicine. We can't  
15 expect perspective biosimilar manufacturers to be eager  
16 to develop biosimilars and interchangeables when  
17 lawsuits and regulations allow reference product  
18 manufacturers to withhold needed information.

19 Drug prices and all of this talk about price  
20 competition means nothing if the patient doesn't see a  
21 reduction in their out-of-pocket costs.

22 Here are RetireSafe's recommendations. To

1 make doctors feel safe in prescribing these medicines  
2 we need detailed informative labels and requirements to  
3 test a biosimilar-to-biosimilar switch. We need a  
4 final workable, effective and safe definition of  
5 interchangeable medicines.

6 And finally, the sick can't continue to foot  
7 the bill. There continues to be cost barriers for the  
8 use of reference biologics and biosimilars. We need to  
9 lower the patients' out-of-pocket costs, even if it  
10 means an increase in premiums. There are barriers to  
11 getting the right drug to the right patient at the  
12 right time. It should always be the doctor and the  
13 patient who defines what is right.

14 RetireSafe will continue to work toward the  
15 goal of reducing the barriers in accessing the right  
16 drug.

17 Thank you.

18 DR. SHERMAN: Thank you for your comments.  
19 Our next speaker is Dr. Dennis Cryer from Biologics  
20 Prescribers Collaborative.

21 DR. CRYER: Good afternoon. My name is Dennis  
22 Cryer. I'm the lead physician co-convener of the

1 Biologics Prescribers Collaborative. We're BPC.

2 My training is in genetics and metabolic  
3 diseases. Our seven member organizations represent  
4 physicians who regularly prescribe biologics and  
5 include the Alliance for Patient Access, the Coalition  
6 for State Rheumatology Organizations, the American  
7 Association of Clinical Endocrinologists, the American  
8 College of Rheumatology, American Gastroenterological  
9 Association, the Society of American College of Allergy  
10 Asthma and Immunology.

11 I personally serve on the boards of several  
12 nonprofit organizations whose missions are  
13 complimentary to the FDA and sadly I have no conflicts  
14 of interest.

15 BPC is enthusiastic about the Biosimilars  
16 Action Plan, the BAP, and we reiterate our support of  
17 scientifically based patient centered standards. We  
18 believe the FDA to be the paradigm of the regulatory  
19 bodies around the world and advocate maintaining the  
20 highest standards of safety and efficacy, while  
21 encouraging innovation and competition.

22 Among the elements of the BAP, education and

1 communication are critical. While improving efficiency  
2 of the biosimilar and interchangeable pathways is a  
3 critical goal of BAP, it is important to provide more  
4 information rather than less. Prescribers and to  
5 patients, to support clear understanding of these  
6 rigorous processes.

7 And we do believe that many patients these  
8 days are becoming sophisticated enough to appreciate  
9 some of these details, believe it or not.

10 The FDA guidances provide clarity around  
11 regulatory pathways and we join with others in  
12 encouraging the FDA to finalize its interchangeable  
13 guidance with all reasonable haste. Supportive data  
14 must be rigorous and risk based, and we strongly  
15 recommend clinical studies which include a minimum of  
16 three switches between the reference product and  
17 proposed interchangeable.

18 And lastly, BPC will continue to advocate for  
19 a finalized interchangeability guidance,  
20 distinguishable, nonproprietary, names for all  
21 biologics, physician and patient involvement in all  
22 switching decisions, including non-medical switching,

1 clear and thorough labeling, case-by-case determination  
2 of extrapolation, and to a sister agency, unique J-  
3 codes for each biosimilar product.

4 On behalf of the Alliance of the Biologics  
5 Prescribers Collaborative, a project of the Alliance  
6 for Patient Access, I thank you.

7 DR. SHERMAN: Thank you for your comments and  
8 you made it right under the wire. Our next speaker is  
9 Dr. David Charles, Alliance for Patient Access. Dr.  
10 Charles, do you mind, we'll call up another speaker  
11 while finding your presentation? And the next speaker  
12 before Dr. Charles will be Dr. Fred Atuf (phonetic)  
13 from USP.

14 DR. ATUF: Good afternoon. My name is Fred  
15 Atuf. I'm Vice President of Global Biologics at the  
16 United States Pharmaceutical. On behalf of USP I would  
17 like to thank the Agency for the opportunity to comment  
18 on the competition and innovation in the biologic  
19 product marketplace, including facilitating  
20 availability of biosimilars and interchangeable  
21 product.

22 USP is a scientific nonprofit organization

1 dedicated to protect and improving public health. We  
2 have a long history of collaborating with FDA and other  
3 stakeholders to develop public standards and related  
4 programs that support quality of medicines, including  
5 biologics and drug ingredient.

6           Public standards have an important role in  
7 helping ensure medicine's quality, including enabling  
8 development and market entry. USP has a longstanding  
9 program in biologic standards development. For  
10 example, we have developed and maintained standards for  
11 insulin product and have contributed to development of  
12 international standard for this widely-used rug.

13           This type of standard gives diabetes patient  
14 confidence that the insulin they take is of reliable  
15 and consistent quality. USP's portfolio consists of  
16 several hundred of documentary and physical reference  
17 standard that helps biosimilar manufacturers in the  
18 development and manufacturing of biologics, including  
19 biosimilars.

20           Based on the engagement and input from  
21 stakeholders, including the FDA, we have focused in the  
22 past several years on the development of performance

1 standards. These type of standards are broadly  
2 applicable to product families and product classes and  
3 are intended to address common quality challenges  
4 associated with technologies and methodologies.

5 In the last year we conducted roundtables with  
6 organizations like the Biotechnology Innovation  
7 Organization but also the International Federation of  
8 Pharmaceutical Manufacturers and Associations, and  
9 their membership with a goal to prioritize those  
10 performance standard that most typically address  
11 challenges that companies face throughout the product  
12 development cycle.

13 We believe that the cycle support key areas  
14 identified in the FDA's Biosimilar Action Plan. It  
15 will also help maximize the scientific clarity for the  
16 product development community, and it will play a role  
17 in the development and availability of quality  
18 biosimilars.

19 In conclusion, public standards support the  
20 priorities of all stakeholders, including drug  
21 developers, drug manufacturers and regulators by  
22 identifying quality attribute, creating predictability

1 and facilitating product innovation.

2 USP is committed to actively gathering early  
3 input from healthcare practitioners, industry and  
4 regulators before and during development of standards  
5 for biologics. As the marketplace of biologic product  
6 continues to expand and evolve, USP stands freely to  
7 work closely with FDA and other stakeholder to increase  
8 the development and manufacture of these critical  
9 drugs.

10 Thank you again for the opportunity.

11 DR. SHERMAN: Thank you very much for your  
12 comments. Are we good to go? So now Dr. David Charles  
13 from Alliance for Patient Access.

14 DR. CHARLES: Thank you for the opportunity to  
15 join you today. My name is David Charles. I'm a  
16 neurologist. I serve as Chief Medical Officer at  
17 Vanderbilt's Clinical Neuroscience Institute in  
18 Nashville, Tennessee. I conduct clinical trials and  
19 see patients with movement disorders and related  
20 conditions.

21 I also serve as Chairman of the Alliance for  
22 Patient Access. The Alliance for Patient Access is an

1 organization of over 800 healthcare providers  
2 advocating for patient access to approved therapies in  
3 clinical care, and today I'm speaking on behalf of the  
4 Alliance for Patient Access.

5           The Alliance for Patient Access consists of  
6 several physician working groups, which span a number  
7 of disease states and areas. One of those working  
8 groups is the National Physicians Biologics Working  
9 Group, which brings together physicians in neurology,  
10 rheumatology, oncology, dermatology and so forth, to  
11 address policy issues relevant to biologics and  
12 biosimilars.

13           The group consistent produces educational  
14 materials about relevant policy issues, advocates to  
15 state and federal officials, and is instrumental in  
16 organizing the Annual National Policy and Advocacy  
17 Summit on Biologics and Biosimilars each year in  
18 Washington. We've had the pleasure of Dr. Christl and  
19 Dr. Kozlowski participating in those meetings in the  
20 past. We thank you.

21           Many of the speakers today have described the  
22 all-inspiring power and complexity of biologics and

1 biosimilars and at annual meetings of AFPA's Physicians  
2 Biologics Working Group, I hear similar stories. In  
3 fact, when I was training several years ago as a young  
4 neurologist, I saw patients with debilitating diseases  
5 like multiple sclerosis, struck in the prime of life  
6 causing incredible disability and what do we have to  
7 offer them for treatment? It was steroids and physical  
8 therapy.

9           And today for people with MS we have a  
10 completely different story. Biologics have far  
11 surpassed the treatments we had before and now  
12 biosimilars can provide still more treatment options  
13 and more choices for patients and physicians. But for  
14 that to happen, we need biosimilar uptake and to  
15 achieve uptake we need physicians to have the fullest  
16 confidence in biosimilars.

17           First, physicians want rigorous testing on  
18 biosimilars, particularly interchangeable biosimilars.  
19 Allowing pharmacists to swap an interchangeable  
20 biosimilar with its reference product without the  
21 prescribing physician's involvement suggests utter  
22 confidence in the therapy's similarities. Therefore,

1 it demands thorough evidence.

2 In particular, clinical trials should explore  
3 not only the clinical indication, but explore  
4 switching, not just a single switch, but multiple  
5 switches, so that data will actually predict real world  
6 use.

7 Second, physicians want to see the data for  
8 themselves. They want transparency, complete and  
9 readily available information.

10 Physicians are scientists and educators by  
11 training, and many continue a scientist conducting  
12 clinical trials like I do. As such, we find confidence  
13 in data. Plain and simple, physicians want proof.

14 We'd like to see the data on how multiple  
15 switches affects patients' response to treatment, the  
16 toll it takes on their immune system and the impact it  
17 has on the therapy's efficacy.

18 Physicians welcome more therapeutic options  
19 for our patient and we'll be on the front lines  
20 ensuring uptake. FDA's approach to date has been  
21 rightfully careful, building on a base of knowledge  
22 that can be utilized going forward, and we respectfully

1 request that the FDA should continue seeking and  
2 sharing the data that shows not just safety and  
3 efficacy but also focusing on how these medicines will  
4 be used in practice. This approach will ensure  
5 confidence in these therapies, leading to more  
6 competition and more treatment options for our  
7 patients.

8 Thank you.

9 DR. SHERMAN: Thank you for your comments.  
10 Our next speaker is Mr. James Love from Knowledge  
11 Ecology International.

12 MR. LOVE: Thank you very much. I represent a  
13 group in Washington, D.C. that does advocacy work on  
14 drug prices, intellectual property and innovation  
15 policies.

16 We recently were asked by someone -- we met  
17 with some people on the Hill about biologics  
18 competition, and we just thought it was well known that  
19 there wasn't as much competition for biologic drugs as  
20 there is for small molecules, but the staffer was I  
21 guess new and she insisted we show her some evidence of  
22 that, so we had to crank out some evidence.

1           So one thing we looked at was from 2005 --  
2           from 1995 to 2005, we look at all the novel drugs that  
3           were approved, and we tried to figure out how many of  
4           them by the end of last year, of 2017, face  
5           competition. For at least the same API.

6           For biologics, of course, therapeutic  
7           equivalence was basically zero for that group, but at  
8           least for the API's, about 17 percent of the biologic  
9           drugs face competition for similar API, but the number  
10          for the small molecules was like 61 percent.

11          And then we looked at how long did it take  
12          before you observed competition, and it was roughly six  
13          years longer on average for the biologics and the small  
14          molecules. And then we looked at the number of  
15          companies that were competing, and it was something  
16          like average of one-and-a-half for the biologics that  
17          faced any competition for the same API, and it was  
18          close to nine for the small molecules.

19          So in every dimension, every way you could  
20          describe it, the biologics market is less competitive  
21          than small molecules market, and the whole incentive  
22          system of granting a temporary monopoly to help recover

1 your R&D cost, works very differently for small  
2 molecules than it does for biologic drugs, even though  
3 there's no -- there's no real evidence of the cost of  
4 research and development, are much different between  
5 the small molecule products and the biologic drugs. In  
6 some cases the risk, for example, Phase III trials is  
7 more favorable for novel products for biologics than it  
8 is for small molecules.

9 I'll just -- the next thing we ask is what  
10 would it take to make the biologics market more like  
11 the small molecule in terms of competition, and we have  
12 a scientist to work with us and she's not here today.  
13 She's in Canada.

14 And I'm always kind of afraid I'm going to  
15 mispronounce some of the things that she told me to  
16 say, but in essence the question we had is if you  
17 didn't have to worry about patents or test exclusivity,  
18 what could you do? What could regulators do to make  
19 biologics not only more competitive but to make  
20 patients -- my wife is right now alive because she's on  
21 Concello, which is a Roche biologic drug and she'd be  
22 dead without it. And if I was to ask to switch her

1 from this drug to a biosimilar drug, she's been on  
2 chemotherapy since 2010, I would be, like most  
3 patients, maybe a little worried about that, because  
4 you don't really know and people are always trying to  
5 scare you about that stuff. So things that actually  
6 make you more confidence -- more confident rather than  
7 the biosimilar work the same as the originator's drug,  
8 those would be a positive for the patient.

9 And so she recommended that as a condition of  
10 being regulated at some point the company that sells  
11 the biologic be required to provide access to certain  
12 materials like cellular clones and highbroma (phonetic)  
13 stocks. Maybe somebody knows what those things are.  
14 Plasmid maps, sequences of antibiotic complementary and  
15 determining regions, and physical, chemo, biophysical  
16 characterizations, as well as also methods of growth  
17 conditions and protocols, attenuation or inactivation  
18 protocols.

19 DR. SHERMAN: Excuse me. Could you wrap up  
20 your comments?

21 DR. CHARLES: I am wrapping up. Thank you for  
22 reminding me of the time.

1           But I'd be happy to sort of follow this up in  
2 my written testimony. Thank you very much.

3           DR. SHERMAN: Thank you. Our next speaker is  
4 Mr. (indiscernible). I wasn't even close, was I?

5           Mr. Let me correct the name. My name is Sang  
6 Ju Lee from Sartrian (phonetic). Good afternoon. My  
7 name is San Ju Lee. I'm with the SPB with Sartrian.  
8 Thank you for this opportunity.

9           Initially biosimilar products developed as an  
10 alternative treatment for the original product. What's  
11 the next? As a developer of biosimilar products, I'd  
12 like to talk about innovation of biosimilar.

13           Biosimilar innovation includes two things  
14 maybe. One, adding a new indication which doesn't  
15 exist in the original product. Second, adding or  
16 introducing a new drug delivery system of the product.  
17 Specifically, our company is developing subcutaneous  
18 version of Remicade biosimilar. Now I encourage the  
19 FDA to be more open and flexible in biosimilar  
20 innovation.

21           In consideration of marketing approval for a  
22 change of treatment option, it is desirable to have

1 more flexible requirements, so that patients benefit  
2 from compensation treatment options.

3 Thank you.

4 DR. SHERMAN: Thank you for your comments.  
5 Our last speaker is Sondron Lee.

6 MR. LEE: it was me. Thank you. There was an  
7 error.

8 DR. SHERMAN: Oh, okay. So that concludes our  
9 meeting. Are there any additional questions from the  
10 panel for anyone?

11 On behalf of the panel I'd like to thank all  
12 the presenters and everyone in the audience, whether  
13 you attended in person and, therefore, braved post-  
14 Labor Day traffic, or if you webcast for participating  
15 in today's public hearing, which was very interesting  
16 and very productive.

17 We appreciate your attention, your interest  
18 and the time and effort you spent on your  
19 presentations.

20 As a reminder, and this is a theme you heard  
21 over and over today from the panel, we look forward to  
22 receiving your comments in the docket with as much

1 specificity and as much detail as possible. We did in  
2 the FR call up some very specific topics, but we are  
3 interested in anything -- any comments you have, any  
4 thoughts you have that relate to our biosimilars  
5 program, and it can be a topic that's the subject of  
6 another docket that's already open or perhaps a future  
7 docket, and we will make sure those connections are  
8 made.

9           If we can put up the slide with the -- how the  
10 people on the webcast can send the information for  
11 submitting to the docket is in the FR notice, and will  
12 soon be perhaps on the screen. The docket will be open  
13 through September 21st of this year.

14           A transcript from this hearing should be  
15 posted to the hearing website within 30 days, and the  
16 presentations from today's -- copies of the  
17 presentations from today's presentation will be  
18 available upon request. The information is also at the  
19 table -- and there's everything you need to know.

20           Once again, thank you for your time, for your  
21 attention, and on that note, I close today's meeting.  
22 Oh, one last thing. I'd also like to thank the FDA-ers

1 who made today happen, Alicen Hoffman, Theresa Wells  
2 and Tony. Thanks. Have a good evening and a safe trip  
3 home.

4 (Off the record at 3:43 p.m.)

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CERTIFICATE OF NOTARY PUBLIC

I, Michael Farkas, the officer before whom the foregoing proceeding was taken, do hereby certify that the proceedings were recorded by me and thereafter reduced to typewriting under my direction; that said proceedings are a true and accurate record to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this 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.



Michael Farkas  
Notary Public in and for the  
State of Maryland

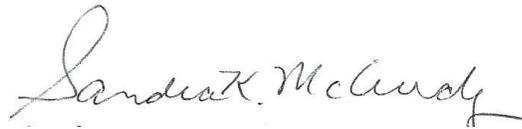
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CERTIFICATE OF TRANSCRIBER

I, Sandra K. McCurdy, do hereby certify that this transcript was prepared from audio to the best of my ability.

I am neither counsel for, related to, nor employed by any of the parties to this action, nor financially or otherwise interested in the outcome of this action.

September 13, 2018



DATE

Sandra K. McCurdy

[&amp; - 90's]

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