

*FDA/FTC WORKSHOP ON A COMPETITIVE  
MARKETPLACE FOR BIOSIMILARS*

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*March 9, 2020*

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<p>Page 6</p> <p>1 P R O C E E D I N G S</p> <p>2 (9:02 a.m.)</p> <p>3 Welcome - Eva Temkin</p> <p>4 MS. TEMKIN: Good morning. I'm told that</p> <p>5 we're already two minutes behind, so I'm going to</p> <p>6 jump in and get started.</p> <p>7 Welcome to the FDA/FTC Workshop on</p> <p>8 Competitive Marketplace for Biosimilars. I'm Eva</p> <p>9 Temkin. I'm the acting director for policy in</p> <p>10 CDER's Office of Therapeutic Biologics and</p> <p>11 Biosimilars, and I am thrilled to be here to kick</p> <p>12 off what I'm sure will be an exciting and</p> <p>13 informative day.</p> <p>14 The purpose of our workshop today is to</p> <p>15 discuss FDA and FTC's collaborative efforts to</p> <p>16 support appropriate adoption of biosimilars,</p> <p>17 discouraging false and misleading communications</p> <p>18 about biosimilars, and deterring anticompetitive</p> <p>19 behaviors in the biologic product marketplace.</p> <p>20 From my perspective, to improve patient</p> <p>21 access to life-saving therapies, we need to look at</p> <p>22 some key factors that we're going to touch on</p>	<p>Page 8</p> <p>1 preregister to attend but are in this room, you</p> <p>2 might want to head to Room 1504. That's our</p> <p>3 overflow room today. We will be streaming live</p> <p>4 audio and video to this room.</p> <p>5 Third, this Workshop is bringing together</p> <p>6 several speakers from FDA, FTC, and stakeholders</p> <p>7 who may use different terminology and bring</p> <p>8 different perspectives. Please note that views,</p> <p>9 thoughts, and opinions expressed throughout the day</p> <p>10 by any individual are not attributable to any other</p> <p>11 participant.</p> <p>12 This is the most glamorous part of my day.</p> <p>13 The restrooms are located in the lobby past the</p> <p>14 coffee area to the right and down the hallway. And</p> <p>15 finally, copies of today's presentations are</p> <p>16 available upon request.</p> <p>17 Contact information is also available at the</p> <p>18 registration table out in the hall. For media</p> <p>19 inquiries, our press officer today is Jim McKinney.</p> <p>20 If any members of the media are here today, please</p> <p>21 sign in, and if you have questions or are</p> <p>22 interested in speaking about this workshop, please</p>

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1 contact Jim.

2       There are no rules of evidence for this

3 workshop today, but there are some general

4 procedural rules that I will read very quickly in

5 the hopes of moving things along. Attendees should

6 not interrupt the presentations at any of the

7 planned panels, which will not be taking questions

8 from the audience. There will be an open public

9 comment period at the end of the day once the panel

10 presentations have concluded.

11       This workshop is subject to FDA policy and

12 procedures for electronic media coverage.

13 Representatives of the electronic media are

14 permitted, subject to certain limitations, to

15 videotape, film, or otherwise record today's

16 proceedings.

17       This workshop will also be transcribed, and

18 copies of the transcript can be ordered through the

19 docket or accessed on FDA's website approximately

20 30 days after the workshop. And on that note, I

21 would ask that all of the speakers and panel

22 participants make sure to speak into a microphone

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1 because the transcriptionist needs us to do that so

2 that the transcription can be accurate.

3       For the open public comment period of our

4 day today, we have approximately 17 speakers

5 registered to speak, and each one of them will be

6 allotted 4 minutes to present.

7       At this point in time, I believe all of the

8 oral presentation time has been allotted to

9 preregistered speakers. If that changes, though, a

10 preregistered speaker doesn't attend or something

11 opens up, there may be an opportunity for

12 additional oral presentations at the end of the

13 workshop. Please sign up at the registration table

14 outside the meeting room if you're interested in

15 doing that by 10 o'clock.

16       We also encourage you to submit to the

17 docket. You can see the Federal Register notice

18 for details on how to submit comments to the

19 docket. And I would say from my perspective, we

20 always review written comments. They're very very

21 helpful, so I really encourage folks to do that.

22 Please submit written comments by April 9, 2020.

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1 This workshop is being webcast live, however, the

2 webcast is not interactive, so viewers cannot

3 comment or ask questions.

4       With that, it is my great pleasure to

5 introduce FDA Commissioner Hahn. Dr. Hahn came to

6 FDA in December of last year after serving as the

7 chief medical executive at the University of Texas

8 MD Anderson Cancer Center.

9       In just a few short months after coming to

10 FDA, Dr. Hahn has helped bring the FDA and FTC

11 joint statement to life, reinforcing the agency's

12 commitments to taking key steps to reduce gaming of

13 current FDA requirements and coordinating with the

14 Federal Trade Commission to address anticompetitive

15 behavior. Dr. Hahn and Tara Koslov, FTC's chief of

16 staff, will be providing opening remarks for

17 today's workshop. Thank you.

18       (Applause.)

19       Opening Remarks - Stephen Hahn

20       DR. HAHN: Good morning, and thank you, Eva,

21 for that kind introduction. I'm really pleased to

22 see so many of you all joining us today, both

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1 virtually and in person. This is a really

2 important topic, and I'm especially delighted to

3 welcome to White Oak -- it's far away from downtown

4 D.C., so I appreciate your being here -- Tara

5 Koslov, who's the chief of staff of our partner

6 agency, the Federal Trade Commission.

7       I just want to stop and take a moment here.

8 This is an incredibly important topic. We'll spend

9 a lot of time today talking about it. But I do

10 want to spend a moment to acknowledge those who've

11 lost their lives to the coronavirus outbreak. We

12 very much care about what happens around the world

13 to folks who have been exposed to this and just

14 want to take a moment to acknowledge that.

15       The other thing I'd like to do is to

16 acknowledge the many people at FDA, CDC, HHS, and

17 around the U.S. government who have worked

18 tirelessly, and I can assure you of that, 24/7, to

19 address this outbreak. They are true American

20 heroes in trying to help us address this across the

21 country and the world.

22       The focus of today's meeting is an important

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1 one, to discuss the FDA's and FTC's collaborative  
 2 efforts concerning the biologics marketplace in  
 3 biosimilars. For those of us who believe in the  
 4 marketplace, it's really important that the free  
 5 market work well, and that includes making sure, as  
 6 my predecessor Dr. Gottlieb had said before, that  
 7 there are no shenanigans. It's a really important  
 8 concept, and work together trying to address that  
 9 issue.

10 We believe that getting more biosimilars,  
 11 and hopefully interchangeable, on the market will  
 12 offer great potential and have a positive effect on  
 13 the American public, both from an availability  
 14 point of view but also from a cost point of view.

15 Last month, as you know, we signed a joint  
 16 statement on our collaboration, which outlined our  
 17 shared goals and objectives and discussed how our  
 18 agencies will work together to support competitive  
 19 markets for biological products. This truly is an  
 20 example of the U.S. government in a transagency  
 21 fashion working together. It also described key  
 22 steps we intend to take to address false or

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1 misleading communication by biological product  
 2 manufacturers. This is not meant to be an us  
 3 versus them situation, but just so that everyone is  
 4 on the same level working field and moving forward  
 5 to provide as much transparent information as  
 6 possible to developers and the American public.

7 We've also released a draft guidance for  
 8 industry called Promotional Labeling and  
 9 Advertising Considerations for Prescription  
 10 Biological Reference and Biosimilar Products:  
 11 Questions and Answers. That's a mouthful but  
 12 really important information contained in that  
 13 draft guidance. We're expecting to get comments on  
 14 that, and we'll work with our partners around that,  
 15 and today we're holding this workshop, the next  
 16 important step in our collaboration.

17 What the partnership of our two agencies  
 18 means is that our combined extensive resources and  
 19 efforts in this area can have a dual focus on both  
 20 the scientific and the legal fronts. This means we  
 21 will do everything possible to support a robust  
 22 market place for biological products, including the

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1 adoption of both biosimilar and interchangeable  
 2 products.

3 On the scientific end, and we are very much  
 4 a scientific organization at FDA, we are working to  
 5 support innovation and advance the scientific  
 6 development of these groundbreaking products.  
 7 We're also engaged in very close participation, our  
 8 partnership with FTC, in activities designed to  
 9 help ensure that healthcare professionals and  
 10 patients receive truthful and non-misleading  
 11 information about biological products and to deter  
 12 anticompetitive behaviors in the marketplace  
 13 related to them.

14 I came to this job as a provider of cancer  
 15 care. I can't tell you how important it is that we  
 16 communicate with patients and providers about this  
 17 and give them the most accurate information. That  
 18 will go a long way to ensuring that these products  
 19 are available to the American public and providers.  
 20 What these activities have in common is the goal of  
 21 helping to reduce costs and enhance patient access  
 22 to these important and potentially life-saving

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1 products.

2 The development of biologics offers us one  
 3 of the best examples we have today of the potential  
 4 offered by unprecedented advances in medical  
 5 science. What we're seeing across the world, and  
 6 particularly in the United States, is  
 7 unprecedented, and we are very much interested in  
 8 bringing science innovation to the patient bedside  
 9 for providers and patients alike.

10 These products, which may be produced  
 11 through biotechnology in a living system, are used  
 12 to diagnose, prevent, treat, and cure diseases and  
 13 medical conditions. We've seen enormous progress  
 14 in this field in a relatively short period of time.  
 15 We're all working to catch up with that amazing  
 16 acceleration of innovation, and these products are  
 17 increasingly playing a central role in the  
 18 treatment of the many serious and life-threatening  
 19 diseases. In fact, in some situations, these are  
 20 the only products available to treat patients with  
 21 life-threatening situations.

22 So there's an urgent unmet medical need for

1 us to do as much as we can in this sphere, and that  
2 will likely continue to grow, and we certainly hope  
3 it does grow. Last year, we approved  
4 10 biosimilars. That makes a total since 2015 of  
5 26 for 9 different related reference products; and  
6 in the early months of 2020, we have continued to  
7 see strong momentum. Congress recognized this  
8 promise 10 years ago, and to support it, passed the  
9 Biologics Competition and Innovation Act.

10 Just as a brief moment here, we know from  
11 the generic space, the prescription side, the drug  
12 side, that the more generics we have  
13 available -- and I'm making a relationship between  
14 generics and biosimilars, and I realize the  
15 translation isn't a hundred percent correct. But  
16 we know when we introduce generics on the drug side  
17 that we significantly reduce costs, so let me give  
18 you a few facts about this.

19 If one generic is introduced to a reference  
20 product, on average, that reduces the price of that  
21 product by about 35-36 percent. If we introduce up  
22 to 6 generics in a product space, that can reduce

1 for the American public, again, with choice and  
2 competition. We've taken Congress' goal to heart  
3 and are doing everything, particularly with our  
4 great partners at FTC, to increase accessibility  
5 and help Americans realize the promise of  
6 biosimilars.

7 We're already making some significant  
8 strides, but we have more work to do, and we  
9 realize that, and we're always looking for ways to  
10 improve. We've improved the efficiency of the  
11 biosimilar and interchangeable product development  
12 approval process.

13 Across the agency we're looking at this.  
14 How do we make it more efficient? How do we make  
15 it easier for developers to provide the information  
16 to us? How do we on our end make it easier for our  
17 reviewers so that the number of review cycles goes  
18 down and the process and the timeline for approval  
19 goes down as well?

20 We are maintaining our gold standard of  
21 safety and efficacy, but we definitely want to  
22 maximize efficiency and want to provide as much

1 the price of those products by as much as  
2 95 percent. We're hoping to get the same sort of  
3 scale and approach in the biosimilar and certainly  
4 in the interchangeable space. The more we can do  
5 in this area, the better it's going to be for  
6 competition and choice for the American people.

7 We think, and our estimates are, that over  
8 the last decade, competition in the generic space  
9 has saved Americans in the healthcare system more  
10 than a trillion dollars, and we need to get working  
11 to have this occur in the biosimilar space and  
12 interchangeable space as well.

13 Biologics account for a disproportionate  
14 amount of the overall spending of prescription  
15 drugs. They're 2 percent of the total of  
16 prescription drugs but account for, by our  
17 estimates, 40 percent of the cost of prescription  
18 drugs.

19 Where we are right now is where we were  
20 before in the prescription drug side of the house  
21 and, again, the more we do work on the biosimilar  
22 interchangeable side, the better it's going to be

1 regulatory clarity for developers as possible.  
2 We're also doing our best to try to strengthen  
3 effective communications with the American public,  
4 providers, and with innovators.

5 The last point has special relevance for our  
6 partnership with FTC, and I want to focus on that  
7 for a moment. We know that a free market, as I  
8 mentioned before, and enhanced competition supports  
9 increased innovation, so it has the virtuous effect  
10 of not only helping in terms of decreasing prices  
11 as we've seen on the generic side, but also  
12 stimulating further innovation. But for it to be a  
13 free market and a fair market, it has to absolutely  
14 be free.

15 Unfortunately, since the earliest stages of  
16 the development of the biologics market, there have  
17 been obstacles to increase competition. That's not  
18 okay. We've seen efforts by manufacturers to delay  
19 competition for biosimilar products and we've seen  
20 the publication of materials that seem designed to  
21 create uncertainty about biosimilars and discourage  
22 patients and healthcare providers from using them.

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1 These behaviors have the potential to put  
 2 innovation at risk, erode public confidence in the  
 3 product, weaken efforts to lower healthcare costs  
 4 through competition, and ultimately undermine  
 5 advances in healthcare, as potential treatments and  
 6 cures are unavailable or go unrealized. At FDA, as  
 7 at FTC, we are very committed to empowering the  
 8 American consumer and the American provider, and we  
 9 must do more in that area.

10 To counter these activities, we've taken a  
 11 number of actions from the creation of the  
 12 biosimilar product development program to a public  
 13 education campaign that you all know about.

14 Our collaboration with the FTC is the next  
 15 step in our efforts to end these types of  
 16 counter-productive activities; and, Tara, I want to  
 17 thank you and Commissioner Simons for the terrific  
 18 work that you've done in partnership with us. It  
 19 will help and support and ensure an environment in  
 20 which biosimilars can fulfill their promise and  
 21 reach the patients who need them because the market  
 22 is a competitive and fair one.

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1 The FDA, as I mentioned, is a science-based  
 2 organization and data-driven, and our work is  
 3 premised on the understanding that decisions must  
 4 be based on good data and sound science. In this  
 5 way, we can promote innovation and support the  
 6 development of new treatments and cures. But this  
 7 activity must be conducted on a fair playing field  
 8 that the patients and our public and our providers  
 9 depend upon.

10 Our collaboration with FTC, as I've  
 11 mentioned, is designed to help ensure this, and I  
 12 very much want to congratulate FTC in all they've  
 13 done. Today's meeting, as I mentioned, is that  
 14 next step and, again, really appreciate the  
 15 partnership with FTC.

16 So on that note, it's my great pleasure to  
 17 introduce the chief of staff of FTC, Tara Koslov.  
 18 Ms. Koslov has served as Chairman Simon's chief of  
 19 staff since he was sworn in as chairman of FTC on  
 20 May 1, 2018. She has worked on healthcare  
 21 competition matters throughout her 23-year career  
 22 at FTC. That's really impressive staying power.

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1 Thank you for your service to the American  
 2 people, including on biologics and biosimilars.  
 3 Just in our brief conversation, I know you feel so  
 4 passionate about this subject. Prior to her  
 5 position as chief of staff, Ms. Koslov was acting  
 6 director of the Office of Policy Planning. She is  
 7 a graduate of Harvard Law and Brown University.  
 8 Ladies and gentlemen, Tara Koslov. Thank  
 9 you.

10 (Applause.)

11 Opening Remarks - Tara Koslov

12 MS. KOSLOV: Good morning, everyone. I'm  
 13 delighted to join Commissioner Hahn in welcoming  
 14 you all here today, and on behalf of FTC, Chairman  
 15 Simon, he truly regrets not being able to be here  
 16 with us today, which is why you get me instead.  
 17 But as Commissioner Hahn mentioned, I have long  
 18 worked on these issues, and I am indeed passionate  
 19 about them. So I'm pleased to be here representing  
 20 my agency.

21 Let me begin with a few thank yous. This  
 22 workshop is part of the decades-long collaboration

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1 between the Federal Trade Commission and the FDA to  
 2 promote competitive markets for pharmaceuticals.  
 3 Today, our focus is on biologics markets and what  
 4 can be done to spark competition for these  
 5 innovative new treatments.

6 I would like to thank former FDA  
 7 Commissioner Scott Gottlieb for initiating this  
 8 joint agency effort and Commissioner Hahn for  
 9 continuing it. I would also like to thank the FDA  
 10 for hosting this workshop and the many FDA and FTC  
 11 staff who made this workshop happen. An incredible  
 12 amount of work went into planning and executing  
 13 this event. As someone who has done plenty of  
 14 events at the FTC, I know exactly what goes into  
 15 putting together something like this, and I'm very  
 16 grateful for everyone's efforts.

17 Biologics, as we all know, our innovative  
 18 treatments for serious and life-threatening  
 19 diseases like cancer, diabetes, and Crohn's  
 20 disease. Often biologics are the only effective  
 21 treatments for these diseases, but biologics can be  
 22 very expensive, some costing tens of thousands and

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1 others costing millions of dollars. Total U.S.  
 2 spending on biologics is growing rapidly and  
 3 reached \$125.5 billion in 2018.  
 4 I'm going to provide the FTC's perspective  
 5 as a competition and consumer protection  
 6 enforcement agency. As many in this room already  
 7 know, the FTC has a broad mission to protect  
 8 consumers and promote competition by preventing  
 9 anticompetitive, deceptive, and unfair business  
 10 practices.  
 11 Because of the critical role competition  
 12 plays in reducing prices and fostering innovation,  
 13 the FTC has long been interested in promoting  
 14 competition in pharmaceutical markets.  
 15 One way the FTC does this is by conducting  
 16 industry studies. More than 40 years ago, for  
 17 example, the FTC published a report on state laws  
 18 that prevented pharmacists from substituting  
 19 generics for branded drugs.  
 20 The FTC concluded that these laws imposed  
 21 substantial unwarranted costs on consumers by  
 22 unduly restricting price competition between

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1 against brand and generic drug manufacturers  
 2 seeking to gain the Hatch-Waxman process by  
 3 entering into anticompetitive reverse payment  
 4 agreements.  
 5 The agency's victories include a landmark  
 6 decision by the Supreme Court in *FTC v. Actavis*,  
 7 holding that such agreements can create antitrust  
 8 liability. We've also seen favorable  
 9 interpretations of activists in other federal  
 10 courts and sweeping settlements that prevent major  
 11 manufacturers from entering into anticompetitive  
 12 reverse payment agreements.  
 13 Perhaps as a result of these successes, the  
 14 number of potentially anticompetitive reverse  
 15 payment agreements has dropped precipitously.  
 16 The FTC's experience with pharmaceuticals  
 17 also extends to the biologics industry. In fact,  
 18 the FTC brought its first enforcement action  
 19 involving a biologic almost 30 years ago. More  
 20 recently, the FTC provided technical assistance as  
 21 Congress developed the abbreviated pathway for  
 22 approval of biosimilars.

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1 generic and branded drugs. These findings helped  
 2 pave the way for now familiar state laws that allow  
 3 automatic substitution of a generic for the brand.  
 4 Similarly, a 2002 commission study on  
 5 generic drug entry recommended the brand name  
 6 companies and generic applicants, settling patent  
 7 litigation under the provisions of the Hatch-Waxman  
 8 Act, should be required to submit those settlements  
 9 to the FTC.  
 10 This recommendation was incorporated into  
 11 the Medicare Modernization Act of 2003 and is now  
 12 the primary means by which the FTC learns about  
 13 potentially anticompetitive patent settlements  
 14 between brand and generic drug manufacturers.  
 15 Following the 2018 amendments to the Medicare  
 16 Modernization Act, the FTC now also obtains and  
 17 reviews patent settlement agreements involving  
 18 biologics and biosimilars.  
 19 Another way the FTC promotes competition in  
 20 pharmaceutical markets is by vigorously combating  
 21 anticompetitive conduct. Notably, the commission  
 22 has a long record of successful enforcement actions

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1 In 2008 when Congress was weighing options  
 2 for an abbreviated pathway, the House Committee on  
 3 Energy and Commerce requested, and the FTC  
 4 provided, lessons learned from Hatch-Waxman to help  
 5 structure the new pathway, and in 2009, the FTC  
 6 testified before Congress about a follow-on  
 7 biologic drug competition to inform the debate on  
 8 the legislation that became the abbreviated  
 9 pathway.  
 10 As an aside, the commissioner who provided  
 11 that testimony at the time was actually the  
 12 commissioner I was working for at the time as her  
 13 attorney advisor, which shows you how far back my  
 14 involvement goes in these issues. So it's kind of  
 15 nice to come full circle.  
 16 Competition between reference biologics and  
 17 biosimilars is just as important as competition  
 18 between brand and generic small molecule drugs.  
 19 Biosimilars, which are as safe and effective as  
 20 their reference biologics, hold the promise of  
 21 reducing price, and therefore increasing access to  
 22 these treatments. This is because when given a



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1 choice between two highly similar products,  
 2 well-informed consumers typically choose the less  
 3 expensive option.  
 4 This competition in turn drives prices down,  
 5 but competition only works when consumers have  
 6 reliable and truthful information. In some  
 7 instances, statements from reference biologic  
 8 manufacturers and the groups they fund may mislead  
 9 patients and physicians into believing the  
 10 biosimilar is not as safe or as effective as the  
 11 reference biologic. Such deception might violate  
 12 both consumer protection laws and antitrust laws.  
 13 On the consumer protection front, while the  
 14 FTC generally supports comparative advertising,  
 15 that advertising must be truthful and not  
 16 misleading. Advertising that creates an impression  
 17 of clinically meaningful differences between a  
 18 reference biologic and its biosimilar is likely  
 19 false or misleading, and therefore would constitute  
 20 an unfair or deceptive practice.  
 21 Similarly from an antitrust perspective,  
 22 maintaining or growing share by deceiving patients

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1 and physicians about competitors offerings is not  
 2 competition on the merits. It also erects  
 3 artificial barriers to entry and creates costs for  
 4 biosimilar manufacturers who have to counter the  
 5 deception. Such deception, therefore, likely would  
 6 constitute an unfair method of competition.  
 7 The FTC is committed to taking appropriate  
 8 enforcement action against false or misleading  
 9 communications involving biologics and biosimilars,  
 10 but the FTC's enforcement priorities in this  
 11 industry extend beyond deceptive conduct. The FTC  
 12 will also seek to deter behavior that impedes  
 13 access to samples needed to develop generics and  
 14 biosimilars.  
 15 For example, just this past January, the FTC  
 16 brought its first case alleging a restrictive  
 17 distribution scheme that anticompetitively blocked  
 18 competition for a small molecule drug. The FTC  
 19 will also continue to review patent settlement  
 20 agreements involving biologics and biosimilars for,  
 21 among other things, anticompetitive reverse payment  
 22 agreements.

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1 In closing, I want to reiterate the  
 2 importance of the more than 65-year history of  
 3 collaboration between the FTC and the FDA. I  
 4 believe this collaboration has benefited American  
 5 consumers in untold ways, but most concretely by  
 6 making safe and effective treatments more widely  
 7 available and at a lower price.  
 8 On behalf of Chairman Simon and the FTC, I  
 9 thank the FDA for its critical support of the FTC's  
 10 investigations and industry studies, and we look  
 11 forward to continuing this legacy of collaboration.  
 12 Thank you all for your time this morning. I'm sure  
 13 you will all have a very productive and engaging  
 14 day. Thanks.  
 15 (Applause.)  
 16 MS. ANDRUS: Good morning. My name is  
 17 Meredyth Andrus. I'm an attorney in the healthcare  
 18 division of the Bureau of Competition at the  
 19 Federal Trade Commission. This first panel we put  
 20 together are some experts in the field to discuss  
 21 the development and licensure of biologics and  
 22 biosimilars and the post-approval uptake process.

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1 I'm going to let all of the panelists  
 2 introduce themselves. The way we will conduct this  
 3 panel is there will be two brief presentations by  
 4 Christine and by Eva, and then we will go through a  
 5 series of questions and answers that we have  
 6 prepared. So without further ado, let's jump in  
 7 and let's do some introductions first.  
 8 Surya?  
 9 DR. SINGH: Hi. Thank you for having me.  
 10 I'm Surya Singh. I'm an independent consultant, an  
 11 internist by training, and former chief medical  
 12 officer of the Specialty Pharmacy at CVS/Aetna.  
 13 I've been interested in these issues for a long  
 14 time, so thanks again.  
 15 MS. BURICH: Hi. Molly Burich, director of  
 16 public policy at Boehringer Ingelheim.  
 17 MS. SIMMON: Hi. Christine Simmon,  
 18 executive director of the Biosimilars Council,  
 19 which is a division of the Association of  
 20 Accessible Medicines, which represents generics and  
 21 biosimilar manufacturers.  
 22 MS. TEMKIN: Hi. Again, Eva Temkin. I am

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1 the policy director for the Office of Therapeutic  
2 Biologics and Biosimilars.  
3 MS. ANDRUS: Why don't we start with Eva,  
4 who will kick it off for us with a short  
5 presentation.  
6 Presentation - Eva Temkin  
7 MS. TEMKIN: Sure, with the goal of making  
8 all of you sick of me before 10 a.m.  
9 I have a short presentation that I'm going  
10 to walk through. I started with this slide because  
11 I thought it was an interesting perspective. We  
12 often hear, as we just did, parallels drawn between  
13 the promise of biosimilars and that of generic  
14 drugs, and many of the challenges, I think, may be  
15 parallel to including allegations of  
16 anticompetitive behavior and what to do about them,  
17 which is why we're all here today.  
18 To kick it off, though, I want to talk a  
19 little bit about terminology and regulatory  
20 framework just so that we can all be in the same  
21 place. What this slide lays out is essentially we  
22 have two pathways for bringing biological products

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1 to market,, 351(a) of the Public Health Service  
2 Act, which is for stand-alone or reference  
3 biologics, which are approved based on a  
4 demonstration that the proposed product is safe,  
5 pure, and potent, also known as safe and effective  
6 in some camps. Then we have the 351(k) pathway,  
7 which is the abbreviated pathway to licensure for  
8 biosimilar and interchangeable products.  
9 Now, these pathways, again, parallel what  
10 happens in the small molecule world, but they're  
11 different by design. Heterogeneity across all  
12 biological products is expected. That's why we  
13 have the standard that we have for biosimilarity.  
14 What is that standard? Well, I've put up  
15 the definition, and I know there are a lot of words  
16 on this slide, but I really want to focus on and  
17 highlight actually what's at the bottom.  
18 When we're talking about biosimilars, we're  
19 talking about products that have been demonstrated  
20 to be highly similar to the reference products and  
21 to have no clinically meaningful differences from  
22 those reference products. This is not a

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1 re-establishment of safety and effectiveness; it's  
2 a demonstration of the relationship between the  
3 proposed product and the reference product.  
4 Once approved, we have a biosimilar product,  
5 and the labeling will include relevant data and  
6 information from the reference product labeling;  
7 although notably, biosimilar product labeling may  
8 differ from reference product labeling for a  
9 variety of reasons, and we can talk about that a  
10 little bit more if it is useful for the discussion.  
11 As an example, I think it's helpful to note  
12 that a biosimilar applicant can seek licensure for  
13 fewer than all of the indications for which a  
14 reference product is approved, so that's an example  
15 of where the labeling may differ.  
16 The approved biosimilar is expected to be  
17 safe and effective just like the reference product  
18 in patients who are treatment experienced, that is  
19 in treatment with a reference product, or treatment  
20 naive, that is they haven't yet been treated with  
21 any product or with the reference product at all.  
22 What does this demonstration mean? I wanted

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1 to touch briefly on the data requirements. For  
2 demonstrating biosimilarity, we have a fair bit of  
3 guidance out in the world on this, and I'm happy to  
4 talk about it at great length, but I will endeavor  
5 to do so in one slide and one minute, essentially.  
6 Essentially, we have a stepwise approach to  
7 generating data to support a demonstration of both  
8 similarity, and what the picture does is attempt to  
9 demonstrate that the analytical similarity data,  
10 the comparative analytical data that we're looking  
11 at in a biosimilar application, is really the  
12 foundation of the analysis and the demonstration of  
13 biosimilarity.  
14 At each step, we take stock and we evaluate  
15 what residual uncertainty might be remaining, and  
16 we move on to the next step of data generation. So  
17 ultimately, the nature and scope of clinical  
18 studies will depend on the extent of residual  
19 uncertainty that remains after analytical  
20 assessment and to the extent, relevant animal  
21 studies.  
22 Generally, we consider all of these pieces

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1 of data together in the totality of evidence  
 2 approach to evaluating the biosimilarity, but we  
 3 generate the data typically stepwise in this way.  
 4 Then we have interchangeability. 351(k) has  
 5 both biosimilarity and interchangeability in it.  
 6 An interchangeable product is defined actually in  
 7 Section 351(i) of the Public Health Service Act as  
 8 a product that can be substituted for the reference  
 9 product without the intervention of the healthcare  
 10 provider, and I think we'll talk a lot, both in  
 11 this panel and over the course of the day, about  
 12 what that means and the importance of  
 13 interchangeability.  
 14 I wanted to make sure that we included a  
 15 little bit about the additional data requirements  
 16 that we typically look for -- well, that we hope to  
 17 typically look for. We don't have licensed  
 18 interchangeables at this point.  
 19 We do have final guidance on demonstrating  
 20 interchangeability, which is where this can all be  
 21 found, but essentially it's still a totality of the  
 22 evidence approach.

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1 We're still talking about stepwise data  
 2 generation, but we do require for an  
 3 interchangeable, the statute requires that the  
 4 proposed product be demonstrated, that it will be  
 5 expected to have the same clinical result as the  
 6 reference product in any given patient, and that  
 7 there won't be an increased risk either in safety  
 8 or in reduced effectiveness from switching back and  
 9 forth between the reference product and the  
 10 proposed interchangeable.  
 11 So that's a lot of words about regulatory  
 12 standards. I wanted to close by circling back to  
 13 how enthusiastic we are about biosimilars and  
 14 interchangeables and how excited we are about the  
 15 potential for these products to really enhance  
 16 patient access.  
 17 We at the FDA have and continue to play a  
 18 critical role in facilitating access to biosimilars  
 19 and hopefully interchangeables some time in the  
 20 soon future. We have 76 development programs  
 21 referencing 38 reference products, and we're  
 22 feeling pretty good about the promise of

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1 biosimilars as we go into this exciting day.  
 2 Presentation - Christine Simmon  
 3 MS. SIMMON: Great. Thank you, Eva, and  
 4 good morning to everyone. I actually want to start  
 5 with my second slide because it's a Monday, so that  
 6 fits.  
 7 I think, as was mentioned this morning,  
 8 there are now 26 biosimilars approved by the FDA,  
 9 which is very exciting. I think we should all take  
 10 a moment to bask in that. Twenty-six. Many of us  
 11 have sat in this room, many, many, many, many  
 12 times, at ADCOM meetings and public workshops  
 13 around biosimilars, and here we are with 26  
 14 approved.  
 15 This slide indicates the 15 that are on the  
 16 market. Think about the 26 that are approved.  
 17 There's the five-year anniversary of the FDA's  
 18 approval of Sandoz's Zarxio just this week or last  
 19 week maybe. The most recent biosimilar to reach  
 20 the market a couple of weeks ago is the third,  
 21 Herceptin, which I think, as Commissioner Hahn  
 22 mentioned this morning, with greater competition

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1 and multiple products in the marketplace, you start  
 2 to see increased access and savings for patients,  
 3 which is of course all of our mission here.  
 4 So that's very exciting. Yet, if 15 of the  
 5 26 approved are marketed, that obviously means that  
 6 there are 11 --  
 7 (Brief pause.)  
 8 MS. SIMMON: Well, what it will show, when  
 9 we see it, are the 11 that are not yet  
 10 approved -- excuse me, not yet marketed.  
 11 I think as we talk about biosimilars here in  
 12 2020, we have every reason to be optimistic. But  
 13 there's a difference between being an optimist and  
 14 being a cockeyed optimist. I think that we do have  
 15 to be mindful of the challenges that we still  
 16 face -- where we can have a slide, and I promise  
 17 you a different slide --  
 18 (Laughter.)  
 19 MS. SIMMON: -- that has 11 that are not on  
 20 the market. So let's try to go backwards.  
 21 (Technical difficulty.)  
 22 MS. TEMKIN: This is not FDA trying to avoid

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1 talking about the biosimilars that have not been  
 2 marketed; I promise.  
 3 MS. SIMMON: I'm going to put the really  
 4 optimistic slide up, and that's the one that made  
 5 it. This is the middle slide of three, and the  
 6 prior slide talks about the challenges that we're  
 7 going to talk about somewhat today.  
 8 There are some challenges, obviously, around  
 9 biosimilars, and we want to focus on those so that  
 10 we can reach the point of cockeyed optimism. You  
 11 think about these in a couple of different  
 12 categories, the challenges around development and  
 13 then the challenges to a viable and competitive  
 14 biosimilars market.  
 15 Ha! There they are, the ones not yet  
 16 marketed, but we've so moved on from that, but  
 17 thank you.  
 18 (Laughter.).  
 19 MS. SIMMON: The challenges around  
 20 biosimilar development, you can think of those  
 21 around the clinical studies, particularly the  
 22 bridging and the confirmatory studies in phase 3.

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1 All these are very costly studies and very  
 2 necessary to achieve the FDA designation of "no  
 3 clinically meaningful differences."  
 4 But as you look at the cost to develop  
 5 biosimilars, and ways to work on the bridging, and  
 6 think about what's really necessary in terms of  
 7 clinical studies -- which I do think the FDA is  
 8 looking at hard and has been helpful and somewhat  
 9 flexible in their guidance, particularly in the  
 10 insulin guidance which came out, which was very  
 11 helpful in its flexibility -- these are things we  
 12 want to continue to examine.  
 13 Obviously patent abuses and patent thickets,  
 14 these are critically important to combat in order  
 15 to get biosimilars to the market and through the  
 16 development process. When you look at the market  
 17 itself, exclusionary contracting practices has been  
 18 a lot in the news of late. This is, again,  
 19 something that's stymieing the ability of a  
 20 biosimilar to get on the formulary and get to the  
 21 market.  
 22 Similarly, the rebate trap, I think we're

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1 all familiar with that. We're familiar with the  
 2 lawsuits that have been filed around that. I know  
 3 today we'll be talking about misinformation. I  
 4 think misinformation is a really broad category.  
 5 You can have explicit misinformation, which  
 6 the agency, FDA, is addressing, and FTC, in their  
 7 guidance document around communication, but also  
 8 implicit misinformation, which we at the  
 9 Biosimilars Council would argue includes current  
 10 policies around naming and even the very existence  
 11 of the interchangeability designation, which of  
 12 course is part of the statute but is also unique to  
 13 the United States.  
 14 Finally, reimbursement and formulary  
 15 replacement issues we may not get to today but,  
 16 again, are very important. Really, more under the  
 17 purview of the Centers for Medicare and Medicaid  
 18 Services, they did, in their most recent draft call  
 19 letter, seek to potentially address this through  
 20 the potential for a preferred and non-preferred  
 21 tiering system in the specialty category, which  
 22 would be useful for biosimilars.

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1 So again, optimism, somewhere between  
 2 cautious and cockeyed. I think that we have a lot  
 3 of good things to discuss, so I look forward to the  
 4 questions. Thank you.  
 5 Panel Discussion - Meredyth Andrus  
 6 MS. ANDRUS: Thank you, Eva and Christine.  
 7 The first question we have involves the  
 8 development of biosimilars. Every single year, for  
 9 the past four or five years, there have been  
 10 increasing numbers of approved biosimilars, but  
 11 there still are questions and uncertainty.  
 12 Are there any areas where the FDA could  
 13 provide additional guidance that would be helpful  
 14 to manufacturers, to consumers, and to healthcare  
 15 providers?  
 16 MS. TEMKIN: I can jump in for a second.  
 17 Some of you have probably heard me talk about a  
 18 white board that I have in my office, which has a  
 19 list of policy development projects and guidance  
 20 development projects that we hope to undertake, and  
 21 that that list is constantly shifting in priority.  
 22 But what we do know -- and I point to the

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1 biosimilars action plan that the agency put out in  
 2 the summer of 2018, I guess.  
 3 The whole point here is to provide  
 4 additional clarity and certainty and to help with  
 5 efficiency in biosimilar development to support  
 6 biosimilar development. That biosimilar action  
 7 plan includes FTC collaboration and a lot of this  
 8 work that we're doing, but it also includes areas  
 9 of additional guidance, and reviewing our  
 10 regulations, and modernizing those, and a lot of  
 11 big ticket projects that we have been undertaking  
 12 and continue to undertake.  
 13 All of that by way of background, it's super  
 14 useful from my perspective to hear what folks need,  
 15 what industry needs, and what people in the world  
 16 outside of the agency are thinking as priorities  
 17 for additional clarity, so we certainly would  
 18 appreciate hearing those thoughts. I'm sure we'll  
 19 hear some of them during the open comment period as  
 20 well.  
 21 MS. ANDRUS: The United States is the only  
 22 major jurisdiction worldwide with an

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1 interchangeable designation for biosimilars. As  
 2 demonstrated with the recent draft insulin  
 3 immunogenicity guidance, FDA has significant  
 4 flexibility in interpreting the statute as well as  
 5 the authority to issue product class-specific  
 6 guidance.  
 7 Two questions: Does the designation still  
 8 hold value here in the United States, and does FDA  
 9 have a role to play in determining that?  
 10 MS. BURICH: I'll start on that. I think  
 11 the answer to does the designation of  
 12 interchangeability hold value in the U.S., the  
 13 answer is yes, although it depends on the product  
 14 and it depends on whether the product is, in fact,  
 15 physician administered, a medical benefit product,  
 16 or a pharmacy benefit product.  
 17 The reason why that's meaningful is, as Eva  
 18 noted earlier, the primary draw of  
 19 interchangeability is that automatic substitution  
 20 that can occur at the pharmacy level. In other  
 21 words, if you don't have that pharmacy interaction,  
 22 whether retail or specialty, interchangeability

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1 doesn't have a whole lot of significance if there  
 2 isn't that pharmacist interaction.  
 3 As Christine's slides noted, the number of  
 4 approved products, all 15 of those products, are  
 5 medical-benefit, physician-administered products.  
 6 I think that's an important piece of context around  
 7 why interchangeability continues to be talked  
 8 about, but we haven't seen it yet. It's really, in  
 9 part, because of the type of products that  
 10 interchangeability is relevant to. And while we  
 11 have several approved self-administered  
 12 biosimilars, we have none that are launched and  
 13 won't be launched for the next couple of years.  
 14 So we still have some time until we see an  
 15 interchangeable potentially come to market and  
 16 until we see the products where interchangeability  
 17 has value in terms of that pharmacist interaction.  
 18 We still have a little ways to go until we get  
 19 there.  
 20 MS. SIMMON: I would just add, again, that  
 21 it is important and helpful to have  
 22 product-specific guidance on interchangeability, as

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1 we did see in the case of insulin. Also, we look  
 2 forward to FDA making more of a determination  
 3 around what the name of an interchangeable product  
 4 will be. It's really not clear. We know that  
 5 transition insulins won't have a suffix, so it  
 6 could be that there might be special considerations  
 7 for interchangeables, and we'll want to hear more  
 8 about that.  
 9 On the point Molly made, interchangeability  
 10 is more important, in some ways, at the retail  
 11 pharmacy setting and when it becomes part of the  
 12 Part D benefit and you see it more frequently. We  
 13 have heard from pharmacists that they might not be  
 14 comfortable doing the switching if the name is  
 15 going to be something that's going to be different  
 16 and confusing for them and their patients.  
 17 Of course there are state laws. We've made  
 18 a lot of progress in amending the state laws to  
 19 account for interchangeable biosimilars, but there  
 20 may be some state laws that still have to be  
 21 addressed.  
 22 DR. SINGH: One quick comment about the

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1 products that have launched already in terms of the  
 2 complexity of the competition, I think in the case  
 3 of infliximab, where you have actually both medical  
 4 and pharmacy adjudicated and the presence of both  
 5 benefits being used, it introduces a whole other  
 6 area, again, of a marketplace complexity.  
 7 The deals that get arranged and the  
 8 influence of rebate bundling, competition, and the  
 9 application of formulary that can be run  
 10 cross-benefit is very splintered to the marketplace  
 11 right now and different by health plan and PBM.  
 12 So you have that presence as well as the  
 13 medical benefit side, and that makes it even more  
 14 complicated, which I'll return to when we come to  
 15 the latter questions.  
 16 MS. ANDRUS: There are, as we saw, 26  
 17 approved biosimilars in the United States, but only  
 18 15 are actively marketed. What might explain why  
 19 the other 11 are not actively marketed?  
 20 DR. SINGH: I can start, and I'm sure others  
 21 have comments about this, too, because it's sort of  
 22 a central theme.

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1 Thinking back to the slides that Christine  
 2 showed, and she articulated this well, I think I'll  
 3 just elaborate a little bit. The first one, before  
 4 I get to some of the purely marketplace commercial  
 5 issues, is the idea of the patent thickets. I  
 6 think there's a paper in JAMA last year -- and this  
 7 is publicly available information, so I'll quote a  
 8 couple of statistics.  
 9 Adalimumab as an example has over a hundred  
 10 patents. Eighty-nine percent of them were filed  
 11 after the original launch of that medication. So  
 12 you just think about that and think about the  
 13 barrier to having a biosimilar for that particular  
 14 medication, or any others into the marketplace,  
 15 it's certainly a lot more complicated to wade  
 16 through that patent thicket, if you will, to use  
 17 that terminology that's taken over the market.  
 18 The second and third are really interrelated  
 19 about the other 11 and why they haven't launched.  
 20 They're both commercial and contracting issues.  
 21 One is that the same manufacturers, or sometimes  
 22 marketplace arrangements between manufacturers, are

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1 involved in both the innovator, if you will, the  
 2 originator biologic, and the biosimilar.  
 3 So the contracting, especially the big  
 4 consolidated procurers of drugs on the specialty  
 5 pharmacy side of the market and the way that the  
 6 contracting happens, there's a relationship between  
 7 the contracting for those new biosimilars and the  
 8 originator biologic that are very hard to  
 9 disentangle.  
 10 That bleeds into the third issue of what was  
 11 called before -- I think part of what was  
 12 underneath the rebate trap, and you may want to  
 13 elaborate on that, is that the rebates in that  
 14 particular category may be driven by a bunch of  
 15 different factors.  
 16 It's different on the medical benefit side,  
 17 again, and the pharmacy benefit side. You'll hear  
 18 all of us, I think, agree that the issues in  
 19 contracting and procurement are pretty unique on  
 20 the medical benefit side where the market is much  
 21 more splintered.  
 22 If you have a few major entities doing

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1 contracting on behalf of a lot of covered lives on  
 2 the pharmacy benefit side, the bundling of  
 3 rebates, if you will, across categories, where  
 4 there are interdependencies, is much more common  
 5 than when you have individual practices or  
 6 hospitals and health systems doing the contracting  
 7 on the medical benefit side. So that's the other  
 8 major issue.  
 9 But getting back to the question of why have  
 10 some of these other 11 not launched, I think what  
 11 I've observed and then heard in a variety of  
 12 different forms in the market is that some of the  
 13 manufacturers are taking a bit of a wait-and-see  
 14 approach, especially in what's going to happen with  
 15 the rebate trap or changes structurally, and the  
 16 way that rebates are both contracted and then  
 17 ultimately invoiced and administered in the market.  
 18 It's a dynamic issue.  
 19 There was obviously a lot of talk about  
 20 removing the anti-kickback protection for rebates  
 21 last year and Medicare, and I think a lot of the  
 22 manufacturers are just watching the changes that

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1 may happen structurally very closely before they  
 2 make a decision.  
 3 MS. SIMMON: Surya, you made a lot of great  
 4 points, and I think that's exactly right. A lot of  
 5 these issues are clearly around the rebate traps,  
 6 the exclusionary contracting, and the cost of  
 7 litigation. I would add on to that a couple of  
 8 things.  
 9 With respect to litigation, we want to  
 10 commend the FDA for its recent changes to the  
 11 Purple Book, making it more easily searchable  
 12 electronically. That's a huge benefit for  
 13 biosimilar manufacturers and others.  
 14 Of course what would help even more, and we  
 15 know this is outside the agency's purview, is to  
 16 require patents to be listed for biologics and  
 17 reference products in the Purple Book. We support  
 18 legislation. There's a bill that's been introduced  
 19 by Senator Susan Collins around this called the  
 20 Biologic Patent Transparency Act -- it rolls right  
 21 off the tongue -- and to ensure that this happens  
 22 to foster the potential for development.

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1 Let's say you're a biosimilar manufacturer  
 2 and you get to see patents listed in the Purple  
 3 Book. Once you've cleaned up your coffee from  
 4 spitting it out when you saw the number of patents  
 5 listed, you start to contemplate litigating them.  
 6 It's about \$3 million to get through this  
 7 litigation, which is a large expense for biosimilar  
 8 manufacturers.  
 9 Think about that Humira, for example, was  
 10 first approved in 2002, and there are 5 biosimilars  
 11 approved for it, but none are on the market. We  
 12 know that there will be a bunch coming onto the  
 13 market but only due to the ability to enter into  
 14 patent settlement agreements with AbbVie.  
 15 Because of patent settlement agreements,  
 16 which in this case are very pro-competitive, these  
 17 biosimilars will get to the market 11 years earlier  
 18 than might otherwise be possible. This is alluded  
 19 to in the introductory remarks. The FTC of course  
 20 has been very active and has done a lot to ensure  
 21 that patent settlement agreements are  
 22 pro-competitive.

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1 So hopefully we can put to rest the misnomer  
 2 of pay-for-delay and think of them as they really  
 3 exist, and how much it will help the patients who  
 4 might not otherwise receive Humira until 2034  
 5 without these settlement agreements.  
 6 We continue to work to make sure that  
 7 biosimilar manufacturers have the ability to enter  
 8 into these settlements and also to use inter partes  
 9 review, which is an administrative process to  
 10 challenge patents that are constantly under threat.  
 11 There are those who seek to exclude pharmaceutical  
 12 products from the ability to pursue inter partes  
 13 review and settle these patent issues or address  
 14 them administratively, which can be more efficient  
 15 and less expensive than going through litigation.  
 16 These are some of the issues I just wanted  
 17 to bring to light as to answer the broad-based  
 18 question of why they're not all on the market, in  
 19 addition of course to the rebate issues as Surya  
 20 pointed out.  
 21 MS. ANDRUS: Thanks.  
 22 Are there any significant differences in

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1 uptake rates between biosimilars that are approved  
 2 to treat ongoing or chronic conditions and  
 3 biosimilars approved to treat acute conditions, and  
 4 what might account for that if there are?  
 5 DR. SINGH: Yes, I can start here also. I  
 6 think the distinction between the acuity or  
 7 chronicity of the underlying condition is helpful,  
 8 but it draws back into focus the very specific  
 9 conditions and the benefit under which they're  
 10 adjudicated commonly that were on the list that  
 11 Christine presented. I think that distinction has  
 12 more impact on what adoption has looked like so far  
 13 than the acuity or the chronicity of the underlying  
 14 condition.  
 15 Just very specifically, now that we have  
 16 bevacizumab, trastuzumab, and rituximab biosimilars  
 17 on the market, as soon as we have enough data to be  
 18 able to really examine what the uptake curves and  
 19 the adoption curves have looked like for those  
 20 medications, we'll be able to validate what I'm  
 21 saying.  
 22 I think in the example of the white and red

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1 cell growth factor biosimilars, the adoption curves  
2 versus infliximab, where I was saying it's been  
3 more complicated because of this dual benefit  
4 approach, that there's a lot of that particular  
5 category for -- just to broaden it a little  
6 bit -- both GI and RA, issues or conditions,  
7 rheumatologic and gastroenterologic conditions,  
8 that the drug treats.

9 The management of it, from both the  
10 utilization management or formulary management  
11 standpoint, has been more complicated because of  
12 that dual benefit approach; whereas on acute or for  
13 a finite period of time, administered medications  
14 purely under medical, again back to the health  
15 system and provider procurement of the medication,  
16 we see a better degree of steeper uptake curve.

17 So I think that's what we're going to see  
18 with bevacizumab, trastuzumab, and rituximab once  
19 the data is available, but that's kind of how I  
20 frame it.

21 MS. SIMMON: I think that's right. You can  
22 sort of put some names to it. You can see that

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1 systems like Kaiser and smaller health systems that  
2 have integrated delivery networks are going to have  
3 greater uptick for all the products. Large  
4 academic medical centers like Mayo and Johns  
5 Hopkins are not having such rapid uptick of  
6 biosimilars.

7 So it does speak to the financial component  
8 that's at play in these systems, which speaks to  
9 the perniciousness of getting to all the factors  
10 that are influencing biosimilar utilization and  
11 uptake.

12 DR. SINGH: I just wanted to make one other  
13 following comment because you've raised a point,  
14 and I'm not sure if there's another place to say  
15 this. So I just want to make sure that I put it  
16 out there.

17 I think the idea of misinformation or  
18 misleading information influencing prescribers  
19 decisions about biosimilars, I think we've sailed  
20 past that. There's a lot of survey data to support  
21 this but anecdotally also. A lot of leaders of  
22 large multidisciplinary practices, Kaiser included

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1 but large oncology practices, rheumatology  
2 practices, et cetera, there's no reluctance anymore  
3 to speak of to use biosimilars. Really, the market  
4 is being driven by economics, and I think that's  
5 what's going to dictate the adoption curves that we  
6 see.

7 MS. ANDRUS: So if there's no lingering  
8 reluctance on the part of the physicians and  
9 there's no real difference between acuity and  
10 chronicity, are there any unique characteristics in  
11 any of the therapeutic categories where biosimilars  
12 have been approved and launched that have slowed  
13 uptake?

14 MS. BURICH: I think the points that have  
15 been raised are really important. I think that in  
16 the same way is it acute versus chronic, is it  
17 immunology versus oncology, I think what we see is  
18 the mix of products, the benefits they're covered  
19 under, and it's sort of all of these factors that  
20 are coming together that are making -- while we're  
21 seeing significant strides in the number of  
22 approved products and the number of launched

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1 products, we still know that uptake in a lot of  
2 areas is lower than we want it to be, both from a  
3 overall outlook of the sustainable nature of the  
4 biosimilar market, but also just to generate  
5 savings at a time when drug pricing is in such  
6 focus within the U.S.

7 So I'm sort of in a similar boat as the  
8 other panelists, which is that I think it's maybe  
9 less about the specifics of the products and more  
10 about where the existing launched products sit  
11 within our system and what some of those dynamics  
12 are. I think that is what is proving to be an  
13 important piece that we haven't quite connected all  
14 the dots to, to get the market moving consistently  
15 across all the products.

16 MS. ANDRUS: Do providers have varying  
17 incentives to use biosimilars or to use the  
18 reference product? Generally speaking, what role  
19 do insurers play in moving share to a biosimilar,  
20 and what is the impact of most biosimilars and  
21 biologics that are dispensed not in a pharmacy  
22 setting but rather in hospitals, and clinics, and



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1 doctors offices, through a medical benefit plan?  
2 DR. SINGH: I can start on this also. The  
3 first question in there, I think that provider  
4 incentives do vary a lot, so let me just take a  
5 step back and give a little bit of a macro picture  
6 using some of the specific classes and agents where  
7 we have biosimilars in the market already,  
8 particularly infliximab.  
9 Again, I'll start with the point that when  
10 it's purely, or at least let's say 90 percent,  
11 adjudicated under the medical benefits, it's a very  
12 different picture than when there's a lot of  
13 pharmacy benefit involvement.  
14 At the inception of white-cell growth  
15 factor, the introduction of biosimilars for both  
16 filgrastim and pegfilgrastim now, much more of it  
17 on a percent basis, if you look at the most recent  
18 publicly available reports from IQVIA and others, I  
19 think they illustrate the point that there's been  
20 more shift towards some white-cell growth factor  
21 going through the pharmacy benefit and being  
22 adjudicated as a pharmacy drug, then medical over

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1 time over the last five years.  
2 As that's happened, and then we watch what's  
3 happened with infliximab, you start to get to the  
4 point that the provider incentives -- there's a lot  
5 in the word "incentives" there. There's the  
6 economic incentive. There's also the ease of  
7 administering the same agent and inventorying the  
8 same agent in your practice for all patients that  
9 you see.  
10 The complication has been the action of the  
11 other stakeholder group that you mentioned in the  
12 second question, is insurers. Insurers have  
13 increasingly used their leverage, basically, to be  
14 able to say we're only going to allow pharmacy  
15 adjudication of some drugs, and we're either going  
16 to, quote/unquote, "white bag" or we are going to  
17 supply through our affiliated specialty pharmacy or  
18 our network specialty pharmacy's drug to a  
19 practice.  
20 That further complicates this issue of the  
21 provider incentive because now the provider, if you  
22 put yourself in their shoes, is stuck saying I have

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1 this inventory of drug that I contracted the best  
2 rate possible. I'd like to give it to all  
3 patients, but I can't use it for everyone. I'm  
4 required to accept drug from a specialty pharmacy  
5 and administer to patients and bill just for my  
6 services rather than billing for the drug.  
7 So the provider incentives vary a lot, and  
8 the complications on their business and how they do  
9 their drug inventory and all that can't be  
10 basically overstated. I mean, it's a huge issue  
11 for many of these practices.  
12 The last thing I'll say before I give others  
13 a chance to comment about the insurer role, there's  
14 both the supply chain aspect and then this idea  
15 that they're not going to allow providers to  
16 contract and bill them for whatever version of  
17 drug, the incumbent or the biosimilar, the original  
18 biologic or the biosimilar.  
19 There's that issue, and they will,  
20 quote/unquote, again, "deliver or white bag" drug  
21 to the practice, and that's more a common practice  
22 now than it was five years ago for sure. I can't

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1 give you a percentage because it's definitely  
2 different region by region.  
3 The other issue for insurers is this whole  
4 idea of fail first and being able to use  
5 utilization management and prior authorization,  
6 which is much more streamlined than it was, but  
7 much more omnipresent I guess on the medical  
8 benefit than it used to be.  
9 PA is used on the medical benefit a multiple  
10 of where it was five years ago. It's always been  
11 used extensively, as I think everyone is probably  
12 aware, on specialty pharmacy drugs on the pharmacy  
13 benefit, but it's much more common on the medical  
14 benefit now as well. So insurers are really using  
15 that as a way to drive their preferred product  
16 strategy.  
17 MS. TEMKIN: Can I ask a little bit of a  
18 follow-up question? I'm going off script, so  
19 forgive me.  
20 Just to tie it back to some of the  
21 discussion about interchangeability and where that  
22 fits in, how does the avenue of interchangeability

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1 versus biosimilarity impact some of the incentive  
 2 structures, if it does?  
 3 MS. BURICH: I think it's a really important  
 4 question. I think this is why I think your  
 5 question is quite apropos on why this medical  
 6 benefit versus pharmacy benefit is such a  
 7 significant difference, and therefore impacts the  
 8 overall flow of incentives and everything else.  
 9 I think when you think about an  
 10 interchangeability designation, your physician does  
 11 not have the same financial skin in the game as  
 12 they do on the medical benefit side because, again,  
 13 interchangeability is very likely tied to products  
 14 that have that pharmacy interaction, so that  
 15 inherently changes the incentive structure because  
 16 physicians aren't inventorying and managing the  
 17 cost of those drugs.  
 18 DR. SINGH: I'm going to paraphrase what you  
 19 said. I think that was really good. I think  
 20 substitutability, substitution, as a result of  
 21 having interchangeable designation for a practice,  
 22 when they have all the issues that I was just

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1 talking about with inventory and so on, they've  
 2 already chosen what they're going to procure and  
 3 gotten best price on what they're going to procure  
 4 and stick in their inventory.  
 5 Forget the white bagging that gets sent to  
 6 them on a patient-specific basis to get  
 7 administered. They've already chosen, and they're  
 8 going to prescribe that specific agent. So  
 9 interchangeability basically does nothing in that  
 10 case.  
 11 Under the medical benefit, when you've  
 12 chosen what you're going to inventory, and you're  
 13 the big practice, and you have 40 sites to manage,  
 14 and everybody got shipped out the same version of  
 15 pegfilgrastim now, and it's a biosimilar, that's  
 16 what they're going to prescribe. It's in their  
 17 EMR, it's in the protocols, et cetera.  
 18 Flip it over to the pharmacy benefit side,  
 19 and now interchangeable really matters because it's  
 20 specialty pharmacy. If I'm the specialty pharmacy,  
 21 it's only going to ship out what is my preferred  
 22 product, and I can only do that if the pharmacist

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1 in my specialty pharmacy has the right to  
 2 substitute. They get the right to substitute,  
 3 without having to go back to the provider to, to  
 4 the prescriber, if they have the interchangeable  
 5 designation.  
 6 So on the pharmacy benefit with drugs, it  
 7 really matters. You'll see, I think, a completely  
 8 different uptake curve, adoption curve, on the  
 9 pharmacy benefit because of interchangeable  
 10 designation. It'll make virtually no difference on  
 11 the medical benefit side.  
 12 MS. SIMMON: Just before I move on, I think  
 13 we'd be remiss if we didn't talk about some of the  
 14 legislative proposals out there around provider  
 15 incentives. There is a bill to increase the  
 16 reimbursement for providers in Part B from ASP plus  
 17 6, the average sales price plus 6 percent of the  
 18 reference biologic ASP; to increase that by  
 19 2 percent to ASP plus 8. We know the ASP plus 6,  
 20 some of the folks are I think wonky in the audience  
 21 and know that sequestration impacts that, so it's  
 22 not a true plus 6.

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1 This is interesting and useful, but I think  
 2 ultimately a limited opportunity to try to increase  
 3 provider incentives. What we support -- many of us  
 4 here at the table support, that might have a longer  
 5 term benefit -- is the opportunity to do a shared  
 6 savings program.  
 7 This practice, which is known as gainsharing  
 8 in Europe and has had success there, would allow  
 9 the provider, and in some cases could be extended  
 10 to the patient, to share in the savings that a  
 11 biosimilar provides to the Medicare program. So  
 12 taxpayers, providers, and patients could benefit  
 13 from the shared savings, which would also increase  
 14 utilization and uptake of biosimilars.  
 15 These are some opportunities, and shared  
 16 savings is something that can be done  
 17 administratively right now by the administration  
 18 via CMS and could also be a legislative proposal  
 19 and has been introduced as an amendment to current  
 20 legislation and introduced today. I think we're  
 21 expecting a bill to be dropped today on that.  
 22 So these are some, again, opportunities

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1 outside the FDA-FTC purview or our ability, but  
 2 that could have a significant impact.  
 3 MS. ANDRUS: What educational efforts to  
 4 support biosimilars have worked well? What  
 5 educational efforts are needed to counteract  
 6 misinformation being published about biosimilars?  
 7 MS. BURICH: I'll start. The materials that  
 8 the commissioner referenced earlier have been  
 9 tremendously helpful and important for all  
 10 stakeholders, physicians, and patients.  
 11 I think the materials that have been  
 12 developed by the agency are very palatable. They  
 13 take complex concepts from A to Z, from biologics  
 14 all the way to biosimilars and interchangeables,  
 15 and really try to break it down in a way, depending  
 16 on where you sit in the chain of using a product,  
 17 that you can consume that information in a way  
 18 that's reasonable.  
 19 While I hate to add to the list of the  
 20 FDA -- and I'm looking at Sarah and Eva -- I think  
 21 that we do need more education from the FDA. I  
 22 think the education that's been developed thus far

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1 was tremendously helpful.  
 2 It also brings a validity and an  
 3 impartiality coming from the FDA, and I think we  
 4 need to see that specifically around some of the  
 5 topics we've already talked about, the  
 6 interchangeables, what they are, what they aren't,  
 7 where they fit in terms of the product specifics as  
 8 we've talked about on this panel, and also where  
 9 physician-led switching can and should play an  
 10 important role for products that don't and will not  
 11 have an interchangeable designation for all the  
 12 reasons that we've talked about today.  
 13 I think that we've seen a tremendous amount  
 14 of resources that the FDA has put out, and we would  
 15 love to see a few more that are focused on a few  
 16 emerging areas because they are so important to  
 17 have that voice and those tools from a trusted and  
 18 reliable source like the FDA.  
 19 MS. ANDRUS: So we're down to our last  
 20 couple of minutes, but I wanted to throw out one  
 21 question about what we can learn, lessons learned  
 22 both from the generic industry, our experience

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1 there, and what, if anything, we can learn about  
 2 the European experience with biosimilars.  
 3 MS. SIMMON: Real quickly, I'll touch on the  
 4 parallels to the generic experience. I think we do  
 5 see some parallels, but there are significant  
 6 differences. When generics were introduced in  
 7 1984, there was slow uptake.  
 8 I just saw something with one of my  
 9 documents from 2006, back before I needed to wear  
 10 glasses to read them. I was talking at a  
 11 conference saying generics were 56 percent of the  
 12 drugs dispensed, so now generics are 90 percent of  
 13 the drugs dispensed.  
 14 Will we see that with biosimilars? That's  
 15 not completely likely, but the uptake did take some  
 16 time. There was misinformation. There were the  
 17 same efforts to mire generics in patent litigation,  
 18 and that goes on today.  
 19 So it's sort of the same playbook. Change  
 20 can be hard. And while we all applaud and  
 21 appreciate innovation, what comes with that is that  
 22 some companies go to great lengths to protect their

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1 ability to charge monopoly prices and prevent  
 2 competition. So we will continue to, I think, make  
 3 progress in the biosimilars area, and I think we  
 4 have already made progress so far, but we'll  
 5 continue that.  
 6 I think the substitution interchangeability  
 7 issue remains one of the thorniest because generics  
 8 were always designed to be substitutable and  
 9 interchangeable. So that's a difference that we'll  
 10 have to continue to work to overcome.  
 11 MS. BURICH: I would just say from a  
 12 European experience, I think what's probably most  
 13 important is that while the European pathway across  
 14 the countries of Europe has existed longer than the  
 15 United States pathway, the countries across the EU  
 16 really took a very active role, in a lot of  
 17 different ways, to drive a robust and sustainable  
 18 biosimilar market.  
 19 You have countries who are implementing  
 20 shared savings or gainsharing programs, doing  
 21 robust educational dialogue between physicians and  
 22 patients, and setting up incentives across the

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1 supply chain. And again, while the systems that  
2 exist over in Europe look very different than the  
3 systems we have here, there are some important  
4 lessons around market preparedness that we can and  
5 should be implementing now to get this market  
6 moving in a very positive direction to really  
7 generate those savings and improve access.

8 MS. TEMKIN: I would just add from my  
9 slightly different lens on all of this -- and I was  
10 not here during the early days of the generics.  
11 Don't worry; I was doing something else.

12 I think the people that are working in the  
13 agency on biosimilars and on these issues have had  
14 a takeaway of the importance of educational  
15 outreach and the importance of engaging market  
16 questions and incentives so that we can understand  
17 and do the best that we can to try to build a  
18 similarly robust structure for our different  
19 products.

20 DR. SINGH: I guess my one quick  
21 comment -- taking a step back to the macro issue of  
22 trying to use biosimilar introduction and all this

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1 competition to be able to create some headroom,  
2 basically, to pay for all of the new innovative  
3 treatments within your premium dollar with your  
4 insurance plan -- I have a lot of hope.

5 I guess parallel to the generics industry,  
6 even though we've harped on and had this refrain  
7 about the difference between the benefits, and even  
8 on the medical side, more competition is better,  
9 it's going to help us drive prices down. It gives  
10 you a better ability. Even though it's splintered  
11 in different health systems, you can procure  
12 differently to drive prices down. So I have a lot  
13 of enthusiasm that we're going to achieve the  
14 long-term goals and create that headroom that I was  
15 just talking about.

16 MS. ANDRUS: Thank you very much. We thank  
17 our panel, and our next panel will begin at 10:30.  
18 (Applause.)  
19 (Whereupon, at 10:16 a.m., a recess was  
20 taken.)

21 MR. SCHILLER: Well, good morning. We're  
22 going to begin the panel now on FDA and FTC

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1 Approaches to Help Ensure Truthful and  
2 Non-Misleading Advertising and Promotional  
3 Communications. I'm Lowell Schiller, and I'm the  
4 principal associate commissioner for policy here at  
5 FDA.

6 As we've been discussing this morning,  
7 biosimilars can offer significant benefits in terms  
8 of competition and patient access. But for those  
9 benefits to be fully realized, it's critical that  
10 patients, healthcare providers, and others in the  
11 healthcare system have an accurate understanding of  
12 what biosimilars are and aren't and how they fit  
13 into the overall armamentarium of therapeutic  
14 options.

15 That's why as FDA has been implementing our  
16 biosimilars program, we've made education and  
17 engagement a critical part of our efforts. We also  
18 recognize that sometimes incorrect or misleading  
19 information may be disseminated about drug  
20 products, including biosimilars, and that  
21 misinformation can have negative consequences for  
22 the public adoption of biosimilars, for the public

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1 health, or both.

2 For example, if a biosimilar manufacturer  
3 falsely states that its product is identical to the  
4 reference product when in fact it's not, that can  
5 mislead patients, providers, and others. On the  
6 flip side, we've seen troubling examples of  
7 biological reference product manufacturers  
8 disseminating information that could frighten  
9 patients and healthcare providers away from using  
10 biosimilars.

11 For example, we've seen communications that  
12 could sow seeds of doubt by suggesting to patients  
13 and healthcare providers that biosimilars are less  
14 safe or less effective than their reference  
15 products, or that there may be clinically  
16 meaningful differences between a biosimilar and its  
17 reference product when in fact a biosimilar cannot  
18 be licensed or marketed unless it's first been  
19 established that there are no clinically meaningful  
20 differences from the reference product.

21 Some of these communications may avoid  
22 making overtly false statements, but even material

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1 without an overtly false statement can be  
 2 misleading. For example, if it selectively deploys  
 3 a series of statements, which may be true in  
 4 isolation and perhaps omits other important  
 5 information, it's possible for the overall message  
 6 to be misleading and potentially harmful to the  
 7 public health.

8 We've seen this trick before. After the  
 9 Hatch-Waxman amendments passed in 1984 and American  
 10 patients were starting to learn about and accept  
 11 generic drugs, some manufacturers of branded drugs  
 12 disseminated materials to scare patients from using  
 13 generics, for example, by creating the false  
 14 impression that these drugs were less safe, or  
 15 weren't therapeutically equivalent, or were  
 16 inadequate in other ways. Some of the  
 17 communications we're seeing today about biosimilars  
 18 use the same old play from the same old playbook.

19 In looking at what's happened on the generic  
 20 side, the good news is that patients and healthcare  
 21 providers have come to learn the value of generic  
 22 drugs, and the adoption rate has been overwhelming,

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1 as we've heard. I believe we're also on a path to  
 2 a more vibrant biosimilars market, and part of how  
 3 we get there is by encouraging truthful and  
 4 non-misleading communications and by addressing  
 5 misinformation in the marketplace.

6 We can do that in several ways. One is  
 7 through our own education efforts. Another is by  
 8 making our expectation clear that manufacturers cut  
 9 the shenanigans. We have a system of balancing  
 10 innovation and competition that has worked very  
 11 well for many years. The system incentivizes  
 12 innovation through patents and market exclusivity,  
 13 but with the expectation that after a limited  
 14 period of time, there will be a real opportunity  
 15 for follow-on competition to take hold.

16 Brand manufacturers obviously have financial  
 17 incentives to try to stave off follow-on entry, but  
 18 when they do so through deception or regulatory  
 19 gainsmanship, it undermines our system for  
 20 balancing innovation and competition, and  
 21 ultimately we risk undermining the promise of  
 22 biosimilars.

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1 In some cases, other forms of government  
 2 intervention may be appropriate. If a  
 3 communication about a biosimilar crosses the line  
 4 and presents information that's false or  
 5 misleading, it may be appropriate for the  
 6 government to act. Both FDA and FTC have certain  
 7 tools and authorities to encourage truthful and  
 8 non-misleading communications about drug products,  
 9 including prescription biological reference  
 10 products and biosimilar products.

11 Our panelists today will be providing an  
 12 overview. Now, speaking today we have Dominic  
 13 Cirincione, who's a regulatory counsel in FDA's  
 14 Office of Prescription Drug Promotion or OPDP. He  
 15 regularly provides advice and regulatory counseling  
 16 on policy and compliance matters to both OPDP  
 17 reviewers and OPDP management.

18 Our other speaker is Richard Cleland, who's  
 19 assistant director of the Division of Advertising  
 20 Practices within FTC's Bureau of Consumer  
 21 Protection. He joined the Division of Advertising  
 22 Practices in 1991. His primary area of expertise

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1 is in the advertising and marketing of  
 2 health-related products and services, obviously  
 3 relevant today.

4 So without further ado, Dom, do you want to  
 5 take it?

6 Presentation - Dominic Cirincione  
 7 MR. CIRINCIONE: Yes, thank you.

8 Well, good morning, everyone. As Lowell  
 9 said, my name is Dominic Cirincione. I've been  
 10 since 2017 a regulatory counsel with the Office of  
 11 Prescription Drug Promotion, and today I'm here to  
 12 present how FDA, and more specifically OPDP, helps  
 13 ensure truthful and non-misleading advertising and  
 14 promotional communications about prescription drug  
 15 products.

16 OPDP'S overarching mission is to protect the  
 17 public health by helping to ensure prescription  
 18 drug product information is truthful and  
 19 non-misleading and includes a fair balance of both  
 20 benefit information and risk information.  
 21 Prescription drug information includes promotional  
 22 communications as in prescription drug advertising

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1 or promotional labeling made by or on behalf of a  
 2 drug manufacturer, packer, or distributor.  
 3 Generally, FDA and OPDP accomplishes this  
 4 through a comprehensive program, which includes  
 5 surveillance, compliance, education, and  
 6 communication with the public. Our compliance  
 7 tools include issuing warning or untitled letters  
 8 to manufacturers in regard to their disseminated  
 9 promotional materials that violate the Food, Drug,  
 10 and Cosmetic Act, and implementing regulations  
 11 concerning the promotion of prescription drug  
 12 products, particularly where the violation poses a  
 13 risk to public health.  
 14 FDA's authority over promotional  
 15 communications about a prescription drug made on  
 16 behalf of a drug's manufacturer, packer, or  
 17 distributor comes from the Federal Food, Drug, and  
 18 Cosmetic Act, or FD&C or FDCA.  
 19 More specifically, two primary or key  
 20 provisions on which FDA frequently relies are  
 21 Section 502(a) of the Food, Drug, and Cosmetic Act,  
 22 which relates to false or misleading labeling,

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1 including promotional labeling, and Section 502(n)  
 2 of the FDCA, which relates to prescription drug  
 3 advertising.  
 4 FDA has also promulgated a number of  
 5 regulations related to both drug labeling and  
 6 prescription drug advertising in Parts 201 and 202  
 7 of Title 21 of the Code of Federal Regulations or  
 8 CFR. FDA and OPDP rely upon these statutes and  
 9 regulations throughout the course of our work.  
 10 OPDP helps to ensure truthful and  
 11 non-misleading promotional communications about  
 12 prescription drug products through a variety of  
 13 tools. As noted on our previous slide, that  
 14 includes a robust surveillance and communication  
 15 program with the public, and part of that  
 16 communication plan with the public includes OPDP's  
 17 response to industry's voluntary request for  
 18 comment on specific draft promotional materials.  
 19 This process allows OPDP to provide feedback  
 20 on draft promotional communications if the  
 21 manufacturer chooses to request it. This process  
 22 also allows for OPDP to engage with the

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1 manufacturer on specific Communications prior to  
 2 their use in the public domain.  
 3 FDA and OPDP also provide guidance for  
 4 industry in areas related to promotional  
 5 communications. The guidance such as the most  
 6 recent guidance, the Q&A on biosimilar reference  
 7 product communications, provides the public with  
 8 FDA's current thinking on particular subject  
 9 matters, and many of these guidance documents are  
 10 informed, in part, by OPDP's social science  
 11 research program.  
 12 OPDP's research program is designed to  
 13 investigate applied and theoretical issues of  
 14 relevance to direct to consumer, or DTC, and  
 15 professional promotional prescription drug  
 16 materials.  
 17 OPDP's research supports the FDA's goal of  
 18 science-based policy while maintaining our  
 19 commitment to protect public health. And as  
 20 always, we invite the public to visit OPDP's  
 21 website to learn more about our social science  
 22 research program to determine more about the

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1 studies that are being conducted and to review the  
 2 new research and progress.  
 3 OPDP also employs a robust surveillance and  
 4 compliance program to monitor compliance with  
 5 applicable FDA-administered laws and regulations.  
 6 For example, OPDP regularly attends conferences and  
 7 other events to observe industry promotion, as well  
 8 as reviewing the many promotional materials  
 9 submitted to the FDA by firms in accordance with  
 10 the postmarketing reporting requirements.  
 11 OPDP also reviews and investigates  
 12 complaints from healthcare professionals,  
 13 consumers, and competitors regarding violative  
 14 promotional materials in the public domain. And  
 15 while I'm on the topic of surveillance, I did want  
 16 to remind the audience and the public that OPDP's  
 17 BadAd program may also be used to report  
 18 potentially false or misleading prescription drug  
 19 promotion to FDA and to OPDP.  
 20 You may send an email to badad@fda.gov or by  
 21 calling the toll-free number, 1-855-RXB-ADAD.  
 22 Reports can be kept anonymous, however, we would

<p style="text-align: right;">Page 85</p> <p>1 encourage reporters to leave their contact                  2 information in case we need to follow up and                  3 receive more information.                  4 If as a result of our surveillance                  5 activities we see an apparent violation of the                  6 Food, Drug, and Cosmetic Act or implementing                  7 regulations regarding promotional labeling or                  8 advertising for a prescription drug, particularly                  9 ones that pose a risk to public health, most                  10 commonly we will send a warning or an untitled                  11 letter to provide notice of the observation of the                  12 apparent violation and then seek compliance.                  13 The vast majority of our concerns are                  14 typically addressed in this way, but if these                  15 efforts to obtain compliance are not successful,                  16 FDA can work with the Department of Justice to                  17 pursue enforcement actions to address violations of                  18 the Food, Drug, and Cosmetic act. These can                  19 include, for example, seizures and injunctions.                  20 To help you better understand FDA's role in                  21 helping to ensure compliance with the Food, Drug,                  22 and Cosmetic Act and implementing regs concerning</p>	<p style="text-align: right;">Page 87</p> <p>1 leveling is a mission of risk information.                  2 Promotional materials that include claims regarding                  3 a drug's efficacy must also include information                  4 regarding the important risks associated with the                  5 drug.                  6 For example, imagine a sales aid for a drug                  7 that has a black box warning. The sales aid has                  8 multiple pages of information regarding the                  9 efficacy of the drug, but the black box warning                  10 isn't presented anywhere in the sales aid.                  11 The lack of this important risk information                  12 about the sales aid that has numerous claims                  13 regarding the efficacy of the drug would be                  14 misleading. It's an omission of risk. It's                  15 important to also note that the regulation                  16 regarding omission of risk applies to all                  17 prescription drugs, not just those of black box                  18 warnings.                  19 The second common issue related to the first                  20 is the minimization of risk information in                  21 prescription drug promotional materials. Risk                  22 information must be presented with a prominence and</p>
<p style="text-align: right;">Page 86</p> <p>1 the promotion of prescription drug products, we                  2 thought it would be helpful to provide you with                  3 some of the more common issues FDA, and more                  4 specifically OPDP, observes across all prescription                  5 drug advertising and promotional labeling that                  6 could render a presentation false or misleading.                  7 While the issues I'm about to discuss do not                  8 constitute an exhaustive list, FDA will most                  9 commonly send a warning or an untitled letter to                  10 provide notice Of our observation of these kinds of                  11 apparent issues and seek compliance.                  12 Before I continue, I do want to remind the                  13 audience that the agency's warning letters and                  14 untitled letters are publicly available on the FDA                  15 website, and each letter is also typically                  16 accompanied by the violative piece, and the                  17 application of FDA's authorities in this space is                  18 necessarily fact specific. So the details of a                  19 particular piece, including both its content and                  20 the matter of the presentation, are important.                  21 The first common issue OPDP often sees in                  22 prescription drug advertising and promotional</p>	<p style="text-align: right;">Page 88</p> <p>1 readability reasonably comparable to the                  2 presentation of the efficacy information. Many                  3 factors can impact prominence and readability; for                  4 example, the size, the style, and color of the font                  5 and layout of the piece and use of white space.                  6 Imagine, for example, that your own ad                  7 presents efficacy claims in large bold font with                  8 colorful graphics, but the risk information,                  9 however, is buried at the bottom of the page in                  10 very tiny font with no headings or no signals in                  11 any way to alert the reader to the presence of that                  12 important information. This format in which the                  13 risk information is not presented with comparable                  14 prominence to the efficacy claims minimizes the                  15 risks of the drug.                  16 The third issue we often see in promotional                  17 materials is an overstatement of the effectiveness                  18 of the drug. Promotional materials would be                  19 considered false or misleading if, for example,                  20 they; one, overstate or exaggerate the                  21 effectiveness of the drug; two, make claims                  22 regarding the efficacy of the drug that aren't</p>

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1 appropriately supported or; three misrepresent data  
2 from clinical studies.  
3 For instance, if during a sales call, a  
4 sales representative is promoting a prescription  
5 drug product and the sales representative presents  
6 a flyer which contains the claim "it works in as  
7 little as 3 days," however, according to the  
8 package insert, the primary endpoint in the  
9 clinical trials used to support the approval of the  
10 drug was "relief after 10 days," and there is no  
11 available data or evidence to support a shorter  
12 duration of treatment. Therefore, the claim  
13 misleadingly suggests the drug works faster than  
14 what has been demonstrated.  
15 A fourth common issue often seen in  
16 prescription drug promotional materials is  
17 misleading drug comparisons. Claims or  
18 presentations in prescription drug promotional  
19 materials that suggest that a drug is safer or more  
20 effective than another drug would be considered  
21 false or misleading if they are not appropriately  
22 supported.

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1 For example, imagine at a conference there  
2 was a promotional booth for a prescription drug  
3 product. A bar chart on a convention panel at the  
4 booth compares study results from the prescription  
5 drug's package insert and study results from its  
6 main competitor's package insert and includes a  
7 claim stating that it showed improvement in  
8 significantly more patients than its competitor.  
9 This comparison would be misleading because  
10 comparing the response rates for two different  
11 drugs in two different studies does not support a  
12 conclusion that one drug is safer or more effective  
13 than another because, for example, these studies  
14 may have been conducted in different patient  
15 populations or using different clinical study  
16 designs and methodologies.  
17 Just to round out my presentation here, we  
18 provided a graphical representation of observed  
19 violations noted in OPDP's warning and untitled  
20 letters for the last five years, from 2015 to  
21 present, and although false or misleading claims  
22 about the risks of drug products, or complete

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1 omissions or minimization of risk information, are  
2 the largest share of our observed violations and  
3 letters since 2015, FDA does still take very  
4 seriously false or misleading benefit claims about  
5 drug products, including comparative claims that  
6 lack adequate substantiation.  
7 In conclusion, I hope this presentation  
8 highlights some of FDA and OPDP's work to help  
9 ensure truthful and non-misleading advertising and  
10 promotional communications from manufacturers,  
11 packers, and distributors of prescription drug  
12 products. On this slide, please do find our  
13 contact information, and thank you very very much  
14 for your time.  
15 I'm going to pass it over to Mr. Rich  
16 Cleland, assistant director for advertising  
17 practices in FTC's Bureau of Consumer Protection.  
18 Presentation - Richard Cleland  
19 MR. CLELAND: Good morning. I hope you hate  
20 the morning after daylight savings time as much as  
21 I do.  
22 (Laughter.)

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1 MR. CLELAND: If I fall asleep, give me an  
2 elbow or something. I saw a lot of people doing  
3 this, this morning.  
4 This is not my usual audience. I more talk  
5 to dietary supplement companies and OTC drug  
6 companies, but I don't deal a lot in the  
7 prescription space.  
8 So this morning, I thought I would provide  
9 you with a quick tutorial on what enforcement might  
10 look like with regard to promotional material that  
11 is communication that falls outside of the FDA's  
12 jurisdiction. This includes promotional  
13 communications that don't refer to a manufacturer's  
14 or distributor's drug by name, as well as  
15 promotional communications made through what  
16 amounts to surrogates for the drug company.  
17 As a threshold matter, the FTC's  
18 jurisdiction only extends to commercial speech, and  
19 I know I've seen some stuff out there that I really  
20 question whether it would meet that threshold. We  
21 look at a number of factors to determine whether or  
22 not something is commercial speech, the content of



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1 the speech and whether it contained a message  
 2 promoting the demand for a product or service.  
 3 It could also be denigrating a competitor's  
 4 product as well, whether the speech refers to  
 5 specific products or services, whether the speech  
 6 included information about the attributes of a  
 7 product or service such as type, price, or quality,  
 8 including information about the health benefits  
 9 associated with the product; the means used to  
 10 publish the speech; traditionally is it paid  
 11 advertising, is it recognized, and would it be  
 12 recognized by consumers as advertising?  
 13 Then finally, the speaker's economic  
 14 interest in motivation in disseminating the speech.  
 15 In this regard, context matters. For example, a  
 16 peer-reviewed scientific article or a press release  
 17 may or may not be considered commercial speech  
 18 depending upon how its disseminated and how it's  
 19 used.  
 20 Now, looking specifically at advertising,  
 21 assuming we get over the commercial speech barrier,  
 22 the FTC enforces two sections of the FTC Act that

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1 are relevant here, Section 5 and Section 12.  
 2 Section 5 prohibits unfair methods of competition  
 3 and unfair deceptive acts or practices in commerce.  
 4 Section 12 prohibits the false advertisement of a  
 5 food, drug, and service.  
 6 False advertisement is defined under  
 7 Section 12 as an advertisement that is misleading  
 8 in any material respect, including the failure to  
 9 display material information. The FTC has provided  
 10 some gloss over these general principles. We don't  
 11 have all the statutes as the FDA has, but we think  
 12 these two statutes give us some pretty good tools.  
 13 A company is responsible for both express  
 14 and implied claims. In express claims, as you  
 15 heard some reference to this morning, the statement  
 16 says what the message is. They run the gambit  
 17 between express claims, virtual express claims, to  
 18 statements that few consumers would even consider  
 19 to convey a particular message.  
 20 With regard to determining add meaning, the  
 21 FTC's position is that extrinsic evidence such as  
 22 copy testing an expert testimony is not necessary

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1 to establish implied message where the implied  
 2 claim is reasonably apparent on the face of the  
 3 advertisement.  
 4 Advertisements are interpreted based on the  
 5 net impression of the advertisement from the  
 6 viewpoint of a reasonable person in the target  
 7 audience. For example, the net impression of an  
 8 advertisement may be different depending on whether  
 9 the advertisement is targeted at a person suffering  
 10 from diabetes or a physician treating diabetic  
 11 patients.  
 12 Reasonable consumers you have to understand  
 13 don't read everything in an advertisement. They  
 14 read the headlines. They may read some of the  
 15 text. It is rare that a footnote in an  
 16 advertisement will ever alter the net impression of  
 17 an advertisement.  
 18 A reasonable interpretation does not have to  
 19 be an interpretation that's accepted by a majority  
 20 of the viewers of that ad. If a significant number  
 21 of consumers would take a message away from an ad,  
 22 the advertiser is liable for any misrepresentations

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1 or deceptive content in that ad.  
 2 I think this is an important point,  
 3 particularly in this area of biosimilars. When an  
 4 ad conveys more than one meaning and only one only  
 5 one of which is misleading, the advertiser is  
 6 liable for the misleading interpretation, even  
 7 though a non-misleading interpretation of that  
 8 advertisement is possible.  
 9 In this regard, consider the general  
 10 statement that a biosimilar product is not  
 11 interchangeable with this reference product. A  
 12 very knowledgeable consumer might understand that  
 13 to mean that to receive the biosimilar instead of  
 14 the reference product, the consumer may need a  
 15 prescription from the healthcare prescriber written  
 16 specifically for that biosimilar product. That  
 17 would be a correct interpretation of that phrase.  
 18 However, a consumer, like I think most  
 19 consumers out there, relying on the common meaning  
 20 of the word "interchangeable" might interpret that  
 21 to mean that an approved biosimilar could not be  
 22 prescribed in lieu of the reference product, and

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1 that would be misleading.

2 Claims can essentially run afoul of the FTC

3 Act in three ways. It can be a false claim, it can

4 be an unsubstantiated claim, and it also can be

5 deceptive because it fails to disclose a material

6 fact.

7 Looking at some specific claims now that

8 I've observed, for example, there are clinically

9 meaningful differences between a reference product

10 and a biosimilar or that the products are not

11 similar. Biosimilars may be highly similar to

12 their reference products, but there's still a

13 chance that a patient may react differently; the

14 biosimilar product is less safe or effective than

15 the reference product or that the reference product

16 is safer or more effective than the biosimilar.

17 These statements could all be potentially

18 challenged as false, as unsubstantiated, and for

19 the failure to disclose material information. The

20 particular remedies that are available to the FTC,

21 we also have on occasion used warning letters where

22 we thought education was an appropriate first step,

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1 but we also have enforcement tools that don't

2 require us to go through the Department of Justice,

3 which gives us a great deal of flexibility. We can

4 bring our actions. These are either

5 administratively or we can use our Section 13(b)

6 authority and file them directly in district court.

7 Thank you.

8 Panel Discussion - Lowell Schiller

9 MR. SCHILLER: Well, thank you both. I

10 think we have time maybe for one question, so let

11 me start with this. We've just heard about two

12 different frameworks, I think, hopefully

13 complementary frameworks, for helping to ensure

14 truthful and non-misleading communications. I'll

15 ask both of you.

16 How do you see the recently announced

17 collaboration between FDA and FTC helping to ensure

18 the protection of public health and fair

19 competition in the marketplace with respect to

20 prescription biosimilar products?

21 Dom, do you want to start?

22 MR. CIRINCIONE: Sure. I think the

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1 collaboration will showcase how FDA and FTC both

2 support and protect public health and competition

3 in the marketplace for prescription biologic

4 products. Our organizations I think have serious

5 concerns about false or misleading statements about

6 prescription drug products and biologic products

7 and the negative impacts on public health and

8 competition.

9 I think with these shared goals in mind and

10 using our respective authorities, FDA and FTC will

11 help to ensure that healthcare professionals and

12 patients receive truthful and non-misleading

13 information about biosimilar products. It leveled

14 the playing field to support biosimilar uptake and

15 I think facilitated more competitive marketplace

16 for everyone involved.

17 MR. CLELAND: Let me take a 42-second shot

18 at this. We're going to talk more about

19 competition later on in the program today, but just

20 focusing for a second on the consumer protection

21 side, together I think we can cover the whole

22 waterfront. I think the FTC is here to try to deal

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1 with manufacturers or others that are trying to

2 avoid the FDA jurisdiction by using promotions that

3 aren't subject to your authority, so I think

4 together we can cover the full waterfront.

5 MR. SCHILLER: On that note, let me thank

6 you both for very helpful presentations, and I'll

7 try to keep us as on time as we can be. Thank you.

8 (Applause.)

9 MS. GRAY: Good morning. My name is

10 Caty [ph] Gray, and I'm the supervisor for the

11 advertising and promotion policy staff in the

12 Office of Prescription Drug Promotion or OPDP, as

13 you heard from both Lowell and Dom. I share Rich's

14 dislike of the Monday after daylight savings time,

15 so thank you to you all for being here and joining

16 in this important conversation.

17 I'm joined by Betsy Pepinsky and Dom

18 Cirincione to discuss FDA's draft guidance for

19 industry titled Promotional Labeling and

20 Advertising Considerations for Prescription

21 Biologic Reference and Biosimilar Products

22 Questions and Answers.

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1 As Lowell mentioned, Dom is a regulatory  
2 counsel in OPDP. Betsy is also an attorney, and  
3 she works as a health science policy analyst in our  
4 group, primarily focused on guidance and policy  
5 development regarding prescription drug promotion.  
6 I'm delighted that both of these experts are here  
7 to speak on this important topic, and I'm going to  
8 turn it over to Betsy to get us started.

9 Presentation - Elizabeth Pepinsky

10 MS. PEPINSKY: Thanks for that introduction,  
11 and good morning. As Caty said, Dominic and I are  
12 here to discuss the draft guidance that published  
13 just in February of this year on Promotional  
14 Labeling and Advertising Considerations for  
15 Prescription Biological Reference and Biosimilar  
16 Products Questions and Answers.

17 FDA issued the draft guidance to answer  
18 questions that firms may have when developing  
19 FDA-regulated promotional materials for their  
20 reference products and biosimilar products and to  
21 help ensure that these materials are truthful and  
22 non-misleading. This draft guidance represents one

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1 piece of the broader effort to address false or  
2 misleading communications about biological  
3 reference and biosimilar products and the negative  
4 impacts of such communications on public health and  
5 competition.

6 The draft guidance was issued by CDER's  
7 Office of Prescription Drug Promotion in  
8 consultation with CDER's Office of Therapeutic  
9 Biologics and Biosimilars and in cooperation with  
10 the Center for Biologics Evaluation and Research.

11 Again, OPDP's overarching mission is to  
12 protect the public health by helping to ensure that  
13 prescription drug information is truthful and  
14 non-misleading and includes a fair balance of  
15 benefit and risk information. Generally, FDA and  
16 OPDP accomplish this comprehensive program, which  
17 includes surveillance, compliance, education, and  
18 communication to the public.

19 Starting with a bit of background on why FDA  
20 issued this draft guidance, as the number of  
21 biosimilars increases, we have started to see  
22 promotional materials for some of these products

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1 and get questions from firms on promotional issues  
2 related to biosimilars and reference products. We  
3 are especially concerned about promotional claims  
4 and presentations that make false or misleading  
5 comparisons between a reference product and a  
6 biosimilar in a way that misrepresents the safety  
7 or effectiveness of either of these products.

8 The goal for this draft guidance is to  
9 discuss considerations to help ensure that  
10 FDA-regulated advertising and promotional labeling  
11 for reference products and biosimilars are truthful  
12 and non-misleading.

13 The guidance covers promotional issues  
14 involving both reference products and biosimilars,  
15 but some questions are focused only on biosimilar  
16 product promotion, and the guidance does not  
17 discuss considerations unique to promotional  
18 materials for interchangeable biosimilars.

19 In terms of the general requirements for the  
20 content of FDA-regulated promotional materials for  
21 reference products and biosimilar products, FDA  
22 regulates promotional labeling and advertisements

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1 by or on behalf of manufacturers, packers, and  
2 distributors for prescription drugs, including  
3 those that are biological reference and biosimilar  
4 products.

5 Under the FD&C Act in implementing  
6 regulations, these promotional materials must be  
7 truthful and non-misleading, convey information  
8 about a drug's efficacy and its risks in a balanced  
9 manner, and reveal material facts about the drug.

10 All these requirements apply to promotional  
11 materials for reference products and biosimilar  
12 products licensed under Section 351 of the Public  
13 Health Service Act, the same as they would apply to  
14 any other FDA-regulated promotional materials for  
15 prescription drugs.

16 When concerning promotional presentations,  
17 whether a promotional presentation is truthful and  
18 non-misleading involves a fact-specific  
19 determination that takes into account such factors  
20 as how the information is presented, the type and  
21 the quality of the data relied on to support the  
22 presentation, and the contextual and disclosure

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1 considerations.

2 The draft guidance is intended to help firms

3 understand how to support and present information

4 in promotional materials for their biosimilars and

5 their reference products in a truthful and

6 non-misleading way.

7 How should firms identify reference products

8 and biosimilar products in promotional materials?

9 A biological product may be identified by its

10 proprietary name, proper name, or core name in

11 promotional materials, depending on the context in

12 which the product is being described.

13 When developing promotional materials for

14 their products, firms should carefully evaluate the

15 information presented in their materials to ensure

16 that in each instance a product is addressed, the

17 materials correctly and specifically identify the

18 product to which the information applies.

19 Clearly and correctly identifying the

20 relevant biological product or products in

21 promotional materials can help prevent

22 presentations that are inaccurate because they

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1 attribute data or information to the wrong product.

2 It can also help the audience identify which

3 product or products are the subject of a particular

4 promotional presentation.

5 For instance, if a biosimilar's FDA approved

6 labeling uses the core name of the reference

7 product followed by the word "products" to convey

8 that a risk applies to both the biosimilar and the

9 reference product, it would be appropriate for

10 similar presentations about this risk and

11 promotional materials for the biosimilar to use

12 this nomenclature.

13 As another example, if promotional materials

14 include information from a study that used a

15 non-U.S. licensed comparator biologic or otherwise

16 mentioned such products, the non-U.S. licensed

17 comparator should be accurately identified as such

18 in the materials.

19 Questions 3 and 4 of the draft guidance are

20 focused on promotional considerations for

21 biosimilars and they address questions regarding

22 the inclusion of study data and information in

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1 promotional materials for these products.

2 In its guidance entitled Labeling for

3 Biosimilar Products, FDA recommends that a

4 biosimilar's FDA-approved labeling incorporate

5 relevant data and information from the reference

6 product's FDA-approved labeling, and this includes

7 incorporating clinical data that supported FDA's

8 finding of safety and effectiveness for the

9 reference product in the biosimilars labeling.

10 If a firm wants to provide information from

11 studies that supported the licensure of the

12 reference product in promotional materials for its

13 biosimilar when this information is included in

14 both the reference product labeling and the

15 biosimilar labeling, the firm should refer to the

16 biosimilars labeling for this information.

17 For example, in the case where a biosimilar

18 is licensed for fewer than all conditions of use

19 for which the reference product is licensed, the

20 biosimilar's labeling generally will include

21 information from studies on the reference product

22 that is relevant to those conditions of use for

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1 which the biosimilar is licensed. The firm

2 developing promotional materials for its

3 biosimilars should look to the biosimilar's

4 labeling for this information.

5 FDA has also recommended that the

6 FDA-approved labeling for a biosimilar generally

7 not include data and information from the studies

8 conducted to support a demonstration of

9 biosimilarity between the reference product and the

10 biosimilar.

11 We have heard that firms are interested in

12 communicating data and information from these

13 studies to healthcare providers and other

14 interested parties, however, and have questions on

15 whether and how this kind of information can be

16 presented in promotional materials for their

17 biosimilar.

18 If a biosimilar's FDA-approved labeling does

19 not include information from studies conducted to

20 support a demonstration of biosimilarity between

21 the reference product and the biosimilar,

22 promotional presentations of such information

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1 should be consistent with the biosimilar's  
 2 FDA-approved labeling and be truthful and  
 3 non-misleading as described in FDA's guidance on  
 4 medical product communications that are consistent  
 5 with the FDA required labeling, which is referred  
 6 to as the CFL guidance in the draft guidance.  
 7 This guidance describes FDA's thinking when  
 8 examining a the consistency of a product  
 9 communication with the product's FDA-approved  
 10 labeling. It discusses how FDA determines whether  
 11 a communication is consistent with the product's  
 12 FDA-approved labeling and provides general  
 13 recommendations for conveying this type of  
 14 information in promotional materials in a truthful  
 15 and non-misleading way.  
 16 When information from the studies that  
 17 supported a demonstration of biosimilarity is not  
 18 included in the biosimilar's FDA-approved labeling,  
 19 firms should apply the principles outlined in the  
 20 CFL guidance if they include information from these  
 21 studies in promotional materials for their  
 22 biosimilars.

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1 As generally discussed in the FDA-FTC joint  
 2 statement, ensuring that advertising and  
 3 promotional communications subject to FDA  
 4 regulation are truthful and non-misleading can help  
 5 to protect and promote public health by enabling  
 6 patients and healthcare providers to make decisions  
 7 based on the accurate information.  
 8 FDA is concerned that false or misleading  
 9 comparisons between reference products and  
 10 biosimilars in FDA-regulated promotional materials  
 11 can undermine public confidence in these products  
 12 and negatively affect public health.  
 13 What should firms consider when comparing  
 14 reference and biosimilar products in their  
 15 promotional materials? FDA's licensure of a  
 16 biosimilar means that the agency has determined  
 17 that a biosimilar is highly similar to the  
 18 reference product notwithstanding minor differences  
 19 in clinically and active components and that there  
 20 are no clinically meaningful differences in terms  
 21 of safety, purity, or potency.  
 22 FDA recommends that firms carefully evaluate

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1 presentations that compare reference products and  
 2 biosimilars and avoid presentations that represent  
 3 or suggest that a biosimilar is not highly similar  
 4 to the reference product or that a clinically  
 5 meaningful difference in terms of safety, purity,  
 6 or potency exists between the products.  
 7 Although assessment of each promotional  
 8 presentation involves a fact-specific  
 9 determination, such presentations, including those  
 10 suggesting that the reference product is safer or  
 11 more effective than the biosimilar or that a  
 12 biosimilar is safer or more effective than its  
 13 reference product, are likely to be false or  
 14 misleading.  
 15 For example, a presentation suggesting that  
 16 a biosimilar is superior to its reference product,  
 17 based on a difference that is not clinically  
 18 meaningful between the rates of occurrence of a  
 19 particular adverse reaction observed in a study  
 20 that supported the demonstration of biosimilarity  
 21 between the two products, would be misleading.  
 22 It's also possible that individual

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1 statements of accurate information could contribute  
 2 to a misleading presentation when provided in the  
 3 comparative context.  
 4 For example, in the case of a biosimilar  
 5 that is licensed for fewer indications than the  
 6 reference product, presentations that create the  
 7 net impression that the biosimilar is, in general,  
 8 less safe or less effective than the reference  
 9 product, simply because the biosimilar is licensed  
 10 for fewer indications than the reference product,  
 11 would be misleading.  
 12 Also, presentations suggesting that a  
 13 biosimilar is less safe or less effective than the  
 14 reference product in a particular indication,  
 15 because the biosimilar's licensure for that  
 16 indication was based, in part, on extrapolation,  
 17 would be misleading.  
 18 Promotional presentations about a  
 19 biosimilar's licensure, a biosimilar to a reference  
 20 product should accurately describe the biosimilar  
 21 product. For example, promotional materials for a  
 22 biosimilar that FDA has not licensed as

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1 interchangeable should avoid creating the  
 2 impression that the biosimilar has been licensed as  
 3 interchangeable with the reference product because  
 4 this would not be accurate. Promotional materials  
 5 for a reference product should avoid creating the  
 6 impression that a biosimilar is less safe or less  
 7 effective than the reference product because the  
 8 biosimilar has not been licensed as interchangeable  
 9 with the reference product.

10 A biosimilar is not required to be identical  
 11 to the reference product in order to be licensed,  
 12 rather licensure as a biosimilar means that the  
 13 biosimilar has been found to be highly similar to  
 14 the reference product notwithstanding minor  
 15 differences in clinically and active components and  
 16 that there are no clinically meaningful differences  
 17 between the biosimilar and the reference product in  
 18 terms of safety, purity, or potency.

19 Therefore, representations or suggestions  
 20 that a finding of biosimilarity means that FDA  
 21 determined that the reference product and the  
 22 biosimilar are identical to one another generally

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1 would not be accurate, but promotional materials  
 2 for a reference product should avoid presentation  
 3 suggesting that the biosimilar is not as safe or  
 4 effective as the reference product because it is  
 5 not or may not be identical to the reference  
 6 product.

7 I'll now turn it over to Dom to discuss the  
 8 examples talked about in the draft guidance.

9 Presentation - Dominic Cirincione

10 MR. CIRINCIONE: Great. Thank you, Betsy.  
 11 Thank you very much.

12 (Pause.)

13 MR. CIRINCIONE: Well, I'll just keep going.

14 Question 7 in the draft guidance provides  
 15 three longer examples to help illustrate some of  
 16 the general considerations discussed within it.  
 17 For the purposes of these examples, we used a  
 18 fictional biosimilar called NEXSYMEO and a  
 19 fictional reference product called JUNEXANT.  
 20 NEXSYMEO and JUNEXANT are both replicamab products.

21 The first example describes a scenario in  
 22 which a firm provides the route of administration

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1 dosage form and strength of the biosimilar NEXSYMEO  
 2 in promotional materials for NEXSYMEO, and it  
 3 includes a claim that NEXSYMEO has the same route  
 4 of administration, dosage form, and strength of the  
 5 reference product.

6 FDA would not expect to object to this kind  
 7 of a presentation because it is supported by  
 8 NEXSYMEO's licensure as a biosimilar to JUNEXANT,  
 9 which is based, in part, on information showing  
 10 that NEXSYMEO has the same route of administration,  
 11 dosage form, and strength as JUNEXANT.

12 In the same materials, the firm includes a  
 13 claim that NEXSYMEO can be considered for patients  
 14 who are new to replicamab product therapy for the  
 15 treatment of a licensed indication and for patients  
 16 currently being treated with JUNEXANT for the same  
 17 indication.

18 The claim is supported by information  
 19 submitted as part of NEXSYMEO's application for  
 20 licensure as a biosimilar to JUNEXANT, including  
 21 data from a comparative clinical study that  
 22 included patients who underwent a single transition

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1 from JUNEXANT to NEXSYMEO and patients who were new  
 2 to replicamab product therapy, which supported a  
 3 demonstration of no clinically meaningful  
 4 differences between NEXSYMEO and JUNEXANT. FDA,  
 5 again, would also not expect to object to this kind  
 6 of presentation.

7 The second example describes another  
 8 scenario in which FDA would not expect to object to  
 9 the presentation described. In this example, as  
 10 part of NEXSYMEO's application for licensure as a  
 11 biosimilar to JUNEXANT, FDA evaluated a comparative  
 12 clinical study that included patients treated with  
 13 a non-U.S. licensed comparator product to support a  
 14 demonstration of no clinically meaningful  
 15 differences between NEXSYMEO and JUNEXANT.

16 NEXSYMEO's firm wants to present data that  
 17 is not included in NEXSYMEO's FDA-approved labeling  
 18 about outcomes observed in that study. So the firm  
 19 develops a presentation that is consistent with the  
 20 recommendations in the CFL guidance, which Betsy  
 21 mentioned earlier, including recommendations on  
 22 appropriate scientific and statistical support.

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1 The firm clearly and prominently provides  
 2 contextual information about the study design, the  
 3 methodology, the role the study played in the  
 4 biosimilarity evaluation, relevant data on  
 5 NEXSYMEO's FDA-approved labeling, and any material  
 6 limitations in that data. The firm also accurately  
 7 describes the comparator used in the study as a  
 8 non-U.S. licensed product. FDA, again, would not  
 9 expect to object to this kind of presentation.

10 Example 3 illustrates a presentation that  
 11 FDA would consider misleading, however, in this  
 12 scenario, promotional materials for JUNEXANT state  
 13 that in a clinical study, patients on JUNEXANT  
 14 experience a numerically higher overall response  
 15 rate than patients on NEXSYMEO JUNEXANT.

16 The basis for the statement is a comparative  
 17 clinical study that supported a demonstration of no  
 18 clinically meaningful differences in terms of  
 19 safety, purity, and potency between JUNEXANT and  
 20 NEXSYMEO.

21 Although this statement accurately conveys  
 22 the reference product's higher numeric overall

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1 response rates observed in the study, the materials  
 2 do not disclose that this difference in response  
 3 rates was not statistically significant, and they  
 4 do not describe the study design or include any  
 5 other appropriate context.

6 By focusing on the numerical differences in  
 7 response rates, which was not statistically  
 8 significant, the presentation misleadingly implies  
 9 JUNEXANT is superior to NEXSYMEO. It also  
 10 misleadingly implies that there is a clinically  
 11 meaningful difference between the products when the  
 12 data presented in the promotional materials do not  
 13 support that conclusion.

14 How can firms request FDA review of draft  
 15 promotional materials? Well, FDA encourages firms  
 16 voluntarily to seek feedback on promotional  
 17 materials for reference products or biosimilar  
 18 products before their dissemination to follow the  
 19 current process for submitting draft promotional  
 20 materials to FDA for comment.

21 We remind firms that they are also subject  
 22 to the postmarketing requirements for submitting

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1 promotional materials to FDA like all other  
 2 prescription drugs under Form 2253. Firms can  
 3 visit OPDP's website for more information on the  
 4 submission of promotional materials to FDA and for  
 5 general information on our regulation of  
 6 prescription drug and biological product,  
 7 advertising, and promotional labeling.

8 We remind firms that in addition to the  
 9 considerations specifically outlined in this  
 10 guidance, they should ensure that their  
 11 FDA-regulated promotional materials otherwise  
 12 satisfy all the applicable requirements from the  
 13 Food, Drug, and Cosmetic Act and FDA's implementing  
 14 regulations related to promotion for prescription  
 15 drug products.

16 Firms should also ensure that they comply  
 17 with the provisions obligating them to update the  
 18 FDA-approved labeling for their products to ensure  
 19 that the labeling is not false or misleading or for  
 20 any other reason.

21 This is a draft guidance, as you all are  
 22 aware, and as such, we are looking forward to

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1 receiving and then reviewing the comments submitted  
 2 to the docket. As noted in the Federal Register  
 3 notice that announced the availability of the  
 4 guidance, in addition to the draft guidance itself  
 5 for comment, we also are seeking input on specific  
 6 promotional considerations for interchangeable  
 7 products as well.

8 Thank you very very much. I'll turn it back  
 9 over to Caty.

10 Panel Discussion - Catherine Gray  
 11 MS. GRAY: Thank you, Dom and Betsy. I  
 12 wanted to follow up with just a few questions for  
 13 you.

14 Dom, the draft guidance states that it does  
 15 not cover considerations you need for promotional  
 16 materials for interchangeable products. Does that  
 17 mean that the Q&A's in this guidance don't apply to  
 18 interchangeable products at all?

19 MR. CIRINCIONE: The guidance does not  
 20 address considerations unique to promotional  
 21 materials for interchangeables because FDA is still  
 22 contemplating what, if any, considerations are

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1 unique to such promotional materials.  
 2 We are looking forward to the stakeholder  
 3 input regarding what, if any, interchangeable  
 4 specific promotional considerations exist and what  
 5 other considerations can help FDA-regulated  
 6 promotional materials convey truthful and  
 7 non-misleading information about interchangeables  
 8 for a variety or various audiences.  
 9 MS. GRAY: Thank you. I can echo Dom's  
 10 comments that we're looking forward to feedback  
 11 from our stakeholders on this topic as well.  
 12 MS. GRAY: Betsy, the examples throughout  
 13 the draft guidance suggest that an evaluation of  
 14 whether comparisons between reference products and  
 15 biosimilars are truthful and non-misleading can be  
 16 quite nuanced. Do you have any more advice on how  
 17 firms should approach these presentations and  
 18 promotional materials for the reference and  
 19 biosimilar products?  
 20 MS. PEPINSKY: Yes. FDA appreciates the  
 21 complexities around these types of presentations,  
 22 and as noted in the draft guidance, they do require

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1 attention.  
 2 (Applause.)  
 3 (Whereupon, at 11:21 a.m., a lunch recess  
 4 was taken.)  
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1 consideration of the specific facts. In general,  
 2 however, firms should keep in mind that whether  
 3 presentation is truthful and non-misleading  
 4 depends, among other things, not only on the  
 5 specific claims in isolation, but also the net  
 6 impression to which those claims contribute.  
 7 So we encourage firms to carefully consider  
 8 individual claims in a promotional piece, as well  
 9 as the presentation as a whole, considering the  
 10 overall impression it makes about the safety and  
 11 effectiveness of the product.  
 12 I would just note that we make the same  
 13 recommendation not only for firms evaluating  
 14 proposed comparisons between reference products and  
 15 biosimilars, but also for firms developing any  
 16 presentation in FDA-regulated promotional materials  
 17 for prescription drugs and biologics.  
 18 MS. GRAY: Thank you very much for your  
 19 attention to our panel. At this point, we're going  
 20 to wrap up for the morning session. I encourage  
 21 you to enjoy your lunch, and we will see you back  
 22 here at 12:15. Thank you very much for your

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1 AFTERNOON SESSION  
 2 (12:15 p.m.)  
 3 MS. FALB: Thank you for your attention.  
 4 This panel is What's at Stake? The Benefits of  
 5 Competition. I want to let you know for this  
 6 structure, we've organized this panel into three  
 7 sections. There will be a presentation by one of  
 8 our panelists at the beginning of each section and  
 9 then some prepared questions and answers. The  
 10 sections we will cover our biosimilar markets  
 11 overview; the impact of biosimilar entry; and  
 12 barriers to biosimilar entry.  
 13 Before we get started, I would like to ask  
 14 the panelists to introduce themselves. I will go  
 15 first, and then we can continue to my left. My  
 16 name is Alison Falb, and I am a regulatory counsel  
 17 in CDER's Office of Therapeutic Biologics and  
 18 Biosimilars.  
 19 DR. HERNANDEZ: My name is Inma Hernandez,  
 20 and I am faculty at the University of Pittsburgh.  
 21 MR. BRILL: Hi, everybody. I'm Alex Brill,  
 22 and I'm a resident fellow at the American



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1 Enterprise Institute.  
 2 MR. SCHMIDT: Good afternoon. I'm David  
 3 Schmidt. I'm an assistant director in the Bureau  
 4 of Economics at the Federal Trade Commission.  
 5 MR. SCHICK: Hello. I'm Andreas Schick.  
 6 I'm the director of economics at the FDA's Office  
 7 of Program and Strategic Analysis.  
 8 MR. AITKEN: Good afternoon. I'm Murray  
 9 Aitken. I'm executive director at the IQVIA  
 10 Institute.  
 11 MS. FALB: We're going to be starting with a  
 12 presentation of slides by Murray Aitken, so I think  
 13 we can pass you the clicker and hope for the best.  
 14 (Laughter.)  
 15 Presentation - Murray Aitken  
 16 MR. AITKEN: I'm going to spend a few  
 17 minutes just to frame out the overall biologics  
 18 market so that we can also understand biosimilars  
 19 in the context of the overall market and talk a  
 20 little bit about the market dynamics that we see  
 21 playing out based on IQVIA data and measurement of  
 22 the market, both on a dollar and a volume basis.

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1 Just a comment about the data that I'll be  
 2 drawing from; this is data that we gather at IQVIA  
 3 from a variety of sources, including wholesalers  
 4 who track the flow of medicines, all types of  
 5 medicines, through the distribution system. We  
 6 also gather data from manufacturers who are direct  
 7 shipping their products.  
 8 We also gather data from retail pharmacies  
 9 for that part of the market. We also have access  
 10 to insurance claims data. So we tend to take a  
 11 360 degree-ish view of what's happening and  
 12 consolidate all of that to develop an overall  
 13 perspective of the market.  
 14 When we measure the size of a market in  
 15 dollar terms, we generally use what we call invoice  
 16 price, which is what we capture from wholesalers.  
 17 So you can think of it as list price, but it's  
 18 before the application of rebates and discounts,  
 19 which we know can be significant. However, we do  
 20 estimate the magnitude of the rebates and discounts  
 21 and other forms of price concessions that go on in  
 22 the marketplace.

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1 So you'll see some of the charts where we  
 2 are using net prices, and when we say net, we're  
 3 looking at that from the perspective of  
 4 manufacturers, so the net amount that is received  
 5 by a manufacturer.  
 6 Let me summarize the points, and I've got  
 7 slides to support these. As we've already heard  
 8 today, biologics are a growing share of the overall  
 9 market, and certainly relative to small molecules,  
 10 we've got different dynamics playing out both on  
 11 what happens when a drug loses exclusivity front,  
 12 as well as the mix of new drugs coming out of the  
 13 pipeline through FDA approval and into the  
 14 marketplace.  
 15 When we look at the pipeline, particularly  
 16 the late-stage clinical development pipeline  
 17 products that are in phase 2 clinical testing or  
 18 later, it suggests that we're going to continue to  
 19 see the growth dynamic of biologics not only in  
 20 traditional biologic oriented therapy areas but in  
 21 other disease areas as well.  
 22 Biologics reach the market through multiple

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1 channels and pay types, and this is where things  
 2 get complicated quickly as, again, you've heard  
 3 reference to this morning. I don't think we're  
 4 going to have enough time to go through all the  
 5 pieces of the market and all of the characteristics  
 6 and payment dynamics, but understanding at least a  
 7 relative size and importance of different parts of  
 8 the market we think is important in order to  
 9 understand not only what's happening in biologics,  
 10 but specifically in biosimilars as well.  
 11 We'll take a look at the dynamics that we  
 12 see play out in the small molecule part of the  
 13 market and then the large molecule or biologics  
 14 part of the market, and we look at this in a couple  
 15 of ways.  
 16 One is what share of the dollar value of the  
 17 market is subject to generic competition or  
 18 biosimilar competition for large molecules, and  
 19 then for that part of the market, what's the  
 20 relative volume dispensed or used as the generic or  
 21 biosimilar relative to the total use of those  
 22 molecules. Those are the two metrics that we use

1 to try to assess how the market is evolving.  
 2 Starting with the big picture, and this is  
 3 on an estimated net price basis, we've got a total  
 4 medicine market in nominal dollars of \$344 billion  
 5 in 2018. We're still polishing the 2019 numbers.  
 6 That total is up 21 percent since 2014. But you  
 7 can see in dark blue, the small molecule share has  
 8 fallen from 70 percent to 58 percent over this  
 9 5-year period, so all the growth is essentially  
 10 coming from the biologics part of the market at the  
 11 top, which has gone from about \$85 billion dollars  
 12 in 2014 to \$144 billion in 2018.  
 13 Again, that's a reflection of the shift in  
 14 science, the movement, the gradual movement towards  
 15 biologics in R&D, as well as the impact of the  
 16 entry of new competition when patents expire or  
 17 other forms of exclusivity expire.  
 18 If we just convert things to a real net per  
 19 capita basis -- we've made those adjustments to the  
 20 earlier numbers, adjusting for inflation and  
 21 adjusting for population growth -- the pattern is  
 22 similar, but I think it's also useful just to look

1 areas that is represented by  
 2 biologics or biotech products.  
 3 In terms of how these biologics reach the  
 4 market, and now I'm switching to an invoice price  
 5 level because, frankly, we don't have net prices at  
 6 the payer type or channel level, so we can only  
 7 estimate net prices at the overall market level.  
 8 On an invoice price basis, retail and mail  
 9 represents about 60 percent of the total biotech  
 10 market and 40 percent in non-retail.  
 11 On the right-hand side, we've got some of  
 12 the smaller segments of the market. So starting at  
 13 12 o'clock and moving clockwise, we've got the  
 14 retail and mail commercial payer market, which is  
 15 26 percent of the total; then we've got retail and  
 16 mail Medicare Part D market, an additional 17  
 17 percent; retail and mail Medicare Advantage, 5  
 18 percent; and then retail and mail managed Medicaid  
 19 at 8 percent; followed by retail and mail  
 20 fee-for-service Medicaid at 2 percent; and then  
 21 we've got 1 percent retail and mail cash.  
 22 Then continuing on, we've got the non-retail

1 at the number at the top, \$1044 per person -- this  
 2 is in 2019 dollars, I believe -- that was spent on  
 3 all medicines of which \$435 was for biologics, up  
 4 from \$291 in 2014, and then the spending on small  
 5 molecules has fallen by about 12 percent.  
 6 So you've got a 50 percent growth in the top  
 7 of the chart and a 12 percent growth in the bottom  
 8 of the chart. That's why we're all here.  
 9 Just looking into the pipeline, the trend of  
 10 new drugs towards biologics will continue to grow.  
 11 Sometimes, frankly, it gets overstated. Right now,  
 12 about 40 percent of new drugs are biologic;  
 13 60 percent are small molecules. Not all innovative  
 14 targeted cancer treatments are biologics. There's  
 15 a good number of small molecules in there as well.  
 16 I do notice sometimes there's a little bit  
 17 of confusion as to what's biologic and what's small  
 18 molecule when it comes to innovative medicines, but  
 19 we show here a number of the therapy areas, again,  
 20 including ones that in the past have not been  
 21 particularly biologic oriented, and just show the  
 22 share of the late-stage pipeline in these disease

1 part of the market, non-retail commercial hospitals  
 2 about 3 percent; commercial office site about  
 3 13 percent; and then non-retail Medicare  
 4 fee-for-service, 2 percent; followed by non-retail  
 5 Medicare Advantage, 11 percent; and non-retail  
 6 Medicaid and other, 12 percent.  
 7 As you see on the chart, these are  
 8 directional estimates. Frankly, I don't think  
 9 anyone has a good way of teasing out these  
 10 different parts of the markets, but I think it is  
 11 important and relevant to understand the different  
 12 segments of the market to the extent that there are  
 13 different incentives. There are different  
 14 reimbursement levels that play out in each of these  
 15 segments. I'm sure we'll talk about this as we get  
 16 to the discussion.  
 17 Just looking at the top 10 biologics that  
 18 are on the market as of September 2019, this is  
 19 invoice price sales. I just thought it was useful  
 20 to look at the cumulative invoice sales of these  
 21 drugs since they were launched and through  
 22 September of 2019. This is for the branded version

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1 of the drugs if there's a biosimilar in the market.  
 2 As you can see, all the top 10 have  
 3 cumulative sales of more than \$40 billion. I also  
 4 just indicated the number of years since their  
 5 launch, which also speaks to these are pretty old  
 6 drugs by now.  
 7 I think we don't have quite enough  
 8 discussion about the extent to which there is a  
 9 next-generation treatment available in the case of  
 10 these molecules in particular and the extent to  
 11 which the dynamic of investing in and promoting a  
 12 next-generation of biologic, to the extent we're  
 13 going to see likely see more of that going forward  
 14 than we have in the in the past, where  
 15 manufacturers have not necessarily been  
 16 particularly motivated while they don't face  
 17 competition from biosimilars.  
 18 Just to wrap up in terms of what we see  
 19 happening, again, at the overall market level in  
 20 terms of the dynamics of generics and biosimilars,  
 21 this is our view of the small molecule market. The  
 22 bars are measuring the percentage of the small

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1 molecule for which there is a biosimilar available,  
 2 and that of course goes up and down with the entry  
 3 of new biosimilars, so it resets the denominator.  
 4 But we're now at 20.2 percent of the volume of  
 5 biologics dispensed. When there's a biosimilar  
 6 available, it goes out as a biosimilar.  
 7 This is what we watch the most, I would say,  
 8 in terms of the impact and the uptake, at least  
 9 from a market dynamic perspective, a separate  
 10 discussion on pricing a course. But if we just  
 11 look forward a little bit, the dark blue bar here  
 12 and the green line are the same as on this chart,  
 13 just rescaled because we've introduced now the  
 14 biologic molecules for which a biosimilar has been  
 15 approved but not yet marketed, so that's the light  
 16 blue.  
 17 That includes adalimumab, etanercept, and  
 18 teriparatide, where there are biosimilars approved.  
 19 If you include those in the calculation, then we're  
 20 at 50 percent of the value of the biologics market  
 21 subject to biosimilars. Now, that won't actually  
 22 happen until 2023 or some time later, but it's a

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1 molecule market that's accessible to one or more  
 2 generics by molecules, so we build this up molecule  
 3 by molecule. This is in quarterly view, and from  
 4 2014 to the fourth quarter of 2019 we're at 40  
 5 percent.  
 6 Basically, 40 percent of the value of the  
 7 small molecule market is subject to a generic, and  
 8 then the green bar at the top, when a generic is  
 9 available, it's dispensed in volume terms  
 10 96.5 percent of the other time. This is what we're  
 11 used to in terms of the small molecule market.  
 12 Here's the same view but now for biologics,  
 13 starting at q1 of 2013. So again, the bars show  
 14 what percentage of the value of the market is  
 15 subject to a biosimilar. You can see the  
 16 additional biosimilars entering the market. These  
 17 are not approvals; this is entering the market.  
 18 You can see that now 17.5 percent of the value of  
 19 the biologics market is now from molecules that  
 20 have one or more competitors as biosimilars.  
 21 The green line is tracking, again, the  
 22 volume share that the biosimilar has of the

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1 sign of where we're going in terms of the overall  
 2 market place for biosimilars.  
 3 So with that, I will pause. Thank you.  
 4 MS. FALB: Thank you.  
 5 As we continue our conversation about the  
 6 biosimilars market, what aspects of that market are  
 7 most important to keep in mind, or would anyone on  
 8 the panel like to highlight?  
 9 MR. SCHMIDT: Sure. I'll take a first crack  
 10 at that. I'm going to adopt an unfamiliar position  
 11 for me, which is to caution against too much  
 12 pessimism. I think we see statistics like what  
 13 Murray put up, which are incredibly informative and  
 14 useful, but we shouldn't interpret it as evidence  
 15 that the biosimilars are a failure or are in some  
 16 way lagging way behind what these small molecule  
 17 generics have accomplished.  
 18 It's very early days for the biosimilars  
 19 right now, and it's also very early days for  
 20 economists and others to be analyzing these  
 21 markets. So we're still working on gathering good  
 22 data, and I know many of the people on this panel

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1 are contributing to that and it's great to see.  
2 But to get to the heart of the question, I  
3 think what would be really useful would be able to  
4 look at good comparison groups like how are  
5 biosimilars doing relative to other drugs that are  
6 paid for by the same types of payers in the same  
7 dispensing settings and do we see a huge difference  
8 there.  
9 Is it something inherent about the payer  
10 type or the dispensing setting that's causing the  
11 innovator products to hold on to market share more  
12 than they do for the stereotypic small molecule  
13 drug dispensed at your local pharmacy?  
14 I think, as of yet, we don't know the answer  
15 to that, and I think some of these researchers are  
16 pushing in that direction, and it's great to see.  
17 But I think, obviously, it has been highlighted,  
18 payer type is important, dispensing location is  
19 important, and keeping that in perspective when  
20 we're looking at some of this information I think  
21 is incredibly important.  
22 MR. BRILL: Just a quick addition or comment

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1 on Dave's comment. First, I fully agree that we  
2 can say we're in transition. We're not in  
3 equilibrium at the moment. We are in the beginning  
4 of a process and the market is continuing to  
5 evolve.  
6 The question that we're all wondering, I  
7 think, is what will that equilibrium look like and  
8 what can we be doing to make sure that it is as  
9 robust a marketplace as possible? But these  
10 snapshots are just that, snapshots in a moment as  
11 we move towards a more robust market that's  
12 evolving.  
13 But I would also say that with regard to  
14 trying to find comparators, there's, in my mind,  
15 two ways to think about that. One, if I understand  
16 correctly, Dave's comment is to try to find similar  
17 scenarios in the small molecule world and look for  
18 differences. I think that there are lessons to be  
19 learned from those types of comparisons, but also  
20 within the biologic/biosimilar marketplace by payer  
21 type.  
22 One of the things we know in the small

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1 molecule generic space is that we have really high  
2 utilization rates of generics pretty much all the  
3 time. Shortly thereafter of a launch, we don't see  
4 wide disparities by payer type and generics.  
5 Another way to look at this in this market is to  
6 say are there differences by payer type, or  
7 location, or dispensing mechanism. I think it's  
8 reasonable to think that there shouldn't be.  
9 So not necessarily are we're going to  
10 achieve the realization rates that we see in the  
11 small molecule space; I think the competition  
12 dynamics are different there. But there's no  
13 reason in my mind -- and I'd be concerned if we saw  
14 very different behaviors in the Medicaid market  
15 than we see in the Medicare commercial market.  
16 MS. FALB: Following up on that point, are  
17 there important differences? It sounds like you  
18 don't think that there should be, but perhaps there  
19 are between biologics and expensive small molecule  
20 drugs that might impact their respective markets.  
21 You can take it or someone else can take it.  
22 DR. HERNANDEZ: Well, I think -- and I'm

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1 going to try to tie it with what I'm going to say  
2 in the next few slides -- it comes back to  
3 financial incentives. We know that we usually  
4 reimburse for generics based on a maximum allowable  
5 cost, so then pharmacies can dispense whichever  
6 generic they want because everything is going to be  
7 at the same level.  
8 For that reason also, discounts don't play  
9 an important role in the small molecule generics.  
10 We have basically brand names with high-list prices  
11 and rebates higher or lower, and then we have  
12 generics where there's transparency, and the list  
13 price is more representative of what we're paying.  
14 I'm going to talk a little bit about how  
15 that's very different for biosimilars, and I think,  
16 especially for the drugs that go through the  
17 pharmaceutical benefit, that's an important  
18 differentiation with small molecules, how we're  
19 paying for them and how we're going to continue to  
20 pay for them. If biosimilars are not  
21 interchangeable, we cannot pay all of them in a  
22 similar way as we're paying for generics, and

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1 that's a differentiation that is important to make,  
 2 I think.  
 3 MS. FALB: I think we can use that as a  
 4 segue to your presentation.  
 5 Presentation - Inma Hernandez  
 6 DR. HERNANDEZ: I'll get started in the  
 7 meanwhile and say that I'm going to present a  
 8 couple of studies that we've done in my research  
 9 group around biosimilars. The first one of them,  
 10 we're going to describe what happened to prices of  
 11 originator biologics when they're faced by similar  
 12 competition.  
 13 On the second of them, we're going to talk  
 14 about financial incentives in Medicaid in the  
 15 uptake of the biosimilar for Lantus, that I know is  
 16 not a true biosimilar because it was not approved  
 17 through a biosimilar pathway, but for financial  
 18 incentives, works in a similar way.  
 19 So let's start with the first one. I'm so  
 20 happy the slides are working. Here we looked at  
 21 all originator biologics that faced biosimilar  
 22 competition by December 2018. Again, when I say

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1 biosimilar competition, I also include within  
 2 molecules substitutes that were not approved  
 3 through the biosimilar pathway. We had the four  
 4 that are listed on the slides.  
 5 Here, we wanted to look at what happened to  
 6 net prices, list prices, and discounts before and  
 7 after the launch of the biosimilars. I know that  
 8 Murray already introduced the contents of list  
 9 price, but I'm just going to go through them again  
 10 because it's important to know what's in the net  
 11 price.  
 12 List prices represent what wholesalers are  
 13 paying to pharmaceutical manufacturers, but we know  
 14 this doesn't represent the whole picture. If we  
 15 have a drug covered through the pharmaceutical  
 16 benefit, the wholesaler will sell the drug to the  
 17 pharmacy that will dispense the drug to a patient.  
 18 We often have patient insurance plans, and the  
 19 health insurer will reimburse the pharmacy through  
 20 a pharmaceutical benefits manager.  
 21 Often pharmaceutical benefits managers and  
 22 health insurers negotiate formulary placement with

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1 the pharmaceutical manufacturers for discounts or  
 2 rebates. These discounts are proprietary  
 3 information because they are confidential, so they  
 4 are not available to us for research or for any  
 5 other purpose.  
 6 However, we found out a few months ago that  
 7 there is an investment firm called SSR Health that  
 8 tries to calculate discounts using company reported  
 9 sales to stakeholders. Since these data come from  
 10 company reported sales, they are only available for  
 11 drugs manufactured by publicly traded companies, so  
 12 we will not have BI or Purdue Pharma for instance.  
 13 The denominator to estimate net comes from  
 14 Symphony Health, and it tries to estimate all the  
 15 units sold in the U.S. in a given quarter. Because  
 16 of this calculation, net represents the average  
 17 amount that pharma gets per unit of product, and  
 18 this is net of all discounts, not only rebates to  
 19 payers but also coupon cards, 340(b), discounts to  
 20 federal service, anything that you can make. Using  
 21 this net price, the discount is estimated as the  
 22 difference, and they are able to separately

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1 estimate discounts in Medicaid and in other payers.  
 2 I'm not going to present another paper where  
 3 we've validated the data, but we got last week in  
 4 JAMA a big paper using all of these, and we showed  
 5 in very comprehensive sensitivity analyses how this  
 6 data is pretty robust to the research. So if you  
 7 are wondering about the validity, I'll refer you to  
 8 that.  
 9 Now I'll show you the results of this one.  
 10 This is for filgrastim. You can see that list and  
 11 net prices increase in parallel until 2013 or so.  
 12 Net prices for the originator biologic started to  
 13 decrease in 2015 around the time that Zarxio  
 14 reached the market, and this was driven by  
 15 discounts in payers other than Medicaid.  
 16 Obviously, the Medicaid discount was not  
 17 going to increase if the list price is not  
 18 increasing any further. You can also see how the  
 19 net price continues to decrease over time with the  
 20 entry of more competition.  
 21 For pegfilgrastim, we only have one data  
 22 point after biosimilar entry, so the data is not

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1 very robust. But you can see a very similar story  
 2 where list and net prices increased in parallel,  
 3 and then once we have competition, list prices  
 4 stagnate and net prices seem to decrease.  
 5 This is infliximab, very similar. We see  
 6 list and net prices increasing in parallel until  
 7 2013. You can see that net prices have started to  
 8 decrease around 2013, which is a few years before  
 9 biosimilar entry. I would like to acknowledge that  
 10 there are many other factors in the market other  
 11 than biosimilars.  
 12 In this case Simponi Aria, which is a direct  
 13 competitor, was approved in 2013, so it's hard for  
 14 me also sometimes to say that all of these  
 15 decreases that we are seeing are just a product of  
 16 biosimilar competition. Anyway, you can see that a  
 17 few years later when biosimilars did come to the  
 18 market, prices continued to decrease.  
 19 Finally, these are the results for Lantus.  
 20 You can also see the net prices have started to  
 21 decrease before Basaglar was approved, but there  
 22 were other molecules in the long-acting insulin

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1 market. I'm not sure of the direct competitors of  
 2 Lantus, really, but there's also been a lot of  
 3 social pressure against prices of insulin, so I  
 4 think there's also a lot of factors that play in  
 5 account here. All of these results were published  
 6 last year if someone wants to look at them in more  
 7 detail.  
 8 I think this shows, in general, as a  
 9 summary, the list price of originator biologics is  
 10 stagnated but did not decrease after biosimilar  
 11 entry, however, net prices did decrease. This was  
 12 driven by increasing discounts in payers other than  
 13 Medicaid.  
 14 I was asked to talk where the net prices  
 15 start to decrease before or after biosimilar entry.  
 16 In the case of infliximab and Lantus, we see that  
 17 they start to decrease before but, again, there are  
 18 factors at play in the market, so I don't want to  
 19 fully attribute these two biosimilars.  
 20 I was also asked to talk about the more  
 21 biosimilars that come into the market, the higher  
 22 the discounts we see. I think we don't have enough

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1 data to answer that question yet. For instance,  
 2 for filgrastim, we see three competitors and net  
 3 prices have decreased substantially, but the  
 4 others, I have data to compare only half, one data  
 5 point after the entry.  
 6 So I think once we have more data, we'll be  
 7 able, really, to compare what's the difference in  
 8 net price between biologics that have seen three  
 9 biosimilars versus those that have seen one. But  
 10 again, I don't think this is a fair comparison  
 11 right now because I don't have enough to say that.  
 12 With that, we'll change pace to the second  
 13 paper, which is very similar. It looks at the  
 14 uptake of Basaglar in Medicaid. Since the passage  
 15 of the ACA, states collect rebates for drugs that  
 16 are reimbursed under Medicaid managed-care  
 17 organizations.  
 18 What does this mean? We have the same scale  
 19 that we had before, and this patient is covered  
 20 under Medicaid. In this case, it's under a  
 21 Medicaid managed-care organization that has a  
 22 contract with a state Medicaid agency. Before the

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1 ACA, the rebates for the drugs used by this patient  
 2 could go to the MCO, which are the ones paying for  
 3 drugs.  
 4 After the ACA, the rebates for these drugs  
 5 go directly to the state. So basically the MCO is  
 6 paying the list price, but the rebates are going to  
 7 the state. This creates differential incentives in  
 8 the sense that states are incentivized to use drugs  
 9 that maybe have higher list price, but after  
 10 discounts have a lower net. However, MCOs are  
 11 incentivized to use drugs with a lower list price  
 12 because they don't see the rebate money, because it  
 13 comes back to the state.  
 14 In some cases, to promote the use of branded  
 15 products among MCOs, Medicaid and state agencies  
 16 are implementing preferred drug lists, which are a  
 17 compilation of drugs that they have to favor over  
 18 others.  
 19 Here, we look at the utilization of Basaglar  
 20 in 2018 before four types of states: states that  
 21 have fee-for-service Medicaid only; states that had  
 22 managed-care organizations but with carved-out drug

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1 benefits, meaning the drug benefits were still paid  
 2 on a fee-for-service basis; states that had MCOs,  
 3 and the MCOs did not have to follow preferred drug  
 4 lists for insulin glargine; and finally, states  
 5 with MCOs where there were preferred drug lists for  
 6 insulin.  
 7 We looked at all the states with preferred  
 8 drug lists, and we saw that all of them that  
 9 included insulin glargine in the preferred drug  
 10 lists, they all preferred Lantus over Basaglar,  
 11 100 percent. The data to use these comparisons was  
 12 Medicaid drug list utilization data, which as you  
 13 may know is publicly available. The outcome was  
 14 the proportion of insulin units paid for insulin  
 15 glargine that was accounted by Basaglar.  
 16 Here you can see the results. You can  
 17 basically see that the market share of Basaglar is  
 18 close to zero in all the states, except for the  
 19 ones that have Medicaid managed-care organizations  
 20 that are not subject to preferred drug lists. In  
 21 the paper, we go a little bit further and we show  
 22 the correlation between the penetration of

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1 managed-care organizations and the uptake of  
 2 Basaglar, and you can see that it's pretty  
 3 significant.  
 4 In summary, we only see a substantial uptake  
 5 of Basaglar in the states that have Medicaid  
 6 managed-care organizations that are not subject to  
 7 preferred drug lists. I think this is timely  
 8 because more states are implementing preferred drug  
 9 lists these months and these years, and they are  
 10 also including more drugs in the preferred lists.  
 11 Originally, many PDLs started just with the drugs  
 12 for hep C, but increasingly, they are implementing  
 13 more drugs that are subject to the preferred drug  
 14 lists.  
 15 As a summary of my presentation, I don't  
 16 think the biosimilars are showing they're exerting  
 17 some competition in the market. It does seem like  
 18 all the competition happens in the discount space,  
 19 so it's very important to not only look at what  
 20 happens in the list price but trying to use these  
 21 estimates, the same as Murray talked. The best  
 22 system we have is net prices because it's really

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1 where we see the competition. That's all I have.  
 2 MS. FALB: Thank you.  
 3 When thinking about the impact of biosimilar  
 4 entry on the market, what impacts do we see or do  
 5 we anticipate that are positive, how do we further  
 6 those, which do we see or anticipate that are  
 7 negative, and what could be done to either minimize  
 8 or prevent them?  
 9 DR. HERNANDEZ: I always make this comment  
 10 when talking about list and net prices, and I'm  
 11 also going to make it here. I think it's good that  
 12 net prices are decreasing. I think that's always a  
 13 good sign now. It means that premiums are not  
 14 going to increase at least.  
 15 I'd still like to point out that there are a  
 16 lot of patients exposed to list prices. We know  
 17 that co-payments are usually based on list price,  
 18 and we know that patients on high-deductible plans  
 19 or without insurance, they're also exposed to list  
 20 price.  
 21 So as much as we like to look at the net  
 22 price data because it's probably a good sign now of

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1 what payers are supposed to, I think we need to  
 2 remember that the patients that probably have the  
 3 most access barriers are the ones that are exposed  
 4 to list. So I think we still need to keep that in  
 5 mind that there's value in list price.  
 6 MR. SCHMIDT: I agree with that, but I would  
 7 also add that I think it would be useful to look  
 8 directly at what the patients are paying to the  
 9 extent that we have claims data sets that might  
 10 identify exactly what the incidence is on patients  
 11 and not just realize list price as a proxy for  
 12 that.  
 13 DR. HERNANDEZ: I forgot to say that. Yes.  
 14 We haven't looked at out-of-pocket payments yet,  
 15 but I would like very much to do so. But I'm  
 16 looking for a grant to do that, so if anybody's  
 17 interested in funding this type of work,  
 18 [indiscernible].  
 19 MR. BRILL: I'll just add that when we think  
 20 about the winners, we want to think, just as Inma's  
 21 presentation shows, that the effects across the  
 22 whole market on all the reference product prices

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1 are relevant when we think about the savings. I  
2 think this illustrates one of the real differences  
3 in the market for biologics and biosimilars  
4 relative to the market in the small molecule space  
5 for brand and generic products.  
6 We're seeing, at least initially, a very  
7 different dynamic, where as we know in the small  
8 molecule space, the reference products, the brand  
9 products, are generally holding their price  
10 constant when generics enter and giving up large  
11 market shares, and we're seeing a very different  
12 behavior among reference products in the biologic  
13 space.  
14 I think that that's interesting. I think  
15 that that was unanticipated by many of the folks  
16 who were trying to think about what the cost  
17 savings in this market might be. But at the same  
18 time, it may present challenges ultimately for the  
19 desired maturity of this market because is it the  
20 ability of the biosimilars to compete or is their  
21 ability relative to the reference product, their  
22 pricing relative to the reference product?

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1 So there needs to be some opportunity for  
2 them to earn back their large fixed-cost  
3 investments, so there's a little bit of a tradeoff  
4 in that dynamic.  
5 MR. SCHMIDT: The thing I was really struck  
6 by is it suggests to me that the competition here  
7 is more similar to the classic brand-on-brand  
8 competition that we see in small molecules, where  
9 they don't generally compete on list price and do  
10 compete on rebates and other sorts of discounts,  
11 co-payment programs and such. I think that's an  
12 interesting dynamic in this market.  
13 MR. AITKEN: I think what we see is not so  
14 much the distinction between the small molecule and  
15 the large molecule, but it's more the distinction  
16 of the payer type and the channel. This notion  
17 that we've had for a while that biologics are  
18 different, I think we need to get beyond that and  
19 say more different payment types.  
20 Fee-for-service Medicaid is different than  
21 MCO managed-care Medicaid; that Part B and Part D  
22 is different; that commercial is different than

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1 Medicare and so on, and to look through that lens  
2 at what's going on as opposed to is it a large  
3 molecule or a small molecule, now that we have the  
4 cohort of large molecules approved and able to  
5 access the market that we didn't have three years  
6 ago or five years ago.  
7 MS. FALB: What impact do you anticipate  
8 that the entry of interchangeables will have on the  
9 market?  
10 DR. HERNANDEZ: I think we discussed it this  
11 morning. I think it will be important for the ones  
12 covered under mostly the pharmaceutical side  
13 because payers will be less concerned about rebate  
14 traps. If they are interchangeable, you're going  
15 to be able to virtually shift all of the patients.  
16 So I think that will be a big improvement in that  
17 sense.  
18 Still, getting back to the point that we're  
19 making, it's very important to think about how we  
20 are paying for drugs and how we're going to pay for  
21 interchangeable biologics and interchangeable  
22 biosimilars.

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1 MR. BRILL: I think that's right. I think  
2 it's to be determined how the pricing works for an  
3 interchangeable obviously because we don't have  
4 them. As was discussed in the morning session and  
5 as Inma just noted, it's only relevant, I think, in  
6 the pharmacy space. But I do think there is the  
7 potential for simplicity and reduced friction in  
8 the market for an interchangeable biosimilar that  
9 could facilitate higher uptake rates.  
10 MS. FALB: Thank you. Alex, if you could  
11 present?  
12 Presentation - Alex Brill  
13 MR. BRILL: Thank you very much, and thank  
14 you, everyone, for being here this afternoon. I  
15 was asked to speak about some of the barriers that  
16 we see in the marketplace today for biosimilars,  
17 and this is based on some work that I've done in  
18 the last few years trying to identify, categorize,  
19 and put in buckets these types of barriers. One of  
20 the big themes there is there's not one, there's  
21 many, and it's the cumulative effect of these  
22 barriers that I think may be impeding the market to



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1 some extent.

2 I want to talk about this from a broad

3 perspective when we think about barriers. I think

4 the first thought when we say "barriers" is we

5 think barriers are bad; they're things that are

6 blocking.

7 I want to step back a bit and say we need to

8 think about the barriers in the broadest terms

9 possible. There are some good barriers, as I'll

10 get into, and there are certainly many bad

11 barriers. And I think we're here to talk about the

12 bad barriers not the good barriers. But I think

13 it's important to recognize that barriers can be a

14 useful tool, can provide a service, and can provide

15 value, and then I'll talk about some of the

16 consequences and policy implications.

17 As I mentioned, when we say "barriers" I

18 think we think of that as being a negative. I want

19 to speak of two types of barriers. Besides just

20 being good or bad, we can think of barriers as

21 being barriers to entry and we can think of some

22 barriers as barriers to utilization. The

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1 utilization barriers I think our uniformly going to

2 be bad. Once we have entry, we shouldn't be trying

3 to inhibit the utilization of a product that is

4 biosimilar and is less costly.

5 When we think about entry, just to be

6 honest, I think it's a little bit more complicated

7 and there are some appropriate barriers to protect

8 both the innovator, to some extent, and to protect

9 the consumer. That's not to say that all barriers

10 to entry are good but it's mixed.

11 So what kind of barriers might be

12 reasonable? Well, it's actually not controversial.

13 I think that patents are barriers and patents are a

14 valid and important part of this ecosystem here.

15 BPCIA created an additional barrier, an exclusivity

16 period.

17 I cut my teeth in this industry arguing over

18 this exclusivity period with a Duke University

19 professor named Henry Grabowski and the economics

20 of exclusivity, and I lost that battle. I would

21 have thought that seven years would have been a

22 sufficient period of time, but I also think that

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1 it's true that zero isn't the optimal period and

2 that there's a balance to be struck.

3 I think this is important, in part, in the

4 policy context because oftentimes the disagreement

5 in policy circles between those who are interested

6 in creating barriers and those who are interested

7 in reducing barriers sometimes gets murky and there

8 can be some crosstalk. I think if we split this

9 debate, recognizing that there can be valid types

10 of barriers, we can disarm some of the debate, and

11 we can focus on those barriers that are negative

12 and adverse to competition.

13 Finally, I think there's another set of

14 non-controversial barriers, which is, in essence,

15 the approval process is a barrier. Of course it

16 is. It's costly, it's time-consuming, it's

17 uncertain, and it's for the safety and efficacy of

18 the product. It's in the interest of the patient.

19 We all recognize the importance of having high

20 standards. Even though those standards pose a

21 barrier, they are barriers that are yielding good,

22 good for both the patient of course, but good for

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1 the market ultimately.

2 Then of course there are the bad barriers,

3 the barriers that we need to identify and root out.

4 Many of them were discussed this morning.

5 Christine Simmon described them in the first

6 session. They really fall across a whole host of

7 categories. Some of them are policy related and

8 some of them are more market-based. Some of them

9 are things that regulators could do better or

10 differently. They could try to reduce their

11 burdens that they're imposing on the markets.

12 Some may be things that agencies could

13 recognize as bad behavior in the market and they

14 can work to mitigate. A few of them are up here,

15 things like the contracting practices engaged in by

16 the payers that may favor in a near-term

17 arrangement a brand product, and thereby inhibiting

18 or discouraging the development or the maturing of

19 their biosimilar marketplace, and the rebate trap

20 that we've discussed earlier.

21 While I think that patents are an obvious

22 and good barrier in many senses, we should also

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1 recognize that that's a tool that can and I think  
 2 has been abused, whether that's the thickest  
 3 or other strategies around patenting that are  
 4 merely about extending monopoly beyond a reasonably  
 5 fair period.  
 6 Then there are what I'd call knowledge- or  
 7 information-related barriers, and this may be  
 8 getting better. I think we're making progress on  
 9 this front, but I think we still have a lot of  
 10 education that needs to be done. I think the FDA  
 11 is doing a great job of late in trying to fill  
 12 those gaps, but we should recognize that those gaps  
 13 still exist and they are not comparable. We  
 14 haven't closed that gap the way we have I think in  
 15 the small molecule space with generic drugs.  
 16 When we think about what the consequences of  
 17 these barriers might be, the bad barriers, undue  
 18 barriers to biosimilar entry will have many  
 19 consequences, and I should say entry and  
 20 utilization have many consequences. We're  
 21 extending the monopoly rent period. That's what  
 22 happens when we don't have competition.

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1 As was just discussed a moment ago in the  
 2 last presentation here, this can have implications  
 3 for the patient costs. It depends of course on the  
 4 benefit design, but the limits on competition are  
 5 going to mean both higher premiums and presumably  
 6 higher out-of-patient costs as well.  
 7 Also it's important not to think about this  
 8 in a binary sense of is there a competitor or not,  
 9 but the number of competitors is important, and we  
 10 saw that in Inma's presentation. The more  
 11 competition we can have for a given reference  
 12 product, the more discounting, both with respect to  
 13 the price of the biosimilar we should anticipate,  
 14 as well as the price of the reference product.  
 15 Together, those two prices are affecting the  
 16 average price for a given product and the cost to  
 17 the healthcare system in total.  
 18 Finally, there's I think a different type of  
 19 barrier that's also worth recognizing. What we can  
 20 do about it I think is tricky, and that's the  
 21 reality of uncertainty in the marketplace. I think  
 22 we've faced over the last decade a lot of

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1 uncertainty, and we continue to face uncertainty in  
 2 this biosimilar market. It's getting better. I  
 3 think the work in the last year or so from the FDA  
 4 has helped provide more information. I think that  
 5 the number of products that have successfully gone  
 6 through the approval process creates some degree of  
 7 increased certainty and there's learning on both  
 8 sides in that regard.  
 9 There are uncertainties that remain, and  
 10 many of these are natural. They're natural in a  
 11 free and open market, but it is uncertain to the  
 12 biosimilar how the reference product is going to  
 13 behave. As I was mentioning a few minutes ago, I  
 14 don't think it was well anticipated that the  
 15 reference product prices were going to evolve in  
 16 the way that we've seen, and that has implications  
 17 for pricing strategies for biosimilars. That's an  
 18 uncertainty that over time will resolve itself as  
 19 we have more experience.  
 20 There are a set of uncertainties, again,  
 21 that can't necessarily be eliminated, but I think  
 22 we should strive to mitigate, which include the

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1 legislative and regulatory uncertainties, the  
 2 degree to which, on either end, either at the  
 3 capitol or in the agencies, new policies are being  
 4 proposed, getting done, and not getting done.  
 5 These uncertainties impose costs and in fact can  
 6 encourage biosimilar manufacturers to wait. I  
 7 think that there's important economic literature  
 8 around uncertainty and the dynamic by which it  
 9 causes market participants to wait.  
 10 So if we ask ourselves why isn't more things  
 11 happening quicker, it's often because it may often  
 12 be the case that participants in the market are  
 13 saying if we wait, we'll know more about this  
 14 market in the future. So we can combat that by  
 15 trying to educate participants in the marketplace  
 16 and have quick and clear and certain regulatory  
 17 guidance.  
 18 All of this is to say -- in broad terms  
 19 again; these aren't action items -- that it's  
 20 important that we strive for an environment where  
 21 the biosimilar manufacturers can anticipate the  
 22 barriers that they're going to face. Barriers can

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1 be okay, as I think I made clear, but they should  
 2 be predictable. So something like an exclusivity  
 3 period is a very definitive and clear barrier with  
 4 a specific duration. Things like patent thickets  
 5 are very unclear. So there's an incredible lack of  
 6 predictability if there's a sort of self-help  
 7 strategy that a reference product manufacturer can  
 8 pursue.

9 To the extent possible, policymakers should  
 10 try to minimize the costs related to approvals.  
 11 Again, there's a push and pull here. Of course  
 12 these barriers can be very valuable because they  
 13 ensure, I should say, that the products are safe  
 14 and are in fact similar, but that process we should  
 15 strive -- and I think we will achieve over time  
 16 streamlining in that process that will reduce those  
 17 costs; then finally, the education piece, I think,  
 18 the information gaps that exist in the marketplace.

19 It's not on this slide, but I think it's  
 20 also important for policymakers to recognize that  
 21 in an environment where there are impediments,  
 22 barriers, that there can be a justified case, at

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1 least on a temporary basis, for incentivizing the  
 2 market to get over a hurdle. Because there are  
 3 these natural incentives for biosimilars perhaps to  
 4 wait, and for other market participants to wait,  
 5 there may be natural logic for prescribers to wait  
 6 before they start to prescribe biosimilars, to wait  
 7 for more information.

8 To help resolve some of these frictions in  
 9 the marketplace, I think it's worth  
 10 considering -- and this was also discussed this  
 11 morning -- incentive structures to try to help  
 12 boost the system to get over an initial hurdle, to  
 13 help address the information gaps, and to help  
 14 demonstrate the opportunities and efficiency gains  
 15 from the utilization of biosimilars.

16 These types of structures, whether it be the  
 17 Shared Savings Program or the ASP plus 8 program  
 18 that's been mentioned earlier, can help draw in  
 19 participants to the market, both on the  
 20 manufacturer side, as well as the payer and  
 21 prescriber side.

22 So I'll just wrap up. I'll say that many of

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1 these barriers have dissipated over time,  
 2 particularly in the last couple of years as we've  
 3 seen more guidance. We're doing better, but I  
 4 think at the same time, there's still opportunities  
 5 for policymakers to be engaged. They shouldn't be  
 6 satisfied with the degree of competition we see in  
 7 this market place today and should be pursuing  
 8 policies to help further extend competition in the  
 9 biosimilar marketplace.

10 Panel Discussion - Alison Falb  
 11 MS. FALB: Thank you.

12 For the panel, which barriers do you think  
 13 have the greatest impact on the go or no-go  
 14 decision for a biosimilar manufacturer?

15 MR. SCHICK: I always think that there are  
 16 two really important barriers that are particularly  
 17 problematic in this space. The first one is  
 18 manufacturing these products consistently with good  
 19 quality and then to scale up that production. It's  
 20 just not as trivial in this market as compared to  
 21 the small molecule market. Of course our small  
 22 molecules are difficult to manufacture. The

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1 biosimilars are just very difficult. It's hard to  
 2 get the Coca-Cola recipe, as some people refer to  
 3 it, right each and every time.

4 Another thing I think that is always  
 5 important to emphasize -- and Murray kind of  
 6 alluded to this in his talk -- is that this is a  
 7 very lucrative market. This is the up-and-coming  
 8 market for getting a high amount of sales.

9 There's a very extensive playbook that's  
 10 well established for incumbents for how you deal  
 11 with people not coming into your space and taking  
 12 away your sales. Unfortunately, the playbook  
 13 really benefits the incumbents very well. A lot of  
 14 manufacturers, they're on both sides of this aisle.  
 15 It's great when they're the incumbent and it's not  
 16 so great when they're not the incumbent, and how to  
 17 deal with that is very difficult.

18 One reason -- in addition to everything Alex  
 19 mentioned -- why we might be seeing so many  
 20 barriers is that people are fighting very hard to  
 21 keep their very lucrative cash cows to themselves  
 22 as long as possible.

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1 MR. SCHMIDT: One thing I would add to  
 2 amplify Alex's point about education is that I  
 3 think one development that was very important in  
 4 getting small molecule generics such great  
 5 acceptance, obviously, was all the state  
 6 substitution laws. I think FDA can play an  
 7 important role in educating people and state  
 8 capitals about what the appropriate role is for  
 9 interchangeable and biosimilar products.  
 10 This is complicated stuff. Speaking as an  
 11 economist, it's very complicated stuff. To the  
 12 extent that we have scientists here that can help  
 13 state legislators understand appropriate rules for  
 14 substitution, I think that could be incredibly  
 15 helpful.  
 16 MR. AITKEN: I would add one comment. We  
 17 haven't really talked about markets outside of the  
 18 U.S., but as we recognize, we live in a global  
 19 world, and there is a relevance to the European  
 20 markets as it relates to decisions made by  
 21 manufacturers as to whether they will invest in the  
 22 production capacity and regulatory submissions for

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1 additional biosimilars to come to market.  
 2 I think when we observe what's going on in  
 3 Europe, there's been a significant decline in the  
 4 prices there for biosimilars: heated competition,  
 5 use of winner takes all  
 6 price-based tenders and so on, all of which reduces  
 7 the attractiveness of that part of the market; and  
 8 it's not an insignificant share of the global  
 9 market for biologics and the potential for  
 10 biosimilars.  
 11 So there is an interconnectedness I think as  
 12 we think about what's it going to take for us to  
 13 have sustainable levels of competition in this  
 14 market. We need more than just one or two players  
 15 in biosimilars. We want to see 3 or 6 or 9  
 16 different types of competitors to make this market  
 17 really effective. To that extent, I think just  
 18 watching what's going on in other parts of the  
 19 world, in particular Europe, is also very relevant.  
 20 MR. BRILL: Just to add on to Murray's  
 21 point, what we've seen so far is competition in the  
 22 blockbuster market of biologics, and when we think

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1 about what other barriers exist, this is a  
 2 high-fixed cost business. It's hundreds of  
 3 millions of dollars to get in, not millions of  
 4 dollars. And over time, I think there's a  
 5 technology piece that we need to see evolved so  
 6 that we can see competition in the smaller and the  
 7 lower size market space as well.  
 8 MS. FALB: Thank you all very much.  
 9 (Applause.)  
 10 MS. IKENBERRY: Hi. My name is Sarah  
 11 Ikenberry, and I'm the senior communications  
 12 advisor in CDER's Office of Therapeutic Biologics  
 13 and Biosimilars. I'm pleased to be able to discuss  
 14 a very important topic related to biosimilar uptake  
 15 and acceptance, and unfortunately it's not medical  
 16 extended reality.  
 17 (Laughter.)  
 18 MS. IKENBERRY: It is improving stakeholder  
 19 engagement, education, and understanding.  
 20 While we're working on the slides, I'll go  
 21 ahead and let you know that the objective of the  
 22 session will be to discuss some real-world

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1 considerations surrounding biosimilars and how  
 2 healthcare providers' and patients' knowledge,  
 3 awareness, and perceptions regarding biosimilar and  
 4 interchangeable products can impact uptake and  
 5 acceptance.  
 6 I'm co-moderating this panel with Elizabeth  
 7 Jex, an attorney advisor specializing in  
 8 biopharmaceutical health policy in the Federal  
 9 Trade Commission's Office of Policy Planning. Just  
 10 to kind of give a brief sketch of how we'll work  
 11 this panel, I'm going to briefly introduce  
 12 everyone, and then I think give a quick  
 13 presentation about some of FDA's education and  
 14 outreach initiatives, and then I'm going to turn it  
 15 over to the panelists.  
 16 What's unique about this panel is that we  
 17 have one of our panelists beamed in from Canada,  
 18 and she will be presenting remotely, so I believe  
 19 that she will be on the screen. Her name is Cheryl  
 20 Koehn. She's from the Arthritis Community Experts  
 21 in Canada.  
 22 Do you know if Cheryl can hear us on the

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1 line? Is her mic unmuted?  
 2 MS. KOEHN: I can hear.  
 3 MS. IKENBERRY: Oh, great. Wonderful.  
 4 MS. KOEHN: I can see myself. I'm not sure  
 5 you can see me there in the room, but I don't think  
 6 that matters, as long as you can hear me.  
 7 MS. IKENBERRY: Okay. Well, I think we'll  
 8 work to get your face on the screen as soon as we  
 9 can.  
 10 Cheryl is from Arthritis Community Experts  
 11 in Canada, and she is a patient that lives with  
 12 rheumatoid arthritis, and in over the last 30 years  
 13 has become a national patient community leader, a  
 14 patient research partner, and published author.  
 15 Let's see here. At the end of the table, we  
 16 have Michele Andwele. She's the editorial director  
 17 for health content at the Arthritis Foundation,  
 18 where she oversees the content strategy and  
 19 development of patient education materials.  
 20 We have Sameer Awsare, associate director  
 21 for the Permanente Medical Group in charge of  
 22 pharmacy, adult and family medicine, mental health,

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1 and many other areas; I did not write them all  
 2 down; and Hillel Cohen, the executive director of  
 3 scientific affairs at Sandoz, where he helps  
 4 explain the principles of biosimilars and related  
 5 policies to the healthcare community, patient  
 6 advocacy groups, and other stakeholders. He is  
 7 also the co-chair of the Education Committee for  
 8 the Biosimilars Forum.  
 9 Just briefly, I'm going to give an overview  
 10 of our education and outreach efforts here at the  
 11 FDA that we've done. As noted by many on these  
 12 panels throughout the morning and the day,  
 13 education has been mentioned quite a lot.  
 14 Here at the FDA, we take this very  
 15 seriously, and we've been working for a long time  
 16 to help improve understanding of biosimilars among  
 17 patients, healthcare providers, and payers. We've  
 18 been doing this in a couple different ways, by  
 19 engaging with various stakeholders and developing  
 20 materials for the stakeholders to use.  
 21 The thing is that this requires  
 22 multistakeholder engagement. What that means is

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1 that FDA can't do it alone. We can develop the  
 2 materials, but what we need is for these healthcare  
 3 provider organizations and patient stakeholders to  
 4 take them and disseminate them to the people.  
 5 People can take our materials and use them, however  
 6 they would like, to get the information to their  
 7 constituents.  
 8 This is just a snapshot of some of our  
 9 healthcare provider materials. We have an  
 10 infographic, various fact sheets, some ads, and  
 11 other web content. I'm not going to go into  
 12 details.  
 13 Most recently, we released some educational  
 14 materials for patients. It's a website and an  
 15 infographic that uses patient-friendly language, so  
 16 we really try to boil it down to the most important  
 17 concepts that are the most important to patients.  
 18 We tested this, reworked it, and tested it again  
 19 and reworked it. We're happy with this basic  
 20 foundational piece, but we are also working on a  
 21 lot more things.  
 22 This is just to build a foundation of basic

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1 understanding that highlights the similarities of  
 2 biosimilars and reference biologics, and it  
 3 highlights the benefits of increased access, so the  
 4 goodness of biosimilars for patients, and access,  
 5 and hopefully lowering costs. It demonstrates our  
 6 efforts to always ensure the safety and efficacy of  
 7 biosimilars or just patients to talk to their  
 8 doctor and visit our site for more information.  
 9 As I alluded to, we are developing  
 10 additional materials for patients and healthcare  
 11 providers, and we're going to begin testing for  
 12 additional patient materials soon. Hopefully,  
 13 we'll be able to provide some real quality pieces  
 14 of video and some other information for patients  
 15 soon, in addition to developing additional  
 16 materials for healthcare providers.  
 17 As always, you can go to our website's  
 18 biosimilars page, our Purple Book, and drugs@FDA  
 19 for information.  
 20 I'm going to end that, and turn it over now  
 21 to Cheryl Koehn, from Arthritis Consumer Experts,  
 22 to provide her presentation. Thank you very much

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1 for joining us, Cheryl.  
 2 Presentation - Cheryl Koehn  
 3 MS. KOEHN: Thank you very much, and I  
 4 apologize I'm not there in person. Given the  
 5 events of the day, it's probably a good thing that  
 6 I'm not. But I want to thank the FDA and the FTC  
 7 for organizing this important meeting, and I look  
 8 forward to hearing and learning from my fellow  
 9 panelists.  
 10 Can you hear me ok, Sarah?  
 11 MS. IKENBERRY: Yep, we can hear you great.  
 12 MS. KOEHN: Okay, great.  
 13 Following on Sarah's comment, I was  
 14 parachuted in from Canada to give you that  
 15 perspective. We're this little country just north  
 16 of your border --  
 17 (Laughter.)  
 18 MS. KOEHN: -- and most of our population is  
 19 sprinkled along the US-Canada border, so we're very  
 20 aware of the events that have been going on in the  
 21 United States with respect to biosimilars and have  
 22 been engaged in the conversation, as have you, for

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1 as long.  
 2 This first slide really speaks to where we  
 3 come from as a patient organization. I've been a  
 4 person living with rheumatoid arthritis for the  
 5 past 31 years and have spent that past 31 years  
 6 volunteering and working in my community as a  
 7 health educator and deliverer of evidence-based  
 8 information.  
 9 We were the first to be invited into the  
 10 conversation around biosimilars, or on biosimilars,  
 11 nine years ago by Health Canada, by BIOTECCanada,  
 12 and then subsequently by our provincial government.  
 13 The reason being, we are the largest arthritis  
 14 patient organization in the country with 50,000  
 15 members coast to coast, and Arthritis Research  
 16 Canada is our scientific partner. So everything we  
 17 do is based on the evidence.  
 18 You've seen my disclosures. I believe  
 19 they're on the website in my speakers bio. I am  
 20 employed by ACE full-time, but I'm here today as a  
 21 volunteer.  
 22 Truth to power is really an important piece.

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1 Really, I think what's most important for this  
 2 audience to hear from us is, from the beginning, we  
 3 really clearly articulated what our patient  
 4 organization rules and responsibilities are. I  
 5 think that's a really important part of this  
 6 conversation when we speak about information and  
 7 education.  
 8 Knowing the truth and speaking the truth is  
 9 what we are all about. Operating independently and  
 10 disclosing all sources of funding in this  
 11 conversation, and in every conversation, about  
 12 therapies in particular given the dollars at stake,  
 13 is an absolute must. To consult incredible  
 14 independent clinicians and researchers, and most  
 15 importantly, our membership, is what is the bedrock  
 16 of the development of our materials.  
 17 So it doesn't come from the outside. It  
 18 doesn't come from being bombarded by advertising on  
 19 television. We feel that to be an honest knowledge  
 20 broker for your community, policymakers, and  
 21 payers, you have to actually be so morally solid  
 22 and have that north star firmly positioned in the

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1 sky that you're willing to give up your own  
 2 financial health, if that's what's at stake, to be  
 3 credible.  
 4 To be reasonable and look beyond the needs  
 5 of your own organization, if it's the right thing  
 6 to do, is paramount, especially in this  
 7 conversation that is so shrouded by myth and by  
 8 many other things like litigation and so on and so  
 9 forth. I'm sure you've talked about those things  
 10 already this morning.  
 11 First, I think the most important thing that  
 12 we do as an organization is to follow the evidence  
 13 and then deliver the evidence. Our job as  
 14 knowledge translators is really to take the  
 15 evidence in a truthful way and reflect on its  
 16 impact, and then put that into language that is  
 17 accessible to our community. ACE does that by  
 18 developing free research-based information and  
 19 education programs that are relevant to not just us  
 20 but the patient at large.  
 21 Sarah touched on, very briefly, the  
 22 materials that the FDA-FTC have developed, and

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1 they're fabulous. I think for the first time ever,  
 2 Canada was ahead of the United States. We launched  
 3 our information hub about biosimilars back in 2016,  
 4 and it remains one of those beacons for information  
 5 sources here in Canada and beyond.

6 I think one of the most important things  
 7 that you may talk about on this panel is the nocebo  
 8 effect. You have seen in this conversation,  
 9 patients have seen, and the public has seen on the  
 10 ground a whole lot of white noise. That white  
 11 noise is like concerns about safety and efficacy,  
 12 them not being identical, them not being  
 13 interchangeable. Those things are actually very  
 14 strategic when it comes to consumer-level  
 15 information delivered by, in many instances,  
 16 originators, originator manufacturers.

17 I think it's really important for everyone  
 18 to understand that the nocebo effect is real, and  
 19 the number one way of creating the nocebo effect is  
 20 actually to speak negatively; to have negative body  
 21 language in clinic about them; to see ads that use  
 22 subtle words, or I should say not so subtle words,

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1 such as, "I love my product. I love my brand X."  
 2 I think these are really important and strategic  
 3 words that are being chosen to create nocebo  
 4 effect.

5 The way in which you manage a nocebo effect  
 6 is really important, and it takes this solid  
 7 information, this evidence-based lay language type  
 8 information, to manage the nocebo effect as you  
 9 begin to transition patients from their reference  
 10 product, or their originator brand, to their  
 11 biosimilar brand.

12 You heard the previous speaker talk about  
 13 how this is not an inexpensive proposition making  
 14 biosimilars or originators. Biosimilars in our  
 15 view are still brands. They deliver the same  
 16 thing, but when you use words, like "copy" and  
 17 "cheaper" and "generic," those things are, in many  
 18 cases and many instances, intended to create  
 19 nocebo, and this is just morally wrong when the  
 20 evidence shows that they're every bit as effective  
 21 at sustaining efficacy and safety.

22 So it's super important, when it comes

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1 downstream from our regulators, for educators,  
 2 patient organizations, and larger health charities  
 3 such as the Arthritis Foundation, to use really  
 4 solid, unbiased, and positive if it applies,  
 5 information about biosimilars, which mitigates  
 6 anxiety regarding a switch or a transition from  
 7 patient to patient or in whole-disease communities.

8 I think lastly, I'll just add this. In  
 9 Canada, we are, again, finding ourselves in a  
 10 unique position. We're ahead of the United States  
 11 in terms of what we call up here transitioning or  
 12 switching policies.

13 To date, we have three Canadian provinces  
 14 that have implemented transition policy, the most  
 15 recent being the province of Alberta. We have 11  
 16 provinces and territories, and the province of  
 17 Ontario, which is our largest province here in the  
 18 country, is now contemplating implementing  
 19 transition policy. So everyone that is stable and  
 20 doing well on their originator or their reference  
 21 product will be moved to the biosimilar that has  
 22 been authorized for use here in the country.

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1 I can say this in closing, that the  
 2 transition has gone very well. British Columbia's  
 3 entering almost its first year, and probably 1 to  
 4 2 percent of all those transitions make special  
 5 access or exemption requests, and about 1 percent  
 6 of those were approved. So it's not as though  
 7 people who have very specific needs are not being  
 8 considered, they certainly are, and they're being  
 9 considered by specialists.

10 So all in all, here in the country, we're  
 11 doing exceedingly well at maintaining gold-standard  
 12 quality of care, as you see there on my last bullet  
 13 point. I see my slides were jumping around a bit.  
 14 I hope that wasn't too confusing for folks.

15 But the bottom line is that we can buy an  
 16 awful lot of health care for close to \$2 billion  
 17 Canadian in our publicly-funded healthcare system  
 18 without compromising quality of care. For me as an  
 19 individual patient, it's not enough that I can find  
 20 my way or fight my way, because of my literacy  
 21 level, to the best treatments available. It's up  
 22 to me and all of our community to make sure that

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1 everyone living with a form of autoimmune arthritis  
2 can find their way to effective therapy. So I'll  
3 just end there, and thank you for listening.  
4 MS. IKENBERRY: Thank you, Cheryl.  
5 Now, let's see who slides come up next.  
6 (Laughter.)  
7 MS. KOEHN: It's like a caffeine finger.  
8 I'm sorry. The slides just kept bouncing around.  
9 MS. IKENBERRY: No, it was fine. They were  
10 stuck on the first one for a little while, but we  
11 figured out how to move them. But for everyone  
12 watching here in the room and at home, you can  
13 access all of the slides on the meeting website, so  
14 Cheryl's slides will be there as well.  
15 It looks like Sameer is next.  
16 Presentation - Sameer Awsare  
17 DR. AWSARE: Alright. I'm Sameer Awsare.  
18 I'm an internal medicine physician, and I still see  
19 patients. For those of you who are not familiar  
20 with Kaiser Permanente, a quick slide, that we take  
21 care of 12 million patients and spend about  
22 \$12 billion dollars on pharmacy expenses. You can

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1 see we're in eight states and the District of  
2 Columbia with a whole lot of clinicians taking care  
3 of these folks.  
4 What I wanted to show you is the methodology  
5 that we use not only for biologics but also for all  
6 of our generics. Unlike the external world, where  
7 the health plan actually figures out what the  
8 formulary is, and then the physician has to do,  
9 "Mother, may I?" we actually do it just the  
10 opposite way, where we have the pharmacists and the  
11 physicians looking at the research and getting the  
12 right specialist involved.  
13 So if it's an oncology drug and it's a  
14 lymphoma, then the lymphoma specialists all look at  
15 it and weigh in on it before it comes to the  
16 pharmacy and therapeutics committee, and then we  
17 make a decision. And then we go to contracting and  
18 say go find a good deal.  
19 So rather than doing it the other way as the  
20 rest of the competition does, this is what we can  
21 do; and when we can do that, we can actually  
22 promise to move 90 percent of the market share to

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1 whichever product that we're going to then end up  
2 choosing. So that really is a big differentiator  
3 for us, but it also gets us that engagement.  
4 So we don't really have any  
5 preauthorization, we don't have step therapy, and  
6 our compliance from our physicians is usually in  
7 the 99 percent rate without anybody slapping them  
8 or telling them to call someone for permission.  
9 I'm just using this slide for Inflectra, and  
10 as you see, look at the evidence; yes, the European  
11 evidence, too. Our doctors are like, "What? Are  
12 the studies from Europe?" Do we have studies from  
13 America? Okay, we found an American study. "How  
14 about some studies from Kaiser Permanente?" I'm  
15 like, "Oh well, alright, we can do that, too."  
16 So for Inflectra, we initially had to start  
17 new patients on the biosimilar. Once we had the  
18 experience with about 700 patients, we looked at  
19 people who had been on the originator product, and  
20 we found no meaningful difference, and people are  
21 sold. So it took a little bit of a while.  
22 It also helps when we have specialists in

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1 that particular area who can then endorse it. We  
2 have some world specialists in inflammatory bowel  
3 disease who have written articles, et cetera. And  
4 if we have other GI doctors who are saying, "Well,  
5 I'm not sure about this biosimilar," actually  
6 talking to a colleague who has expertise really  
7 helps that.  
8 We have the right tools in the electronic  
9 medical records, and when you're ordering things,  
10 the right kind of thing pops up. We actually  
11 follow all of these patients to see how they're  
12 doing, and we have clinical pharmacists helping our  
13 physicians and helping our patients do that, and  
14 then we also see what happens post-starting these  
15 medications.  
16 For this particular one, we actually did do  
17 switching, and unlike the provinces in Canada where  
18 it was a statewide decision, we actually have  
19 conversations with our patients, and we were  
20 definitely able to do a lot of switching. The  
21 nocebo effect was mentioned, and actually any of  
22 these biologics, whether it's the originator



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1 product or the reference product, don't always work  
2 for this particular disease, so our physicians were  
3 a little bit concerned that perhaps even the  
4 originator product didn't work and we saw that  
5 perhaps the switch rate was about 9 percent. So  
6 it's a little higher than Canada, but in line with  
7 what you see in Europe.  
8 We also found -- and we haven't published  
9 this as yet -- when we had clinical pharmacists  
10 helping, the switch rate was perhaps 5 percent. So  
11 again, patients were quite good at staying on the  
12 biosimilar once they had had the right education  
13 and the physicians had had the right education.  
14 We just published the data. I think we were  
15 on a panel two years ago, and you said, "When will  
16 Kaiser Permanente actually publish any of this?"  
17 So about two weeks ago, we published in BioDrugs,  
18 and it's the largest U.S. study on the  
19 Inflectra-Remicade switch.  
20 We actually found no meaningful difference  
21 and no inferiority at all, so patients did just as  
22 well on both. It's only available electronically

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1 right now. It will be published in the journal  
2 very shortly. I think you have to pay \$3,000 or  
3 something crazy to get this right now, but  
4 electronically you can see it.  
5 We have similar experiences with the other  
6 two biosimilars that have come out for Avastin and  
7 Herceptin. What I would want to point out is when  
8 the first biosimilar came, it took a little bit of  
9 effort. We had to actually educate our physicians,  
10 educate our patients, get the specialists to talk  
11 to the right specialists, and it took 3 or 4 months  
12 to get that market share.  
13 With the last two biosimilars, this uptake  
14 to almost 100 percent happened in a 2-week period.  
15 So once physicians felt very comfortable with the  
16 first one, the next ones have been a lot easier.  
17 So I'll stop there and wait until the Q&A to  
18 give you other details. Let's see whose name shows  
19 up next.  
20 MS. IKENBERRY: Thanks, Sameer.  
21 (Laughter.)  
22 MS. IKENBERRY: I think Michele might be

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1 next.  
2 Presentation - Michele Andwele  
3 MS. ANDWELE: That's why I wore green, but I  
4 am next.  
5 Hi, everyone. For those who are not  
6 familiar with the foundation, we're the largest  
7 nonprofit patient advocacy organization for both  
8 adults and children with musculoskeletal and  
9 rheumatic diseases.  
10 We started collecting patient insights  
11 around biosimilars when the first biosimilar was  
12 approved, the biosimilar for Remicade in 2016. As  
13 you can see from the slide, we found naturally a  
14 lot of other misleading or confusing information  
15 that was available for patients. We did another  
16 round when the fifth biosimilar was available, but  
17 we recognized that the key concerns remained, and  
18 as you can see from this slide, they fall into  
19 three categories.  
20 Efficacy, obviously, "Will I flare if I  
21 switch? Will it work as well for me; because I am  
22 stable? Are they safe?" which is a normal

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1 medication concern, biosimilar or not. Then the  
2 cost coverage matrix gets a little bit more  
3 complicated because there are so many variables  
4 that determine will I pay less, everything from  
5 insurance coverage to are they underinsured, and  
6 are they part of a patient assistance program. So  
7 navigating that matrix requires a lot more  
8 conversation and a lot more variables.  
9 We also found what we call a push-pull  
10 dynamic for a lot of our patients with regard to  
11 healthcare decisions in general, but medication  
12 specifically. The push part of that dynamic is the  
13 extent to which the patient is kind of personally  
14 motivated to make decisions, but the pull dynamic  
15 is a lot stronger because they are trusting  
16 primarily their ATP to guide them in the right  
17 direction. That's the individual they see that has  
18 the most information.  
19 So to the extent to which their physician is  
20 not even bringing it up helps them to determine is  
21 it a conversation that they should have, and even  
22 if they are personally motivated or interested,

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1 that barometer from their physician plays a  
 2 critical role. To a lesser but also important  
 3 effect are larger influencers. Are there patient  
 4 organizations and patient advocates who are looking  
 5 out for their best interest? That's where  
 6 foundations like the Arthritis Foundation play an  
 7 important role.

8 The three key takeaways for what patients  
 9 are thinking, first, I like to call it interest  
 10 without urgency. It's kind of floating out there,  
 11 but they don't really have this tipping point for  
 12 them to feel that this is something that they need  
 13 to really focus on; then, as I mentioned before,  
 14 the provider influence is key.

15 From the HCP patient advocacy perspective,  
 16 we have been doing -- and I'll mention it in the  
 17 slide in a minute. As a patient advocate, we have  
 18 been trying to identify ways to strengthen  
 19 collaboration with other provider and HCP patient  
 20 advocate organizations so that we're speaking the  
 21 same language. What we have identified from some  
 22 of these earlier conversations is a challenge

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1 around language, and that's where education plays a  
 2 critical role.

3 Within both provider organizations and  
 4 patient advocates, there is inconsistency with how  
 5 we're all talking about biologics and biosimilars  
 6 and the terms that we're using. We recognize the  
 7 importance of a consensus among all the patient  
 8 advocates and provider groups of where language  
 9 should be.

10 Some of the provider concerns are  
 11 independent of biosimilars. There are time  
 12 constraints in every conversation. Where does a  
 13 detailed conversation about biosimilars fit into  
 14 15 minutes, 20 minutes, 27 minutes, with patients  
 15 who are dealing with a lot of issues in addition to  
 16 their medication?

17 I mentioned insurance coverage earlier.  
 18 Naturally, if it's not going to be covered or there  
 19 isn't a patient assistance program, why would a  
 20 provider even bring it up when they understand  
 21 their patients unique needs? The last is the issue  
 22 around liability exposure potential with the

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1 interchangeability -- I'll try to say that  
 2 fast -- designation and what that means.

3 There's a shared belief of a promise of  
 4 biosimilars; we're all clear. We look to the FDA  
 5 as our continued expert partner, and we recognize  
 6 their varying levels of knowledge that we really  
 7 need to address and the role of peer-to-peer  
 8 information, both from the patient perspective and  
 9 provider perspective, as Sameer mentioned earlier.

10 We're going to try to learn from our  
 11 partners in Europe and Canada, from some of their  
 12 lessons learned. And this is just a takeaway from  
 13 a physician who transferred all his patients to  
 14 biosimilars and the extent to which the trust  
 15 factor played a critical role in him being able to  
 16 make that move.

17 How are we responding? The foundation,  
 18 independently we have been focused on a strategy of  
 19 what we call communicating parity, so we have  
 20 started to create communication materials to  
 21 reinforce a singularity in the conversation on  
 22 biosimilars and biologics. We're going to be doing

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1 some additional work with the consortium to see how  
 2 this needs to evolve and change. We've had  
 3 discussions about do we keep them separate or do we  
 4 do them together? We made the decision to test  
 5 some of our patient education materials around this  
 6 parity conversation, online and in print, and we  
 7 also leverage various media as you see here.

8 I mentioned earlier some of the work we're  
 9 doing around stakeholder and HCP engagement. We  
 10 have been leading an initiative that we're calling  
 11 the Biosimilars Consortium. It has currently  
 12 21 provider and patient organizations that we have  
 13 put together. We've had a series of meetings, the  
 14 most recent in October of 2019, I believe, and FDA  
 15 was there.

16 We are working through our 2020 priorities  
 17 as a collaborative consortium. Here are the three  
 18 main areas that we are going to be focused on in  
 19 2020. Rather than just researching independently,  
 20 we want to identify ways in which all our  
 21 organizations can both share data within our own  
 22 realm and others. We want to really look

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1 aggressively at language. We recognize the role  
 2 that bias plays in the biosimilars conversation, so  
 3 we want to address that.

4       Once we are able to look at some of those  
 5 triggers, then we are hoping to collaborate very  
 6 closely on best practices across all our  
 7 communication so that we are speaking with one  
 8 voice, and we think that plays a very important  
 9 role with regard to consistency in communication  
 10 and education both for providers and for patients.

11       MS. IKENBERRY: Thank you, Michele.

12       Now, we have Hillel Cohen, who is going to  
 13 speak a little bit. I believe there's a slide.

14       Presentation - Hillel Cohen

15       DR. COHEN: Hillel Cohen from Sandoz, but  
 16 I'm speaking today as the co-chair of the Education  
 17 Committee of the Biosimilars Forum, a trade  
 18 association group developing and promoting  
 19 biosimilar use in the U.S. I see my goal here  
 20 primarily to identify the problems companies have  
 21 seen over the past several years and to make  
 22 recommendations to address them.

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1       We've seen several different types of  
 2 disparagement and misinformation over the years,  
 3 since 2015 when Zarxio was first approved in the  
 4 U.S. as the first biosimilar. These include -- and  
 5 people have spoken about them, and my apologies  
 6 that there will obviously be duplication of what  
 7 I'm saying with what others have said -- misleading  
 8 information. We've also seen incomplete  
 9 information that's factually correct as presented  
 10 but that omits important facts. FTC has talked  
 11 about that earlier today.

12       We've also seen negative framing of factual  
 13 statements to create a negative perception. You  
 14 can say a patient will have the same clinical  
 15 outcome, the same safety and effectiveness, or can  
 16 say there's no clinical meaningful differences.  
 17 It's the way in which we express it, and I think,  
 18 Michele, you expressed that a lot just a few  
 19 moments ago. On occasion, but not often, there  
 20 actually have been statements that have been  
 21 factually incorrect.

22       General targets, we've seen. We've seen

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1 people talking about efficacy. We've seen some  
 2 comment and messages on safety, on quality, and on  
 3 regulatory. We haven't spoken about that yet. Let  
 4 me give you a couple of specific examples of the  
 5 messages that we've encountered. This is four  
 6 member companies, not necessarily one company in  
 7 particular.

8       On efficacy, we've seen messages that the  
 9 efficacy of a biosimilar is not yet fully proven.  
 10 We've talked about the purpose of those trials are  
 11 not efficacy trials, but still people say it hasn't  
 12 been proven yet, or we've seen that the efficacy of  
 13 a biosimilar may not be as good as that of the  
 14 reference product. We've seen comments about  
 15 extrapolation. Some type of physicians, or  
 16 patients, will say extrapolation is not  
 17 appropriate. It wasn't studied in my indication.

18       Safety. We've seen statements that the  
 19 safety of a biosimilar's not yet fully proven.  
 20 Again, it wasn't the purpose of these studies, but  
 21 those are comments that have been made to us. Some  
 22 people have said it's a potential that a biosimilar

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1 may be more immunogenic than that of the reference  
 2 product.

3       Switching. We've heard the experience that  
 4 we talked about in Canada. There still are  
 5 comments out there that we don't have enough data  
 6 to let us conclude that switching from a reference  
 7 product to a biosimilar is safe, the implication  
 8 being that switching may be unsafe. I realize  
 9 physicians always have the ability -- we haven't  
 10 talked about this yet -- to prescribe whatever  
 11 product they feel is most appropriate. You don't  
 12 need interchangeability for that.

13 Interchangeability is a pharmacy-level decision.  
 14 Physicians now have that ability to make the  
 15 substitution if they make that choice.

16       We've also seen comments about the quality  
 17 of a biosimilar. Well, the quality of a biosimilar  
 18 may not be as good as that of the reference  
 19 product. Probably more often we've seen people say  
 20 it's only similar or only highly similar, not  
 21 identical; never mind the fact that its many  
 22 differences are not clinically relevant. That's a

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1 mouthful that's difficult to understand.  
 2 We've talked about interchangeability.  
 3 There have been statements out there that  
 4 interchangeability is a higher standard. Again, I  
 5 don't want to say everyone is saying that. It's a  
 6 couple of messages and a couple of statements that  
 7 have been out there, the implication being that  
 8 biosimilars are of lower quality than an  
 9 interchangeable biologic. In fact, it's not the  
 10 situation. It's just a different standard  
 11 requiring different additional clinical data. In  
 12 fact, they're absolutely identical;  
 13 [indiscernible], so they have to be identical.  
 14 The regulatory pathway has also created a  
 15 little bit of a problem in the sense that the BPCIA  
 16 talks about an abbreviated pathway. The  
 17 abbreviated pathway talks about the clinical  
 18 development. Some people would say the regulatory  
 19 pathway, it's only abbreviated if it's not as  
 20 rigorous as a pathway for reference products.  
 21 Actually, it's very rigorous.  
 22 What recommendations can we make? These are

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1 just general messages that we've encountered.  
 2 Clearly, all parties should be required to share  
 3 truthful and complete information. There's an  
 4 information flow that we've talked about, a little  
 5 more exact: FDA to healthcare professional  
 6 societies; these societies to their  
 7 physicians and also to the patient advocacy groups  
 8 with which they work; and then for the physicians  
 9 and the patient advocacy groups to patients.  
 10 The forum believes that patient discussions  
 11 with the healthcare providers are really extremely  
 12 important and will go a very long way towards  
 13 gaining acceptance.  
 14 Positive framing. Cheryl Koehn talked about  
 15 that to a degree, and we can talk about it later in  
 16 detail. You want to highlight the quality and the  
 17 benefits of a biosimilar, to talk about it in a  
 18 positive sense.  
 19 It's also important to have easy to  
 20 understand messages. The FDA has been developing  
 21 these messages and making sure that you've been  
 22 testing them to make sure they're easily

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1 understandable by the patients. That's really  
 2 critical. It's also important to make sure they  
 3 can be readily accessible. Most patients, and  
 4 maybe many doctors, go to Dr. Google as an  
 5 important source of information.  
 6 (Laughter.)  
 7 DR. COHEN: Messages should be based on the  
 8 FDA documents. Not all of the FDA documents are  
 9 purposely designed to be easy to understand. Some  
 10 of them are directed to the industry, some to  
 11 healthcare professionals also, and only some  
 12 towards patients. But anyway, all the messages  
 13 designed by the myriad of organizations developing  
 14 these should be based on the FDA documents and  
 15 tailored to their audience.  
 16 It's also important to realize that there  
 17 actually is a lot of information out there already  
 18 available in print on the Web, and the material out  
 19 there, people should review them, those who put  
 20 them out to review them, and if necessary, revise  
 21 them. Of course the forum is willing to work with  
 22 FDA and other stakeholders to create this easily

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1 understandable information with biosimilars and  
 2 interchangeable biologics.  
 3 Just a few more things. More education is  
 4 needed for the average patient and the doctor  
 5 engaged in everyday patient care. I appreciate  
 6 that for the large purchasing organizations, they  
 7 may be fully on board with biosimilars. They've  
 8 read the details, they have now knowledgeable  
 9 people, and they're on board.  
 10 Kaiser Permanente, you've done the analysis;  
 11 you're on board. In fact, the patient advocacy  
 12 groups, many of them have delved into them in great  
 13 detail, especially those which have skin in the  
 14 game. The Arthritis Foundation and the National  
 15 Psoriasis Foundation have studied these things in  
 16 detail, but the average patient is not  
 17 knowledgeable.  
 18 From bottom up, we need education. Patients  
 19 need to be educated. The physicians need to be  
 20 educated. Rheumatologists we found are more  
 21 knowledgeable; gastroenterologists, maybe less so,  
 22 so specialties may have to be focused on. Also,

1 obviously, we urge the FDA and the FTC to exercise  
2 their authorities when possible and under the  
3 jurisdictions to prevent disparagement and  
4 misinformation.

5 Now, there's an initiative that I believe is  
6 in the early planning stages that the forum  
7 strongly endorses, which is incorporating  
8 biosimilar education to the curricula of medical  
9 schools, nursing schools, and pharmacy schools.  
10 There are a small smattering of schools that are  
11 already doing that, but it really needs to be  
12 incorporated broadly in the U.S.

13 Finally, we would recommend that advocacy  
14 groups and lobby organizations -- sometimes they're  
15 closely linked -- should disclose their corporate  
16 alignments, their funding, and the conflicts of  
17 interest. Now, let me be clear. There's nothing  
18 wrong with someone speaking their positions.  
19 That's absolutely fine. Everyone is entitled to  
20 their positions on all sides. It's just that we  
21 think it's important to have full disclosure in  
22 place. With that, thank you very much for your

1 and to patients? What recommendations, in addition  
2 to those that you've mentioned today, can we make  
3 to either the webpage or to future joint efforts,  
4 or research as you've discussed today on these  
5 topics? So I just lay that out for any and all.

6 MS. KOEHN: It's Cheryl here, Liz. Perhaps  
7 what I'll do is just let you know that what we did  
8 here in Canada was that it's easy to say everybody  
9 needs to be educated, but we live in a time,  
10 obviously, when people get education on a  
11 catch-if-can basis. So we created a series of  
12 videos that live on our website. Our provincial  
13 governments are referring people to those. We have  
14 online materials that can be printed.

15 I think our little 5-minute video series are  
16 super, super helpful, and I would encourage the FTC  
17 and the FDA to produce some really bite-size little  
18 videos that people can access when it's topical for  
19 them. We have to remember, this is not for the  
20 general population; this is for the population of  
21 people who will be switched or transitioned if in  
22 fact that's what happens there. That's what we

1 time.

2 Panel Discussion

3 Sarah Ikenberry and Elizabeth Jex

4 MS. IKENBERRY: Thank you, everyone, for  
5 presenting. Now, I'm going to turn it over to Liz,  
6 who's going to do some Q&A here with the panelists.

7 MS. JEX: Thank you, again, FDA for hosting  
8 this event and for conducting the joint statement  
9 with the FTC on this important topic. We've  
10 touched on a lot of the questions that I circulated  
11 to you all.

12 I think the key question I have is the FDA  
13 has recently updated its web pages, for both  
14 healthcare providers and patients, to explain that  
15 FDA-approved biosimilars are just as safe and  
16 effective as the original biologic reference  
17 product, and provide the same treatment benefits,  
18 and could have the same potential side effects as  
19 the reference biologic.

20 How can we best communicate this information  
21 to healthcare providers, to the medical  
22 professional societies, to patient advocacy groups,

1 did, and they have proved to be one of the most  
2 accessed areas on our website.

3 I'll just say that even in the course of  
4 this panel, if we're all saying language is  
5 important, I would really encourage you to change  
6 the materials and change our language. I've heard  
7 now multiple times, just in the span of 45 minutes,  
8 the word "biosimilars" and then "biologic."

9 Biosimilars are biologic. So it's really important  
10 to let the public and the patient public understand  
11 that we are talking about biosimilar/biologic,  
12 otherwise, people think they're two different  
13 things, and clearly they're not.

14 MS. ANDWELE: Another thing that I think is  
15 important to do is develop an influencer strategy.  
16 So much of our decision-making is influenced by  
17 peers, whether it is patient peers or provider  
18 peers. One of the things at the foundation we have  
19 invested a lot of time in is building an online  
20 community and establishing a strong support group  
21 network across the country because we understand  
22 that patients like to see themselves and talk to

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1 people who get it and who understand.  
 2 A lot of people have a positive opportunity  
 3 to impact and influence other people, so we think  
 4 that identifying where those influences are and  
 5 being able to leverage that I think will have a  
 6 great impact in terms of acceptance.  
 7 DR. AWSARE: I think the panelists have  
 8 highlighted the same sort of strategy we used. We  
 9 also created educational materials for our  
 10 physicians and for our patients, and then getting  
 11 the right specialist. But for the FDA, I think  
 12 working with some of the national societies, the  
 13 American College of Gastroenterology or  
 14 Rheumatology, like you are. When Inflectra first  
 15 came out, some of the GI societies were not in  
 16 favor of the biosimilar.  
 17 So having the right education to the right  
 18 people, people are looking to these folks to give  
 19 them direction, and if they don't see that coming,  
 20 they're not interested in switching. I mean, the  
 21 patient's stable. Why am I going to do that?  
 22 You're going to call me, you're going to make more

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1 visits to my office, and you're doing well on your  
 2 current biologic. Why am I going to even switch if  
 3 my professional society is not endorsing that?  
 4 DR. COHEN: We actually asked that of the  
 5 four member companies, what key messages we would  
 6 wish the FDA to have. Obviously, it's different  
 7 than disparagement, so I'm talking in the positive  
 8 sense.  
 9 The positive messages we want, same safety  
 10 profile and effectiveness if possible. I think  
 11 that would go a very long way. That's probably  
 12 number one. Evidence requirements of biosimilars  
 13 are very high. We would like people to be aware  
 14 that there's lots of experience with biosimilars.  
 15 It's at least 700 million patient-days, and I think  
 16 it's actually quite a bit more right now.  
 17 There's a lot of experience. The EMA is on  
 18 the record with their document that came out in  
 19 November of 2019, saying they don't see any  
 20 difference in safety with the originators. Another  
 21 key message is that the scientific methods used to  
 22 characterize the manufacturer and evaluate them are

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1 rigorous, and they show that the biosimilars work  
 2 just as well as the reference products. So to get  
 3 back to will it work for me, the answer would be  
 4 yes.  
 5 Finally, the fifth point that we had as a  
 6 group is that the regulatory pathway is based on  
 7 sound scientific policy. Doctors and patients are  
 8 used to looking at clinical trials. You don't have  
 9 it with biosimilars. It's a different paradigm.  
 10 But these methods are very sound, and they use  
 11 methods that really ensure the safety, efficacy,  
 12 and the quality of a biosimilar.  
 13 I think a coordinated effort from the FDA to  
 14 the professional societies, working with the  
 15 patient groups -- and I know that this is an effort  
 16 that you've been initiating; the forum has been  
 17 part of that as well. As I said before, it's a  
 18 cascade that has to come down.  
 19 MS. ANDWELE: One thing I'd like to add is  
 20 some work around message segmentation because  
 21 you're going to have patients who are treatment-  
 22 naive, who a biosimilar may be their first

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1 medication versus someone who is stable on a  
 2 biologic. To the same extent, you'll have  
 3 physicians who have been working with biologics for  
 4 a very long time and those who are newer with  
 5 biologics. I think looking at segmentation, both  
 6 on the patient and provider perspective, may have  
 7 an impact on the communication strategy.  
 8 MS. JEX: I see we're out of time. I want  
 9 to thank my panelists for your excellent insights  
 10 into the patient and doctor experience with  
 11 biosimilars and ask everyone to give them a hand.  
 12 Thank you very much.  
 13 (Applause.)  
 14 MS. IKENBERRY: Thank you, all. I think we  
 15 could have sat up here for at least another half an  
 16 hour and discuss this. But as always, we're  
 17 interested in everything and what everyone has to  
 18 say about this, and take that into consideration as  
 19 we develop additional materials and information.  
 20 MS. TEMKIN: We're going to have a break  
 21 now, and we'll be back at 2:15.  
 22 (Whereupon, at 2:04 p.m., a recess was

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1 taken.)

2 MR. WEINSTEIN: Everyone, welcome back. My

3 name is Randy Weinstein. I'm an attorney at the

4 Federal Trade Commission. Earlier today, we've

5 talked about disparagement in the context of FDA

6 and FTC enforcement, but what about private rights

7 of action? Does disparagement resonate in the

8 context of antitrust enforcement, either by the

9 government or private litigants? These are the

10 questions we're going to talk about right now.

11 Joining me today are Michael Carrier.

12 Michael carrier is a distinguished professor at

13 Rutgers Law School. He is an expert in

14 intellectual property and antitrust law. Rebecca

15 Tushnet is the inaugural Frank Stanton professor of

16 First Amendment law at Harvard Law School. Her

17 work focuses on copyright, trademark, and

18 advertising law. I also learned, in fact, that

19 she's an expert on the law of engagement rings.

20 Professor Carrier, by chance, are you an

21 expert in any matrimonial hardware?

22 (Laughter.)

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1 DR. CARRIER: No, I'm not.

2 MR. WEINSTEIN: Okay.

3 Of course you all know Rich Cleland, my

4 colleague, from the Federal Trade Commission who

5 spoke earlier today.

6 Both Professors Carrier and Tushnet are

7 experts in their respective fields, which happened

8 to be the topics of this panel. More information

9 about their prestigious backgrounds can be found on

10 our web page.

11 Let's begin. We talked a little bit earlier

12 today with some examples of disparagement that

13 we're seeing in this industry, but is there a way

14 to kind of organize these thoughts into some

15 buckets, for example, or a way to kind of think

16 more broadly about them?

17 Presentation – Michael Carrier

18 DR. CARRIER: Yes. We certainly have heard

19 a whole bunch of examples. Let me categorize them

20 into four categories. The first category is the

21 most extreme. We haven't heard it, but it was

22 explained in a Washington Post article in January

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1 2019. It will be discussed by a couple people who

2 will show up in the public comment period, things

3 like -- and this is from the Alliance for Safe

4 Biologic Medicines -- "We need to proceed

5 cautiously with moving to biosimilars," quote, "so

6 we don't end up with another thalidomide.' That's

7 when we had children with birth defects," or,

8 quote, "all the other things that happen when

9 safety is not considered."

10 Then we had another quote from someone

11 affiliated with the organization who said that,

12 "Switching," quote, 'disrupts the continuity of

13 care. You could end up in an emergency room or

14 being hospitalized. You can exacerbate or flare

15 your disease or even bring it out of remission."

16 So this is not appropriate given that, by

17 definition, biosimilars are highly similar to and

18 have no clinically meaningful differences from.

19 That's the first category that really makes a joke

20 of what the standard is, and then we get a little

21 more subtle.

22 The second category is where we hear that

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1 the biosimilar is not identical to or acts

2 differently from the original reference product. A

3 lot of this stuff shows up in the Pfizer citizen

4 petition, so if you look at that filed with the

5 FDA, we see that Amgen says that no two biologic

6 medicines are identical; they behave differently in

7 the body. You look at an Amgen tweet, "Biologics

8 or biosimilars. It's not just apples to apples.

9 It may be highly similar, but the patient may react

10 differently." The Genentech website says that the

11 FDA requires highly similar but not identical.

12 So the benefit to the FDA's proposed

13 guidance is that it takes on these

14 misrepresentations precisely. If you look at

15 question 6, the biosimilar is not required to be

16 identical, that's really important, and I'm glad to

17 see that.

18 The third category deals with

19 interchangeability, and as we've heard this

20 morning, there are some intimations that just

21 because a biosimilar's not interchangeable, maybe

22 it doesn't meet that highest standard of safety and

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1 efficacy. For example, Janssen said, "Even though  
 2 the biosimilar is very similar to Remicade, it  
 3 doesn't mean it's interchangeable," and really  
 4 emphasized that throughout its materials. And  
 5 there in question 6 in the FDA's guidance, we see  
 6 that just because it's not interchangeable doesn't  
 7 mean it's not safe and effective.  
 8 Then finally, and perhaps most subtly, is  
 9 where the company says that the drug acts  
 10 similarly. Janssen for example says you may be  
 11 asked to switch to a biosimilar that works in a  
 12 similar way to Remicade. This is a little more  
 13 subtle than the others, but still the assumption is  
 14 that it doesn't act the same way. And we see the  
 15 FDA in question 5 on its guidance, the FDA also  
 16 saying you don't look at the number of indications  
 17 for which the product is licensed; that doesn't  
 18 tell you how safe it is.  
 19 So with all of this, we see different levels  
 20 of categorization, but in all of them there is some  
 21 sense in which there is not equivalency with the  
 22 biosimilar and that it presents real issues. As we

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1 go through this panel, it's worth thinking about  
 2 what the net impression is. If there is one  
 3 interpretation that really shows that it's not as  
 4 safe or effective, what can we do with it? So that  
 5 would be how I would categorize these statements.  
 6 MR. WEINSTEIN: Thank you, Professor  
 7 Carrier.  
 8 Professor Tushnet, we talked in an earlier  
 9 panel today about the FDA and FTC enforcement  
 10 paradigm. What about private rights of action in  
 11 the context of disparagement?  
 12 Presentation – Rebecca Tushnet  
 13 DR. TUSHNET: Great. I'm just going to give  
 14 a quick overview of the Lanham Act false  
 15 advertising cause of action. Private competitor  
 16 plaintiffs can often also bring state law claims,  
 17 but they probably shouldn't detain us for very  
 18 long.  
 19 The key element of the Lanham Act claim are  
 20 the falsity or misleadingness of a statement, the  
 21 materiality of the statement to a reasonable  
 22 consumer's purchase decision, and the likelihood of

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1 harm to the plaintiff. In the kind of case that  
 2 we're talking about here, the likelihood of harm to  
 3 the plaintiff is probably fairly clear.  
 4 A couple things that are mostly unique to  
 5 the Lanham Act cause of action compared to an FTC  
 6 or state consumer protection claim, the key thing  
 7 is the sharp doctrinal difference between false and  
 8 misleading claims. False and misleading claims are  
 9 actionable, but in a Lanham Act case, the burden on  
 10 the challenger is much greater if a claim is  
 11 misleading than if it is literally false.  
 12 That puts a premium on distinguishing  
 13 falsity from misleadingness. How does a plaintiff  
 14 establish that a claim is false? Courts ask what  
 15 is the explicit meaning of the claim? Once you  
 16 know the explicit meaning, you can then determine  
 17 whether that factual claim is false. However, of  
 18 relevance here is that courts are sometimes willing  
 19 to make general inferences from disparagement about  
 20 what the claim is. It is also important to  
 21 distinguish lay audiences and expert audiences.  
 22 Different people may differ or different groups may

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1 differ in their understanding of the term.  
 2 My favorite example of this is a case where  
 3 the defendant said that the competitor's product  
 4 was subject to catastrophic failure. It was a  
 5 medical device, and the engineering dictionary says  
 6 catastrophic failure is failure that happens  
 7 without any warning; the device is performing,  
 8 performing, performing, and then it stops. But the  
 9 plaintiff established that, to doctors,  
 10 catastrophic failure meant a failure that harms a  
 11 patient, which is a very different thing, and the  
 12 court found literal falsity because of the meaning  
 13 of the term to doctors. So dictionary meanings may  
 14 not be as important as what people are likely to  
 15 understand.  
 16 Suppose a claim is not false? How do you  
 17 establish whether it's misleading? This is  
 18 relevant if a claim is ambiguous and it has  
 19 potentially true and potentially false meanings,  
 20 much of the stuff that we've been talking about  
 21 here.  
 22 The question is what message does a



1 reasonable consumer receive? This is usually done  
2 through surveys of the relevant consumers, and the  
3 rule of thumb is that if 15 percent or more of  
4 consumers, the net of some control, receive a  
5 message, then the plaintiff is relatively likely to  
6 prevail.

7 When is this empirical evidence of consumer  
8 reaction necessary? It's not in literal falsity  
9 cases. Literal falsity is presumed to reach a  
10 substantial number of reasonable consumers, but  
11 surveys are basically always required in  
12 misleadingness cases.

13 There are a couple of exceptions. If  
14 there's an intent to deceive consumers, then that  
15 can substitute for evidence of consumer reaction.  
16 Sometimes direct testimony from deceived consumers  
17 can substitute but probably this is not a great  
18 scenario for that just because you can always find  
19 someone who's confused about something. So if you  
20 have a really broad range of consumers, the survey  
21 is going to give you a better idea of what's going  
22 on.

1 dairy products, so I think this case is quite on  
2 point to some of the claims that we've seen.

3 The other thing that is clearly of relevance  
4 that we haven't really talked about is the  
5 relevance of the First Amendment for the regulation  
6 of these claims. In Lanham Act cases, courts  
7 generally say that the Lanham Act false advertising  
8 cause of action raises no constitutional issues at  
9 all. By definition, it targets only false or  
10 misleading commercial speech that can  
11 constitutionally be banned.

12 According to Supreme Court doctrine, when it  
13 comes to direct government regulation of speech,  
14 there is a distinction between inherently or  
15 actually misleading versus potentially misleading.  
16 So whether the speech can just be banned or whether  
17 instead a disclosure must be added to try and draw  
18 the sting of the misleadingness, this distinction  
19 is not well worked out. Maybe we can address it in  
20 the questions.

21 It's largely been done by courts guessing,  
22 or worse, about what's inherently or actually

1 I did want to mention, and I do have a slide  
2 from this because I think it's hilarious, there's a  
3 Seventh Circuit case, Eli Lilly versus Arla Foods.  
4 If we could get the image up. Eli Lilly sued over  
5 images from an organic producer portraying RBST,  
6 which is a hormone given to cows to increase milk  
7 production. So it's being portrayed as a  
8 scary-toothed monster with electric fur that will  
9 shock you if you touch it.

10 The Seventh Circuit finds that there's  
11 nothing in this ad that is literally false, but  
12 that it is still misleading and enjoins it without  
13 any evidence of consumer perception, basically  
14 because of the disparagement. When you look at  
15 this, it is obvious that they are telling you,  
16 well, it's complicated but RBST is scary, which is  
17 a very relevant case for this scenario that we find  
18 ourselves here.

19 The court says the use of monster imagery,  
20 weird stuff language, and child actors combined to  
21 colorfully communicate the message that responsible  
22 consumers should be concerned about RBST-derived

1 misleading versus what is only potentially  
2 misleading. There's a lot of room here for  
3 presenting courts with facts about misleadingness.  
4 It is not the same distinction that's made in  
5 Lanham Act cases, where misleadingness is actually  
6 just one category distinct from falsity.

7 This leads to a related issue, which I hope  
8 we'll discuss, which is the relationship between  
9 private and public enforcement. Courts in private  
10 litigation regularly do defer to the FDA's factual  
11 findings about what is true, but without a lot of  
12 explanation about why they're deferring or with  
13 general references to the FDA's expertise.

14 The First Amendment may start to bear on the  
15 question of the review of these agency  
16 determinations, so what are the medical facts and  
17 what our consumers' perceptions of the messages  
18 that they receive?

19 Those are both actually facts about the  
20 world, but the level of deference that they receive  
21 may differ because courts may have their own sense  
22 of how good they are at figuring out whether

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1 deception is going on. So as a practical matter, I  
2 would expect more deference to agency findings  
3 about safety and efficacy itself versus findings  
4 about deceptiveness, even though both really are  
5 subject to the ordinary mechanisms of proof.  
6 So that is my lightning tour of the relevant  
7 concepts from my perspective, and hopefully we can  
8 now add some richness to that.

9 Panel Discussion

10 Randall Weinstein and Richard Cleland

11 MR. WEINSTEIN: Professor Tushnet, in the  
12 Lanham Act, those are actions brought by  
13 competitors; is that right?

14 DR. TUSHNET: Yes.

15 MR. WEINSTEIN: What about like a consumer?  
16 Where's the ability of the consumer to bring an  
17 action for disparagement?

18 DR. TUSHNET: Really, it would be relatively  
19 difficult, although one can imagine a consumer  
20 class action saying that the disparagement deterred  
21 a whole bunch of people from trying this drug. It  
22 could be done. I think as Professor Carrier will

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1 talk about, the real possibilities for consumers  
2 here probably do lie in the realm of antitrust.

3 MR. WEINSTEIN: And is that because there's  
4 just no good law under which consumers have  
5 standing to bring a claim?

6 DR. TUSHNET: Consumers have standing under  
7 their state consumer protection acts, but there are  
8 just a lot of barriers to a successful class action  
9 at this point, not the least of which are the  
10 contracts that you might likely sign when you buy  
11 something. So depending on how the medication is  
12 transmitted to the consumer, they might actually  
13 have waived their rights.

14 Courts are also very tough on claims that  
15 not all consumers may have seen. So if the  
16 advertising is not actually on the package, then  
17 it's going to be hard to sustain a class action.  
18 So in this space, I think the false advertising  
19 issues are really Lanham Act issues.

20 MR. WEINSTEIN: Thank you.

21 MR. CLELAND: Let me follow up on the First  
22 Amendment issue with just one question here. You

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1 mentioned the difference between inherently  
2 deceptive and potentially deceptive. One of the  
3 things is, for example, in the Palm case, where the  
4 D.C. Circuit said we've now determined that these  
5 claims are deceptive; there go [ph], no First  
6 Amendment issue.

7 If the fact-finder first finds deception or  
8 a misleading, the potentially deceptive part of  
9 that equation should go into what kind of relief is  
10 ordered, not whether the court can ban the claim  
11 that is found deceptive; right?

12 DR. TUSHNET: I think that's a completely  
13 logical way of looking at it. My only caution is  
14 that courts have been very far from logical in the  
15 order in which they approach these issues.  
16 I think that's completely right, but sometimes  
17 courts get a bee in their bonnet about the order of  
18 operations here.

19 MR. CLELAND: And in terms of the  
20 materiality prong on the Lanham Act cases, that's  
21 materiality for the competitor.

22 DR. TUSHNET: It's actually materiality for

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1 the consumer; that is it has to be likely to affect  
2 a reasonable consumer's decision, and then the  
3 materiality to the consumer then produces the  
4 negative effect on the competitor. And again,  
5 you're not looking for it to affect everybody's  
6 decision. As long as a substantial number of  
7 reasonable consumers are likely to be affected,  
8 then we can see an effect on the market.

9 MR. CLELAND: But given, in this particular  
10 market, usually it's the physicians that are making  
11 or at least having a great impact on the decision,  
12 how does that affect materiality?

13 DR. TUSHNET: I think the best answer is  
14 that it's actually open to the plaintiff to show  
15 either the patient or the doctor. As I'm sure  
16 you're all aware, there's plenty of evidence about  
17 the impact that patients have on doctors when  
18 they're asking for a specific medicine. I think  
19 you could readily show actually either group being  
20 a relevant market actor, especially given that the  
21 standard is substantial number rather than uniform  
22 effect.

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1 MR. WEINSTEIN: Turning then to the  
 2 antitrust framework, Professor Carrier, can you  
 3 walk us through the current framework for  
 4 evaluating disparagement as an antitrust violation?  
 5 DR. CARRIER: Sure. So the big picture here  
 6 is we're talking about monopolization, which is  
 7 Section 2 of the Sherman Act. We're not talking  
 8 about mergers. We're not talking about agreements  
 9 among rivals. For monopolization, you have to show  
 10 monopoly power and exclusionary conduct.  
 11 The first piece is monopoly power. You can  
 12 either show it indirectly or directly. Indirectly  
 13 tends to be through a share of the market. We  
 14 usually see at least 90 percent of the market,  
 15 although you could see perhaps lower, maybe  
 16 70 percent, together with barriers to entry. For  
 17 direct monopoly power, we tend to see price  
 18 increases or the price maintained at a high level  
 19 or output reductions.  
 20 Do we have that sort of power here? I think  
 21 that we do. It's clear that biologic products are  
 22 a generally very expensive product. So even if the

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1 biologics are not as much in terms of the  
 2 biosimilars, in terms of the number we see, the  
 3 amount of money is a ton.  
 4 You look, for example, at one case, Pfizer  
 5 sued J&J, Pfizer claimed J&J increased the price  
 6 10 percent and still has 96 percent market share  
 7 and 90 percent of producers refused to stock their  
 8 product at all. In these cases, there tends to be  
 9 such power, there are very few substitutes. So I'd  
 10 say monopoly power is not something that we spend a  
 11 lot of time on.  
 12 Then the question is what about exclusionary  
 13 conduct, and courts here have fallen into one of  
 14 three buckets. The first bucket is that there is  
 15 no liability at all for something like  
 16 disparagement; the second bucket is assuming that  
 17 the harm is de minimis; and the third bucket is a  
 18 case-by-case approach.  
 19 So the first bucket as shown by the Fifth  
 20 and Seventh Circuits is that there's no liability  
 21 at all. These courts say that false statements  
 22 enhance competition in advertising markets; that

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1 business torts are different than anticompetitive  
 2 conduct; and that false statements set the stage  
 3 for competition in the advertising market.  
 4 In short, they basically say there is  
 5 nothing to do about false statements. I think that  
 6 that is wrong. I have an article forthcoming.  
 7 Professor Tushnet and I also have an article  
 8 forthcoming in which we both think it's wrong. You  
 9 can't say that there's no liability at all when you  
 10 engage in this conduct. It's certainly possible to  
 11 get or maintain monopoly power by engaging in this  
 12 behavior of disparaging your rivals. It's  
 13 certainly not something that the rival can fix. It  
 14 certainly can have a significant effect on the  
 15 overall market.  
 16 So we would say that this approach is wrong.  
 17 Nonetheless, if a court were to adopt it, then  
 18 there's no liability because that's just what  
 19 courts say following this approach.  
 20 The second approach is a de minimis  
 21 approach. It's followed in the Second, Sixth,  
 22 Ninth, Tenth and Eleventh circuits. Basically,

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1 it's presumption that the exclusionary effects of  
 2 disparagement are de minimis. That presumption can  
 3 be rebutted if the plaintiff could show six things.  
 4 The case law is not clear as to whether or not you  
 5 have to show all six, but those six are that it is  
 6 a clearly false statement; it is clearly material;  
 7 clearly likely to induce reasonable reliance; made  
 8 to buyers without knowledge of the subject matter;  
 9 continued for prolonged periods; and not  
 10 susceptible of neutralization.  
 11 So again here, the bar is too high. This  
 12 case arose in the leading treatise, or the  
 13 framework is taken from the leading treatise, the  
 14 Hovenkamp treatise in antitrust law. It was  
 15 adopted at a time that the standards of false  
 16 advertising really aren't clear, and there is  
 17 something to say; that not every instance of false  
 18 advertising is monopolization. Certainly, there  
 19 are lots of instances that are not monopolization,  
 20 but the cases that we're worried about, the cases  
 21 in which biologics are disparaging biosimilars, are  
 22 ones where there is monopoly power.

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1 How would this test be applied? Well, we  
 2 start off saying that it is de minimis, then you  
 3 look at the factors. So the first is clearly  
 4 false. And if we've learned anything from the day  
 5 so far, it's that you can have deceptive and  
 6 misleading statements even if they're not clearly  
 7 false. So I would take issue with this factor.  
 8 And if we expand it a little bit to what's  
 9 deceptive and misleading, then, again, that is what  
 10 we've talked about for hours, saying, oh, they're  
 11 not identical; they're not interchangeable; they  
 12 don't work the same way, these are deceptive and  
 13 misleading.  
 14 The second factor, is it clearly material?  
 15 Of course it is. This deals with safety and  
 16 health. What's more material than that?  
 17 Third. Does it induce reasonable reliance?  
 18 Yes, relatedly. Doctors and patients and payers  
 19 are going to care a lot about the assertions that  
 20 are made.  
 21 Fourth, buyers without knowledge of subject  
 22 matter. Here, there's a lot of emphasis on the

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1 drug companies and what the drug companies are  
 2 saying, so this factor shouldn't apply as much.  
 3 Fifth, lasting for prolonged periods. Yes,  
 4 these are monopolies. The monopolies, as we saw in  
 5 one slide, go on for years, so certainly that is  
 6 satisfied.  
 7 Finally, the plaintiff can't neutralize it.  
 8 It's hard to neutralize. Once the biologic company  
 9 says we have some real safety problems here or  
 10 maybe you'll go to the ER, it's tough for you to  
 11 say, "Well, we're not going to go to the ER." It's  
 12 really tough to rebut.  
 13 So applying the test, the first factor of  
 14 clear falsity I'd say is too high a standard, but  
 15 that one you could argue if you were to have  
 16 deception or misleading, and I'd say all the other  
 17 factors are satisfied. So even if it starts off  
 18 with a presumption that it's de minimis, I'd say  
 19 that the factors can be rebutted.  
 20 Then finally, the third bucket is the  
 21 case-by-case approach. This is followed in the  
 22 Third, the Eighth, and the D.C. circuits. Here,

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1 for example, in D.C., the court said there are too  
 2 many forums. It's too dependent on context to  
 3 enumerate all of the varieties. The multiple  
 4 courts say the false statements could be so unfair  
 5 that they constitute an unreasonable restraint.  
 6 Courts have looked at things like whether false  
 7 statements lead to inflated financing costs and  
 8 whether they lock in decision-making.  
 9 So how would all of that apply here?  
 10 Because it's case by case, we have a lot more  
 11 flexibility. Just on those two last factors that I  
 12 mentioned, the first is financing high expenses.  
 13 It's really hard for a biosimilar to get the  
 14 financing it needs if it's subject to all of these  
 15 inappropriate claims. In terms of decision-making,  
 16 that's locked in as well.  
 17 Then we step back and see the regulatory  
 18 situation. It was so rewarding to hear FDA  
 19 Commissioner Hahn, just like FDA Commissioner  
 20 Gottlieb before, talk about things like  
 21 shenanigans. These are not appropriate types of  
 22 behavior.

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1 It certainly is wonderful to see the FDA and  
 2 the FTC working together and this is incredibly  
 3 important, but it's possible that the agencies  
 4 might not be able to solve this problem completely  
 5 on their own. As we've seen for the past several  
 6 decades, drug companies think it's in their  
 7 bottom-line interest to play these games, to get  
 8 away with a slap on the wrist, and to keep their  
 9 monopoly power for years.  
 10 So there could be a role for courts to play  
 11 a role here in terms of the different barriers to  
 12 entry. I'll just mention, as we saw before, the  
 13 cost of development is extremely high. We haven't  
 14 talked about trade secrecy and the manufacturing  
 15 processes that the biologic companies do not want  
 16 to share with their rivals. We've seen that there  
 17 are patent thickets that make it extremely  
 18 difficult.  
 19 Settlements could be a good thing, but  
 20 pay-for-delay is not. The Supreme Court and  
 21 activists said you cannot pay your rival to stay  
 22 off the market. So while we want settlements in

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1 this case, we don't want one company paying another  
 2 to stay off; that's not right.  
 3 Third, the bundling, exclusive dealing, and  
 4 rebates we've heard about, and finally established  
 5 patients are unlikely to switch. So in some of  
 6 these cases there's bundling with the established  
 7 patients and the new patients, which makes it even  
 8 harder for the new patients to consider the  
 9 biosimilars.  
 10 So you put all of these barriers to entry  
 11 together, and you see it's really hard for the  
 12 biosimilar to enter the marketplace. There are so  
 13 many barriers already there. Then on top of that,  
 14 for the few new patients who could consider a  
 15 biosimilar, you threaten all of these safety  
 16 concerns, it's going to be extremely hard.  
 17 So I'd say following the case-by-case  
 18 approach, which I think is the most justifiable of  
 19 the three approaches, I think there's a strong  
 20 antitrust case that could be made.  
 21 MR. WEINSTEIN: Thank you, Professor  
 22 Carrier.

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1 Let's back up and maybe just ask at a high  
 2 level, do we need a disparagement cause of action  
 3 arising in antitrust? I guess on the one hand, is  
 4 there a regulatory or a policy fix available that  
 5 might accomplish the same thing or is the  
 6 enforcement of private or public framework we have  
 7 in the consumer protection context sufficient  
 8 standing alone?  
 9 DR. CARRIER: I'd say yes to all three; yes  
 10 to antitrust; yes to consumer protection; and yes  
 11 to regulatory things that we're talking about  
 12 today. It certainly is wonderful to see the FDA  
 13 and FTC getting together using their complementary  
 14 expertise to go after this conduct, which is subtle  
 15 in nature.  
 16 Is there a role for antitrust? There is a  
 17 role for antitrust because no matter what the  
 18 agencies can do, there's always the possibility  
 19 that some bad actors will cross the line and commit  
 20 an antitrust violation.  
 21 The benefit of antitrust law is that it  
 22 focuses on market-wide effects. There could be

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1 increased price and reduced output that antitrust  
 2 is uniquely able to deal with. Antitrust offers  
 3 treble damages; it offers attorneys fees; it offers  
 4 injunctions; and it offers the chance to consider  
 5 all of this conduct in combination.  
 6 For example, you have a case involving  
 7 Suboxone where you have a grab bag of  
 8 anticompetitive conduct. You have citizen  
 9 petitions, product hopping, and sample denials.  
 10 The court on the sample denial piece said, "Well,  
 11 this is pretty nuance stuff."  
 12 So standing by itself, it's not a violation,  
 13 but as part of the overall course of conduct, it  
 14 could be, and that should be on the table here.  
 15 These biologic companies are not just doing one  
 16 thing; they're doing a whole a bunch of things. So  
 17 putting antitrust on the table is one way of  
 18 dealing with all of that together.  
 19 MR. WEINSTEIN: Now, earlier, Professor  
 20 Tushnet mentioned that perhaps a private class  
 21 action claim in the consumer protection context  
 22 would be hard. What about in the antitrust

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1 context? How would you characterize the  
 2 distinction between  
 3 public and private enforcement from a normative  
 4 perspective?  
 5 DR. CARRIER: Well, I think it also would be  
 6 hard here as well. Courts are not always receptive  
 7 to class actions, and then the question is who's  
 8 going to organize a class when the conduct is  
 9 really nuanced? Saying, well, it's not identical,  
 10 that's a bit nuanced.  
 11 So I think there's always a role for the  
 12 government to play. The FTC uniquely has power  
 13 under Section 5 to go after unfair methods of  
 14 competition and unfair deceptive acts or practices.  
 15 That gives us a little more leeway than antitrust  
 16 law. So I think there's a crucial role for the FTC  
 17 to play.  
 18 MR. WEINSTEIN: With the disclosure that I  
 19 may have had some insight into your forthcoming  
 20 article, have courts correctly evaluated  
 21 disparagement in either of these three  
 22 circuit-split options? If not, is there a better

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1 approach?

2 DR. TUSHNET: The fundamental problem with

3 the majority approach is we have one branch of

4 competition law that presumes correctly that false

5 advertising harms competition; it poisons the

6 communicative environment; it makes it harder to

7 understand and compare products and services; and

8 it is anticompetitive in the most basic way.

9 In the majority approach, we have

10 competition law that presumes that false

11 advertising is fine and maybe even good. Those

12 things both can't be true, and false advertising

13 law is right about the harms of false advertising

14 to competition.

15 We think that false advertising law has had

16 the chance to develop a lot of thinking about how

17 you prove falsity and how you prove that it affects

18 consumers. These are tools that are available and

19 should be used both in Lanham Act cases and where

20 relevant in antitrust cases to show that, in fact,

21 the market did move.

22 Right now, there's a situation where you can

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1 be put into a heads-I-win/tails-you-lose position.

2 There's a case in the Fifth Circuit that is really

3 reflective of what happens, involving Becton

4 Dickinson. Basically, there was a bunch of false

5 advertising, but it seems to have harmed all the

6 competitors in the market.

7 The Court of Appeals first said, "Well, you

8 can't win a false advertising claim because you

9 can't show which of the sales were lost to you

10 because it harmed everybody else in the market,"

11 and then the court says, "And there's no antitrust

12 claim because it's false advertising, which can't

13 harm the market," and does not seem to appreciate

14 the -- that just can't be right.

15 So I think we do need a rethinking, and

16 hopefully at least the circuits that do a balancing

17 or a case-by-case approach at least have the better

18 idea of it.

19 MR. WEINSTEIN: So if you were the king of

20 the world, if you were, or perhaps just the one

21 crafting all of the laws of the United States, what

22 would be the cause of action?

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1 DR. CARRIER: Again, Professor Tushnet and I

2 have an article where we lay out what

3 monopolization should look like. So we presume

4 that there is an anticompetitive effect if you have

5 a monopolist engaging in false advertising. The

6 presumption is appropriate because we're only

7 talking about monopolists.

8 If you go back and look at the treatise,

9 it's worried and it doesn't want to have every

10 instance of false advertising become a case of

11 monopolization. And that's fair, but that is

12 implicit in what we're doing because our test only

13 applies to monopolists. So if you have 1 percent

14 of the market, go do whatever you want. If you

15 have a monopoly, however, there are certain things

16 that you can't do.

17 What we do, as Professor Tushnet pointed

18 out, is we take the learning from false advertising

19 law. We don't think it's appropriate for antitrust

20 courts to say there's no role at all for antitrust.

21 We don't think it's appropriate to say let's just

22 assume the harm is de minimis.

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1 False advertising has built up a

2 well-developed body of law. So if we can show, or

3 if the plaintiff can show, that the conduct is

4 literally false or misleading; if it is material;

5 if it deceives or is likely to deceive consumers;

6 and if it causes or is likely to cause harm, then

7 the elements of false advertising are met and the

8 presumption is that there is monopolization. And

9 the defendant could always come back and show that

10 the false or deceptive conduct is ineffective; that

11 somehow it lost market share or wasn't able to put

12 away its rivals.

13 So we think that is appropriate with

14 thinking about false advertising. It ensures that

15 false advertising is limited to the place where it

16 can do the most damage, and we think it makes a lot

17 more sense than what some of the courts are doing

18 today.

19 MR. CLELAND: Can I follow up with one

20 question? If I'm understanding this correctly, the

21 more penetration that the biosimilar makes in the

22 market, the less compelling the antitrust argument

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1 becomes.

2 DR. CARRIER: Certainly. If the biosimilar

3 is able to enter the market to the extent that a

4 generic has entered the market, where you see the

5 price fall dramatically and the penetration

6 increased significantly, then that would be a less

7 strong case; correct.

8 MR. CLELAND: So it's 20 percent or

9 25 percent?

10 DR. CARRIER: Well, in generic space, you

11 see the generic taking 90 percent of the market and

12 having the price fall dramatically. I'm not sure

13 if we'll ever get that sort of penetration and

14 discounting given how expensive biosimilar

15 development is. So we'd have to think of something

16 in between, to have more competition than we've had

17 now, but maybe a little bit less might be okay as

18 compared to generics.

19 MR. WEINSTEIN: How do we establish

20 competitive harm here, harm to competition? Is it

21 enough to show that we can prove deception? Is

22 that sufficient, or that folks were misled?

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1 DR. CARRIER: Yes. For a biologic company

2 that has monopoly power, I think that's the case.

3 You see this sort of behavior. You see that

4 biosimilars are injured. You also see the

5 regulatory scheme in which this is not like any

6 other industry. We have biosimilars that are

7 supposed to play a crucial role in lowering price.

8 They haven't done it like they should. So the fact

9 that competitors are harmed means that consumers

10 are harmed, and then you supplement that with high

11 price and lack of market share, and I think that

12 you still have an antitrust case.

13 MR. WEINSTEIN: An earlier panelist today

14 mentioned his belief that it would be hard going

15 forward to deceive at least the prescribing

16 physicians or the folks working in hospitals that

17 biosimilars were not as safe or effective as the

18 reference product. If that's true, is there still

19 a role here for harm to competition, at least for

20 the patient and the consumer?

21 DR. CARRIER: Absolutely. The markets that

22 we're talking about here are unique because we have

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1 what's been famously called by the Federal Trade

2 Commission, decades ago, the price disconnect

3 because it's not like any other market where the

4 price quality determination is made by one party.

5 So you have the doctors that are making the

6 decision as to what to prescribe. You have the

7 payors or the insurance companies that pay for it.

8 So there is a lot of room for anticompetitive

9 conduct going here, not just the doctors -- and I'm

10 not sure that that problem has been completely

11 solved -- but the patients as well, and the

12 insurance companies, and the PBMs with the big

13 rebates. I think there's a lot of room for

14 anticompetitive conduct here, so that's why I

15 wouldn't rest on our laurels yet.

16 MR. WEINSTEIN: Professor Tushnet, you

17 mentioned that there was a body of research -- I

18 don't want to mischaracterize you -- describing the

19 role that patients have in their own prescribing

20 decisions. I'm curious what your thoughts are in

21 this context, where perhaps the physician is not

22 persuaded by some disparaging comment but the

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1 patient is.

2 DR. TUSHNET: From my perspective, as

3 somebody who mostly thinks of this from the Lanham

4 Act perspective, I think it's just a matter for

5 proof what is actually going on in the market, and

6 when we figure that out, we will know. I do think

7 that you can infer something from the fact that

8 companies are trying to reach patients directly.

9 They wouldn't be trying to reach patients directly

10 if they didn't think that it had some chance of

11 moving the market or keeping the market where it is

12 in this case.

13 MR. WEINSTEIN: Thank you.

14 Is there any case law currently that exists

15 that supports this -- I don't want to

16 mischaracterize it -- what I'll call a

17 reinterpretation of how we should think about these

18 kinds of cases?

19 DR. TUSHNET: Certainly from the Lanham Act

20 perspective, this is actually a pretty

21 straightforward Lanham Act cause of action. It's

22 just a question of what are the elements and can

1 you prove them. Certainly, I wouldn't expect the  
2 originators to roll over and agree that all the  
3 elements have been met, of course not, but at least  
4 it's straightforward about what needs to be done to  
5 prove the case.

6 Then from the antitrust side, there is this  
7 case-by-case approach, which at least is open to  
8 hearing about the anticompetitive effects, the harm  
9 to the market. Especially in a very small market,  
10 by the way, of course harm to one entrant may well  
11 be harm to the market if that's all you have, which  
12 in some of these cases is what you have.

13 MR. CLELAND: Are you aware of any pending  
14 cases raising the antitrust for disparagement of  
15 biosimilars, other than I think Johnson &  
16 Johnson-Pfizer?

17 DR. CARRIER: I'm not aware. But I would  
18 say, going back to the last question, that  
19 antitrust, as Professor Tushnet points out,  
20 certainly does take the common-law approach. The  
21 big picture here is we're talking about the  
22 pharmaceutical industry. Pharma is basically

1 Commissioner Chopra, FTC Commissioner Chopra, has  
2 stated that he wants to see the FTC make broader  
3 use of its rulemaking authority. Is this an area  
4 where FTC rulemaking might be useful?

5 DR. CARRIER: Sure. As I said to a previous  
6 question, yes and yes; yes for rulemaking and yes  
7 for enforcement in the courts. Rulemaking could  
8 shed light on the problem here, and I think the  
9 guidance that FDA has offered is really helpful.  
10 Why not have the FTC offer similar guidance; just  
11 to make clear that you can't hide behind this fig  
12 leaf of clear falsity and that there's a lot of  
13 deception and misleading conduct that is going on?

14 So I'd say sure. Rules could make a lot of  
15 sense, but certainly not at the effect of enforcing  
16 the antitrust laws because we need to do that, too.

17 MR. WEINSTEIN: What about the distinction  
18 between this claim as a private versus a public  
19 cause of action? What are some of the incentives  
20 that should motivate the government versus the  
21 private sector, either the consumers or  
22 competitors?

1 giving us whack-a-mole all the time. Every time  
2 you think you've figured out what's going on,  
3 there's another mole to whack.

4 Just a couple days ago, we saw the judge  
5 denied most of the motion to dismiss in the Gilead  
6 case, in which there's a new combination of  
7 settlements and product hopping that we haven't  
8 seen before. Go back a little while, once you  
9 thought you figured out everything that pharma was  
10 doing, they transferred patents to a Native  
11 American tribe to avoid review at the patent  
12 office. We couldn't see that coming, but again --

13 (Laughter.)

14 DR. CARRIER: -- it comes with the  
15 territory.

16 So this is just the next stage, and there  
17 are so many different hurdles here, that it's  
18 really clear that this is part of the game, and  
19 antitrust is certainly well equipped to deal with  
20 these, as we've heard about, shenanigans.

21 MR. WEINSTEIN: One of the other possible  
22 options would be some sort of a rulemaking.

1 DR. CARRIER: I think an argument for the  
2 government to act is that sometimes this conduct is  
3 pretty nuanced. And again, imagine that it's not  
4 clearly false but we're raising some sort of safety  
5 intimations that maybe it's only similar to.  
6 That's pretty nuanced and, to me, that sounds like  
7 an ideal recipe for effective FTC enforcement.

8 DR. TUSHNET: The other thing that I would  
9 say, too, is it's always an enforcement decision.  
10 Government agencies have limited resources. There  
11 is definitely a role for private companies. If  
12 they think that they're losing millions of dollars,  
13 they really at some point should put their money  
14 where their mouth is and go to court and fight  
15 about the money that they are losing.

16 So there's a reason that the FTC's  
17 discretion is often limited, where markets are  
18 deconcentrated and where we don't think that  
19 there's some private interest that will actually  
20 fulfill consumer interest by going after its own  
21 interests. But at a certain point, when the  
22 consumer harm is great enough, if for various



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1 reasons private companies aren't acting, then, yes,  
 2 there's definitely a role for the government, too.  
 3 MR. CLELAND: Forgive me. I'm not as  
 4 familiar with all of the players in this area as  
 5 others. Obviously, the cost is a big barrier for  
 6 private rights of action. Are the companies that  
 7 are suffering the most really in a position to  
 8 litigate those rights and assume those costs?  
 9 DR. CARRIER: It certainly is possible.  
 10 We've seen with biosimilars these are really big  
 11 companies. Pfizer suing J&J, we don't usually  
 12 think of Pfizer as the little guy plaintiff. To  
 13 just enter the market, or try to enter the market,  
 14 as a biosimilar, you need to have a lot of  
 15 resources. So, yes, I think they could litigate.  
 16 MR. WEINSTEIN: So if there are no other  
 17 questions, let me just offer Professors Tushnet and  
 18 Carrier an opportunity to make any final remarks.  
 19 DR. TUSHNET: I just think it's great that  
 20 we're having this conversation. The law of false  
 21 advertising is actually pretty good at grasping the  
 22 realities of the market. I hope that also when we

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1 think about antitrust, we can think about being  
 2 better at empirics, which antitrust prides itself  
 3 on in many other categories, and then for false  
 4 advertising has just decided to pretend that there  
 5 are no empirical effects of false advertising.  
 6 That's weird. Hopefully, we can create some change  
 7 on that, and then be realistic about market harms.  
 8 DR. CARRIER: I just want to say how  
 9 promising it is that the FDA and FTC are working  
 10 together on these issues. This is such important  
 11 stuff. It's so nuanced, and the FDA and FTC have  
 12 such unique skills and experiences that they can  
 13 bring to bear, that I really think it's helpful  
 14 because the pharmaceutical industry knows how to  
 15 play these games, and sometimes we need the  
 16 government agencies working together to counteract  
 17 these games.  
 18 So I think it's a wonderful development to  
 19 see the agencies working together on such important  
 20 issues.  
 21 MR. WEINSTEIN: Thank you. I hope you all  
 22 will join me in thanking our panel.

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1 (Applause.)  
 2 Open Public Comment  
 3 MS. IKENBERRY: We have some folks eager to  
 4 get started on the public comment portion of this  
 5 workshop. Again, my name is Sarah Ikenberry. I'm  
 6 a senior communications advisor in the Office of  
 7 Therapeutic Biologics and Biosimilars.  
 8 For the open public comment session, we have  
 9 I think 17 speakers registered. I'm not sure if  
 10 they're all here. But each of them will have  
 11 4 minutes to present. If a speaker finishes early,  
 12 I will ask if the members of the panel have any  
 13 questions for the speaker. If the speaker and/or  
 14 if the questions from the panel do not take the  
 15 full allotted period, we intend to move on to the  
 16 next speaker.  
 17 For the speakers. You can see where she is  
 18 putting up the microphone, so that is your place.  
 19 We have timer lights to guide you. You can see  
 20 them right here on the top of the podium. The  
 21 timer will give you a 2-minute warning before the  
 22 red light goes on. If you have not concluded your

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1 remarks by the end of your allotted time, I will  
 2 ask you to do. Please don't make me do that.  
 3 (Laughter.)  
 4 MS. IKENBERRY: We have a lot of people  
 5 registered to speak, so please be mindful of your  
 6 time and courteous to your fellow speakers. Also,  
 7 please remember that the hearing is being  
 8 transcribed, so please be sure to use the  
 9 microphone with speaking and introduce yourself so  
 10 that your name will be included in the transcribed  
 11 remarks.  
 12 I will now ask the panelists to introduce  
 13 themselves, starting with Eva.  
 14 MS. TEMKIN: Hi. I'm Eva Temkin. I am the  
 15 acting director for policy in CDER's Office of  
 16 Therapeutic Biologics and Biosimilars.  
 17 MS. GRAY: I'm Caty Gray. I'm the  
 18 supervisor for the advertising and promotion policy  
 19 staff in OPDP.  
 20 MS. DUTTA: I'm Antara Dutta. I'm an  
 21 economist at the Bureau of Economics at the FTC.  
 22 MS. BLACK: Hi, everyone. I'm Armine Black.

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1 I'M an attorney in the healthcare division of the  
2 Federal Trade Commission.  
3 MS. IKENBERRY: Alright. Thank you,  
4 everyone.  
5 With that, our first speaker is Juliana Reed  
6 from the Biosimilars Forum?  
7 MS. REED: Good afternoon. I'm Julie Reed,  
8 the vice president of global corporate affairs at  
9 Pfizer, but also the president of the Biosimilars  
10 Forum. The Forum really appreciates the  
11 opportunity to provide our perspective on the need  
12 to discourage false and misleading communications  
13 about biosimilars and to deter anticompetitive  
14 behaviors that interfere with efforts to establish  
15 a competitive marketplace for all biologic drugs.  
16 The members of the Forum represent the  
17 majority of the biosimilars approved and marketed  
18 in the U.S. to date as well as those under  
19 development. The Forum is committed to ensuring  
20 that patients and prescribers have complete  
21 truthful and non-misleading information about  
22 biosimilars.

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1 As my colleague, Hillel Cohen, mentioned in  
2 his remarks, we are very concerned that there has  
3 been and continues to be a pattern of negative  
4 information about biosimilars to patients,  
5 healthcare professionals, and others who have a  
6 role in adoption of biosimilars in the U.S.  
7 Continued misleading information about biosimilars  
8 will have a negative impact on the U.S. healthcare  
9 system, physicians, and patients, ultimately  
10 leading to ongoing lost of cost savings and uptake  
11 of biosimilars in the U.S.  
12 But we know misleading information is not  
13 the only barrier. As all of the speakers have said  
14 today, there are multiple barriers that are  
15 preventing the success of this marketplace. The  
16 members of the Forum have spent hundreds of  
17 millions of dollars to bring each biosimilar to the  
18 market. Pfizer alone has 8 approved biosimilars in  
19 the U.S., but we all know the market is not  
20 working, and it is not working for the patients we  
21 are here to serve.  
22 We are grateful to the FDA for your

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1 incredible work to date over the years. We're also  
2 grateful for the FTC and your incredible work over  
3 the years to help support biosimilars. What we  
4 need now, though, is every other stakeholder to  
5 join us in this fight and to get engaged to  
6 proactively support policies that will remove these  
7 barriers.  
8 We need not only the FDA and the FTC to be  
9 engaged and be proactive when you walk out of the  
10 door here today to get this done, but we also need  
11 Congress, CMS, payers, patients, and others to  
12 start to proactively support the uptake of  
13 biosimilars in this country.  
14 This is about cost savings and it's about  
15 cost savings to patients and the healthcare system.  
16 This is about innovation in the future so that we  
17 can all afford the innovation that is coming, but  
18 ultimately this is about the patients we're here to  
19 serve and that the members of the Biosimilars Forum  
20 are here to serve. Thank you.  
21 MS. IKENBERRY: Thank you.  
22 Our next speaker is Philip Schneider from

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1 the Ohio State University College of Pharmacy.  
2 DR. SCHNEIDER: Thank you, and thank you for  
3 the opportunity. My name is Philip Schneider. I  
4 am a professor of pharmacy at the Ohio State  
5 University where I've been on faculty for almost 40  
6 years, as well as the chair of the Advisory  
7 Committee for the Alliance for Safe Biologic  
8 Medicines, which I've done for 11 years.  
9 I'd like to make a statement, first of all,  
10 correcting misperception, a true and misleading  
11 communication related to my quote in the Washington  
12 Post. That relates to a quote I made about  
13 supporting the FDA's role in assuring the safety of  
14 the medication supply in our country.  
15 ASBM has been involved in working with  
16 regulators around the world, including FDA, on  
17 policies that focus on safety, including  
18 distinguishable non-proprietary names and an  
19 interchangeability classification for biosimilars.  
20 In no way do we feel that is anticompetitive, and I  
21 want to correct the perception that ASBM is  
22 spreading misperceptions and that I did that

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1 personally myself.  
 2 Today I'd like to address my comments on  
 3 what we think to be an incorrect assumption  
 4 underlying the proceedings today, namely that  
 5 biosimilar uptake in the U.S. is strongly linked to  
 6 low physician confidence levels in biosimilars and  
 7 physician confidence has been depressed because of  
 8 anticompetitive practices.  
 9 Last year, ASBM conducted a survey of 579  
 10 physicians in six Western European countries:  
 11 France, Germany, Italy, Spain, Switzerland, and the  
 12 UK. We surveyed physicians in 10 different areas  
 13 of practice, including rheumatology,  
 14 gastroenterology, oncology, dermatology, and  
 15 neurology. All of these physicians prescribe  
 16 biologic in their practice.  
 17 What we found is these physicians were very  
 18 familiar with and confident in biosimilars. This  
 19 is not perhaps surprising because European  
 20 physicians have had 13 years of experience with  
 21 biosimilars.  
 22 Depending on the country, between 82 and

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1 93 percent of prescribers consider themselves  
 2 familiar or very familiar with biosimilars.  
 3 Between 80 and 99 percent would feel comfortable  
 4 prescribing a biosimilar to a new treatment-naive  
 5 patient. Between 46 and 76 would be comfortable  
 6 switching a patient from a reference product to a  
 7 biosimilar even if they were stable on the current  
 8 medicine.  
 9 In spite of that, if we look at the  
 10 biosimilar market share in the six countries that  
 11 we surveyed, there's very wide variation among  
 12 biosimilar adoption in each of these countries.  
 13 For example, market share for the epoetin  
 14 biosimilar ranges from 6 to 84 percent. There are  
 15 similar ranges for other biosimilars.  
 16 Clearly, there are other factors besides  
 17 physician confidence, which is uniformly high  
 18 across the countries. These factors are likely to  
 19 include differences between each country's payer  
 20 policies; differences in the length of time a  
 21 biosimilar has been on the market; the number of  
 22 biosimilars in a given product class; the discount

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1 each product receives relative to the originator  
 2 product; and other factors.  
 3 Healthcare professionals here in the U.S.,  
 4 as in Europe, are not antisimilar. It is  
 5 inaccurate to suggest that negative perceptions are  
 6 holding up biosimilar development and  
 7 commercialization. We are enthusiastic about  
 8 biosimilars and want to see them as much as anyone  
 9 else, and we are pleased to see how far the U.S.  
 10 has come in a few short years. We urge the FDA and  
 11 FTC to continue their work to build a strong and  
 12 sustainable biosimilars market. Thank you for the  
 13 opportunity to comment.  
 14 MS. IKENBERRY: Thank you very much.  
 15 Madelaine Feldman, Alliance for Safe  
 16 Biologic Medicines.  
 17 DR. FELDMAN: Thank you. As you said, my  
 18 name is Madelaine Feldman. I'm a rheumatologist in  
 19 private practice in New Orleans. I'm also  
 20 president of the Coalition of State Rheumatology  
 21 Organizations and the founder of the Rheumatology  
 22 Alliance of Louisiana.

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1 ASBM is an organization of more than 140  
 2 patient advocacy groups and physician societies.  
 3 The work includes sharing the perspectives of  
 4 pharmacists, patients, and physicians with  
 5 regulators and other policymakers at the state,  
 6 national, and international level. I'd like to  
 7 speak on a couple of issues regarding biosimilars.  
 8 The first is that misinformation continues  
 9 to affect the objectivity of physicians and make us  
 10 essentially antibiosimilar. Perhaps  
 11 rheumatologists are a different lot. I just  
 12 presided over a national rheumatology meeting this  
 13 past weekend and polled the entire group coming  
 14 from around the country if anyone felt that  
 15 biosimilars were inferior to originators. No one  
 16 said yes; everyone said no and that they all  
 17 thought they were not inferior; and then would  
 18 anyone have any hesitancy in prescribing a  
 19 biosimilar, and no one had any hesitancy.  
 20 So at least for that group of  
 21 rheumatologists, which was quite representative,  
 22 there appeared to be at least no negative feelings

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1 in that regard. But I have to admit, clinicians  
 2 are generally more cautious and conservative  
 3 regarding new treatments and are hesitant to  
 4 change, particularly when it comes to changing a  
 5 stable patient.  
 6 Because it can take years to months and  
 7 months to years to stabilize the rheumatoid  
 8 arthritis patient, rheumatologists have been  
 9 sensitized to non-medical switching by payers,  
 10 wherein that they are told the medicine that  
 11 finally stabilized our patient will no longer be  
 12 paid for.  
 13 By changing formularies often to a higher  
 14 priced drug that cost the patients more to solidify  
 15 the formulary profit margin, middlemen can legally  
 16 switch patients in the United States and switch  
 17 their medicines every six months. This could  
 18 involve switching back and forth between  
 19 originators and biosimilars, which wouldn't be  
 20 horrible, but they even switch patients, and this  
 21 has happened, to completely different biologics.  
 22 So yes, physicians are leery of a great American

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1 terms of therapeutic offerings and true cost  
 2 savings, and through price reduction to our  
 3 patients in the larger health system and not merely  
 4 increasing middlemen-pocketed-fees and price  
 5 concessions.  
 6 The most important strategies to continue  
 7 the process in the U.S. are strong FDA educational  
 8 programs for healthcare professionals and patients,  
 9 along with pharmacovigilant programs, particularly  
 10 in light of the payer's ability to frequently  
 11 switch patients every 6 months. This will allow  
 12 clinicians the opportunity to learn from real-world  
 13 experience with biosimilars and to gain confidence  
 14 in using them. Thank you for allowing me to -- and  
 15 I have no time for questions.  
 16 MS. IKENBERRY: Thank you.  
 17 Our next speaker is Sundar Ramanan, Biocon.  
 18 DR. RAMANAN: Hi. My name is Sundar  
 19 Ramanan, vice president and head of global  
 20 regulatory affairs for Biocon Biologics, a fully  
 21 integrated biosimilars company. Our goal is to  
 22 transform health care and transform lives by

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1 switching experiment.  
 2 Speaking of incentives in our supply chain  
 3 on the pharmacy side, formulary placement, hire  
 4 list prices, and higher market share are the ones  
 5 that are preferred. That puts biosimilars behind  
 6 the eight ball from the get-go once they've been  
 7 launched. If incentives are implemented for  
 8 biosimilars, any cost consideration should be  
 9 directed to the patient because  
 10 incentives that monetarily benefit the physician  
 11 could actually undermine the patient's trust in  
 12 their doctors.  
 13 Finally, repeating what everyone has said,  
 14 considering the perception that U.S. lags behind  
 15 Europe, thinking that at 5 years out from  
 16 biosimilar approval in Europe, there were  
 17 11 products approved, in the United States we have  
 18 26. The FDA deserves credit for their support in  
 19 building a biosimilar market so quickly without  
 20 compromising on safety or efficacy standards.  
 21 Physicians are enthusiastic about  
 22 biosimilars and the benefits they can bring in

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1 bringing affordable high-quality biosimilars to the  
 2 U.S. patients. We're also an innovative company,  
 3 and we intend to transfer the value of innovation  
 4 to the health systems and patients. We thank the  
 5 agencies for setting up this public workshop and  
 6 working towards a fair and balanced marketplace for  
 7 biosimilars.  
 8 The things that I'm going to cover fall  
 9 under five buckets. Number one, insulin guidance.  
 10 We applaud the agency for issuing a draft guidance  
 11 for insulin. The draft guidance is science-based  
 12 and patient-focused. Despite the expected  
 13 opposition that has come from few companies, we  
 14 urge the agency to finalize the guidance.  
 15 In addition, for molecules like insulin with  
 16 high financial unmet need, we request the agency to  
 17 consider a shorter time frame for the review  
 18 process once the filing is made. The agency  
 19 already has precedence in the generic space. This  
 20 is another critical component to bringing these  
 21 much needed products to insulin patients faster and  
 22 fostering competition.

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1 Number two, interchangeability. With the  
 2 abundance of real-world evidence and frequent  
 3 marketplace driven switching demonstrating the  
 4 safety of biosimilars globally, we request the  
 5 agency to reconsider ON/R [indiscernible], and  
 6 evaluate the need for multiple switch studies for  
 7 interchangeability.

8 Furthermore, we ask the agency to reconsider  
 9 the need for any distinction between the evidence  
 10 requirements for biosimilarity and interchangeable  
 11 biologics. Any regulatory requirement must be  
 12 based on science and evidence and not based on  
 13 fear. Needless to say, we collectively must put  
 14 the patient's safety first.

15 The immunogenicity data requirement for  
 16 biosimilarity already satisfies the data  
 17 requirement for interchangeability. No new or  
 18 additional information will be gained from multiple  
 19 switch studies, however, it only results in time  
 20 delay and wasted resources in bringing  
 21 interchangeable products to patients.

22 From a practical point of view, either due

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1 to the use of exclusive formulary replacement in  
 2 retail pharmacy or through institutional buying  
 3 practices, interchangeability is the de facto  
 4 practice in a large number of cases. Practically  
 5 speaking, though, the regulatory distinction ends  
 6 up giving an opportunity for originators to create  
 7 an incorrect perception that biosimilarity standard  
 8 is not necessarily adequate for safe and effective  
 9 use while not having a meaningful impact on actual  
 10 usage.

11 Number three. Disincentivize  
 12 anticompetitive behavior on the part of reference  
 13 product manufacturers and provide positive  
 14 incentive for biosimilars. The biosimilar market  
 15 is at the critical juncture, and the steps taken to  
 16 encourage it now will be critical to ensure its  
 17 viability.

18 There have been multiple instances where  
 19 biosimilar products have not been encouraged, but  
 20 have been actively excluded from insurance  
 21 coverage. It is critical that positive incentives  
 22 such as ASP plus 8 percent reimbursement and steps

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1 like additional biosimilar or specialty tiers in  
 2 Medicare Part D be provided in order to avoid  
 3 originator behavior intended to discourage entry of  
 4 biosimilars and reduce long-term competition.

5 Delays and cost to frivolous patent  
 6 litigation and patent thickets should also be  
 7 disincentivized. We also request the agency to  
 8 take strong action against misinformation  
 9 campaigned by the reference product manufacturers.

10 Allowing innovation in the biosimilar development  
 11 with regards to evidence required, related to  
 12 immunogenicity, there is little clinical relevance  
 13 of immunogenicity in oncology settings and general  
 14 immunosuppressant status.

15 For drugs with less frequent dosing, say,  
 16 for example, every 6 months, the need for switch  
 17 studies is not value-added. Scientific rationale  
 18 should be encouraged based on the risk of  
 19 immunogenicity.

20 With regard to sample size determination,  
 21 the methodologies need to evolve further to keep in  
 22 time with the times. Specifically, we request the

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1 agency to utilize Bayesian statistics for residual  
 2 uncertainty. We also request the agency to allow  
 3 for mathematical models in PK/PD for extrapolation  
 4 of indications.

5 Lastly on naming, we request the agency to  
 6 consider, with significant experience in the  
 7 marketplace, the need for suffix for biosimilars.

8 We have additional comments, and we'll be  
 9 submitting to the docket. We thank you for the  
 10 opportunity to present.

11 MS. IKENBERRY: Thank you.

12 Next, Andrew Spiegel, Global Colon Cancer  
 13 Association.

14 MR. SPIEGEL: Good afternoon. My name is  
 15 Andrew Spiegel, the executive director of the GCCA,  
 16 and today I am proud to not only represent that  
 17 organization but also the Alliance for Safe  
 18 Biologic Medicines, an organization which I am a  
 19 founding member for more than 10 years ago. We  
 20 have advocated for patient-centered policies  
 21 regarding biosimilars since then.

22 To that end, I have testified numerous times

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1 before the FDA in support of approving biosimilars  
 2 and before state legislatures all across the nation  
 3 in support for updating pharmacy practices to  
 4 facilitate biosimilar substitution. We have also  
 5 worked and held three joint meetings with the FDA,  
 6 Health Canada, and the World Health Organization,  
 7 all with the goal of advancing a harmonized  
 8 international standard for biologic naming to  
 9 improve global pharmacovigilance for all biologics  
 10 and biosimilars.

11 I can assure you as a founding member of  
 12 ASBM that no ASBM member has ever suggested that a  
 13 patient went to the emergency room as a result of  
 14 switching to a biosimilar. Those patients are here  
 15 and can tell you their own story later, but I can  
 16 assure you that not only did that not happen, but  
 17 ASBM has never advocated or suggested that a  
 18 biosimilar is inferior to a biologic originator  
 19 product, and to the contrary, we've been fierce  
 20 advocates for biosimilar uptake all around the  
 21 world.

22 It's also been my privilege to serve in a

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1 number of leadership roles in the international  
 2 patient community such as the International  
 3 Alliance of Patient Organizations and now chairing  
 4 the World Patients Alliance. We know that biologic  
 5 medicines have helped more than 800 million people  
 6 worldwide, and in the case of colorectal cancer, in  
 7 my organization, which has 49 members around the  
 8 world, we've seen these medicines help triple the  
 9 life expectancy of the most advanced colorectal  
 10 cancer patient. We're talking about a life  
 11 expectancy from 10 months to now 3 years thanks to  
 12 not only these new treatment options but also  
 13 getting these treatment options at a reduced cost,  
 14 and we're hoping that biosimilars will help expand  
 15 access to these therapies.

16 With respect to the U.S. marketplace, first  
 17 and foremost, speaking as the head of an  
 18 international patient organization, let me be clear  
 19 that I'm unaware of any attempt to undermine  
 20 confidence in biosimilars, either in the minds of  
 21 the public, or in the patient community, or among  
 22 physicians.

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1 To the contrary, I am encouraged by the  
 2 extremely positive reaction biosimilars have had in  
 3 the United States thus far, and patients,  
 4 physicians, and healthcare providers have all  
 5 seemed to accept biosimilars as a part of standard  
 6 medical care, and they recognize what an important  
 7 tool it can be in containing healthcare costs.

8 Just as a few days ago, I chaired a panel at  
 9 a biologics conference in San Diego, where a number  
 10 of people who are here today were at, and that  
 11 included chairing a panel where we had one of the  
 12 largest reference companies, as well as a  
 13 representative of one of the largest biosimilar  
 14 companies on that panel. I was very encouraged  
 15 that both agreed that the U.S. biosimilar market  
 16 thus far is very much a success story, and both  
 17 agreed that the future looks very positive.

18 This great enthusiasm and confidence  
 19 surrounding biosimilars is in no small part due to  
 20 the phenomenal work that the FDA has done in  
 21 approving so many biosimilars in a relatively short  
 22 period of time, almost half of those approvals

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1 happening within the last year, and the FDA doing  
 2 so without compromising on its standards for safety  
 3 and efficacy.

4 The heart of the U.S. health system, like  
 5 any other country, has its own unique challenges  
 6 different from those in the EU, Canada, Australia,  
 7 or places where we work, but nevertheless, there  
 8 are things that we can learn from other countries'  
 9 successes, particularly those of the EU countries  
 10 who enjoy a robust biosimilars market.

11 The one thing that we've seen across Europe  
 12 is that more and more biosimilars are launched in a  
 13 given product, that more competition drives prices  
 14 down where discounts increase substantially and  
 15 biosimilar market share goes up, and we know what  
 16 to expect and what things to look for, and  
 17 thankfully we're seeing that happen here in the  
 18 United States.

19 Here, we had a biosimilar that launched with  
 20 a relatively low 15 percent discount over its  
 21 reference product, and today with increased  
 22 competition, that product has gained a majority

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1 share in the U.S. market with 55 percent. We have  
 2 every reason to believe this pattern will continue  
 3 as we see it becoming routine for 3, 4,  
 4 5 biosimilar approvals for a reference product.  
 5 And as these come to market, manufacturers will  
 6 continue to compete on price, going from relatively  
 7 low discounts to higher discounts.  
 8 Speaking as a representative of the broader  
 9 patient community, we of course want more  
 10 biosimilars approved and available, but our  
 11 enthusiasm is tempered by the understanding that  
 12 with anything of this scale and where people's  
 13 lives and health are at stake, it's not an  
 14 instantaneous process.  
 15 Simply put, the system is working, a little  
 16 slower than some would have hoped. But just as we  
 17 don't want biosimilars or any other medicines rust  
 18 through the approval process, we urge our  
 19 regulators to be mindful not to unnecessarily and  
 20 possibly counterproductively interfere with a young  
 21 but steadily growing biosimilars market.  
 22 MS. IKENBERRY: Thank you.

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1 insurance marketplaces.  
 2 PCMA commends the FDA and the FTC for their  
 3 collaboration to enhance competition in the  
 4 biologic products marketplace. We also commend and  
 5 strongly support the many important steps the FDA  
 6 has taken to facilitate greater availability of  
 7 biosimilar and interchangeable products, including  
 8 its final guidance on interchangeable biosimilars,  
 9 the 2018 Biosimilars Action Plan, in its  
 10 comprehensive campaign to educate clinicians about  
 11 the benefits and savings possible through these  
 12 innovative therapies.  
 13 We are encouraged by the FDA's more recent  
 14 efforts to reduce barriers to achieving  
 15 interchangeability, including final guidance  
 16 limiting the cases in which switching studies were  
 17 required. The agency also has designed an approval  
 18 pathway allowing manufacturers to use comparative  
 19 products not approved in the U.S. for biosimilar  
 20 development.  
 21 These are encouraging steps. Now, we urge  
 22 the agency to sustain this forward progress by not

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1 MR. SPIEGEL: Thank you very much.  
 2 MS. IKENBERRY: Thank you.  
 3 Our next speaker is Kim Caldwell,  
 4 Pharmaceutical Care Management Association.  
 5 MS. CALDWELL: Good afternoon. I am Kim  
 6 Caldwell, a registered pharmacist with more than  
 7 four decades of experience throughout the practice  
 8 of pharmacy. Included in this time is more than 12  
 9 years as a member of the Texas State Board of  
 10 Pharmacy and a year with CMS as a leader engaged in  
 11 the creation of the program rules for Medicare Part  
 12 D. I appreciate the opportunity to be here today  
 13 on behalf of Pharmaceutical Care Management  
 14 Association, PCMA.  
 15 PCMA is a national association representing  
 16 America's pharmacy benefit managers, which  
 17 administer prescription drug plans and operate  
 18 specialty pharmacies for more than 270 million  
 19 Americans with health coverage through Fortune 500  
 20 companies, health insurers, labor unions, the  
 21 Medicare and Medicaid programs, the Federal  
 22 Employees Health Benefits Program, and health

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1 adopting unnecessary barriers as it finalizes  
 2 industry guidance relating to licensure and  
 3 labeling  
 4 Another encouraging development is FTC's  
 5 commitment to address manufacturer tactics used to  
 6 block biosimilar entry with anticompetitive patent  
 7 settlement agreements. Increasing competition  
 8 through the approval of biosimilar and  
 9 interchangeable products is key to lowering the  
 10 prescription drug costs for consumers, employers,  
 11 and public programs.  
 12 We appreciate the collaboration between the  
 13 FDA and the FTC, which has argued that tactics  
 14 aimed at gaming FDA rules may be anticompetitive  
 15 and unlawful, and we urge consideration for further  
 16 action when manufacturers employ tactics using  
 17 anticompetitive patent settlements and patent  
 18 thickets to delay widespread use of lower costs and  
 19 biosimilars.  
 20 An important and necessary next step to  
 21 further facilitate a competitive biosimilar  
 22 marketplace is for FDA to promote the therapeutic

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1 substitution of lower cost, interchangeable  
 2 biosimilars for the reference products.  
 3 Additionally, we recommend the FDA provide clear  
 4 direction to states in favor of product  
 5 substitution without burdening barriers such as  
 6 notification provisions.  
 7 Patients and clinicians need expressed  
 8 clarity that these therapeutic substitutions are  
 9 really and truly interchangeable. For many  
 10 patients and clinicians alike, these therapies are  
 11 new, and there may be a degree of uncertainty  
 12 around switching and substitution.  
 13 As the FDA's voice is the gold standard for  
 14 safety and efficacy, when the FDA has approved a  
 15 product for interchangeability, it should be  
 16 labeled and marketed as such without conflict or  
 17 confusion. Anything short of that clarity would  
 18 reinforce caution with patients and clinicians, and  
 19 thus impede the ability to achieve a truly  
 20 competitive biosimilar market. Thank you for the  
 21 opportunity to provide input. I'll welcome your  
 22 questions. We have 25 seconds.

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1 (Laughter.)  
 2 MS. IKENBERRY: I'm not sure I could get a  
 3 whole question in 25 seconds.  
 4 MR. SPIEGEL: Oh, go ahead. We have time.  
 5 MS. IKENBERRY: But you mentioned in your  
 6 statement some guidance considerations around  
 7 licensure and labeling, and I would encourage you,  
 8 to the extent that you intend to submit written  
 9 comments to the docket, to spell those out a little  
 10 bit because I didn't quite follow what you were  
 11 saying.  
 12 MR. SPIEGEL: We do and we will. Thank you  
 13 very much.  
 14 MS. IKENBERRY: Thank you  
 15 MR. SPIEGEL: And just so you know, that was  
 16 a lot of words for a guy from Texas to say in that  
 17 time period --  
 18 (Laughter.)  
 19 MR. SPIEGEL: -- and I really wanted to say  
 20 whack-a-mole, but I didn't know if I could get that  
 21 in. Thank you.  
 22 (Laughter.)

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1 MS. IKENBERRY: Yeah, shenanigans and  
 2 whack-a-mole are two of the nice words of the day.  
 3 Next is Andrew Greenspan, Janssen  
 4 Immunology, vice president of medical affairs.  
 5 DR. GREENSPAN: Good afternoon. My name is  
 6 Dr. Andrew Greenspan, and I'm the vice president of  
 7 medical affairs for immunology at Janssen, the  
 8 pharmaceutical company of Johnson & Johnson. At  
 9 Janssen, we have more than three decades of  
 10 experience with biologic development,  
 11 manufacturing, postmarketing safety, and promotion.  
 12 We pioneered biologic therapy with the first ever  
 13 approved monoclonal antibody, Remicade, or  
 14 infliximab, a TNF blocker for which there are  
 15 currently four approved biosimilars.  
 16 From the beginning, we have led in  
 17 advocating for a biosimilar pathway. We have seen  
 18 patients struggle for years with chronic  
 19 progressive disease before getting diagnosed and  
 20 finding a biologic therapy that finally brings them  
 21 relief.  
 22 We are deeply committed to helping patients

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1 remain healthy and safe throughout their treatment  
 2 journey and have affordable access to the therapies  
 3 that they and their doctors decide on. We are also  
 4 committed to reducing overall healthcare costs and  
 5 believe that these goals can and must be  
 6 accomplished together.  
 7 With this perspective in mind, we'd like to  
 8 ask FDA and FTC to consider four points. First, as  
 9 you collaborate to spur biosimilar adoption,  
 10 continue to uphold the critical role of the  
 11 patient-doctor relationship and individual  
 12 treatment decisions. Many patients endure long and  
 13 painful journeys before achieving clinical control  
 14 of their disease. They need valuable information  
 15 about their options to make informed treatment  
 16 decisions with their doctor.  
 17 Second, we heard many perspectives today on  
 18 interchangeability. We believe patients and their  
 19 doctors deserve clear and complete communication on  
 20 the interchangeability status of a biosimilar. For  
 21 treatments that require multiple administrations,  
 22 such as infliximab, patients and doctors should



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1 have relevant data on alternating back and forth  
 2 between products before deciding to do so.  
 3       Implying that a biosimilar is  
 4 interchangeable when it has not been approved as  
 5 such is misleading. To ensure that patients and  
 6 their doctors have clear and complete information  
 7 on the interchangeability status of a biosimilar,  
 8 communications on a biosimilar should disclose its  
 9 interchangeability status.  
 10       Third, we urge the FDA to clarify that  
 11 communications on biosimilars to payers and  
 12 formulary committees continue to be governed by the  
 13 FDA guidance on manufacturer communications with  
 14 payers, formulary committees, and similar entities.  
 15       Fourth, we would like to underscore that  
 16 biosimilar policies are delivering on the promise  
 17 of the BPCIA with lowered costs for the system and  
 18 will continue to as long as there is a level  
 19 playing field for biosimilar and reference  
 20 products.  
 21       The Remicade and infliximab biosimilars  
 22 experience shows that competition is bringing down

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1 prices for the reference biologic and its  
 2 biosimilars alike. Since the introduction of  
 3 infliximab biosimilars, Remicade's average sales  
 4 price, or ASP, has fallen by 31 percent. Remicade  
 5 is now the market's lowest priced innovator  
 6 anti-TNF therapy with annual costs less than half  
 7 of other innovator TNFs.  
 8       Because of Remicade's price competitiveness  
 9 and uptake of biosimilars, the system has seen over  
 10 \$4.8 billion in savings in the past three years.  
 11 Additionally, it is important to note that  
 12 biosimilar development continues to expand with 19  
 13 biosimilars in FDA's biosimilar product development  
 14 program in January 2013 to 63 as of last year.  
 15       In closing, as the FDA and FTC look to spur  
 16 biosimilar adoption, we call on you in parallel to  
 17 1) take a patient-centric approach in your policy  
 18 decisions; 2) ensure interchangeability status is  
 19 disclosed to patients and providers; and  
 20 3) safeguard the competitive market dynamics that  
 21 are dramatically bringing costs down. Thank you  
 22 for the opportunity to speak.

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1       MS. TEMKIN: Can I squeeze in one question?  
 2 The red light just went on.  
 3       You said that communications on a biosimilar  
 4 should disclose interchangeability status. Do you  
 5 have something specific in mind or can you expand  
 6 on that a little bit?  
 7       DR. GREENSPAN: Sure. As explained earlier,  
 8 as the market dynamics may lead to switching as  
 9 frequently as every 6 months with a chronic therapy  
 10 like infliximab, we think the patients and  
 11 providers will have questions about the possibility  
 12 that they may be switched as frequently as twice a  
 13 year from the products.  
 14       My area is immunology where we market  
 15 infliximab, which is a highly immunogenic molecule,  
 16 and we think the interchangeability standard was  
 17 created by the FDA for a very valid reason. I  
 18 think the point made by a speaker this morning is  
 19 very valid, that the interchangeability standard  
 20 should consider specific characteristics of  
 21 molecules. Some are more immunogenic than others,  
 22 and that's why it's more important for particular

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1 molecules like Remicade, for example.  
 2       MS. TEMKIN: Thank you.  
 3       MS. IKENBERRY: Our next speaker is Kathleen  
 4 Arntsen, president and CEO of Lupus and Allied  
 5 Diseases Association.  
 6       MR. GREENBLATT: Hi. I am not Kathleen  
 7 Arntsen. My name is Corey Greenblatt.  
 8       FEMALE VOICE: I think Steve Lucio is next  
 9 on the --  
 10       MS. IKENBERRY: Oh, I'm sorry.  
 11       MR. GREENBLATT: Okay, back up.  
 12       MS. IKENBERRY: Steven Lucio, Vizient.  
 13       DR. LUCIO: Thank you. To the members of  
 14 the workshop and to all esteemed employees of the  
 15 FDA and FTC, my name is Steven Lucio, vice  
 16 president of the Center for Pharmacy Practice  
 17 Excellence at Vizient, the largest member-driven  
 18 healthcare performance improvement company in the  
 19 U.S., on behalf of Vizient, I'd like to express our  
 20 deepest appreciation not only for this forum, but  
 21 also for all the enduring efforts that have been  
 22 made to enhance competition, thereby improving

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1 patient access to safe and effective biologic  
 2 molecules.  
 3 Vizient provides solutions for more than  
 4 50 percent of the nation's acute care providers,  
 5 including 95 percent of the nation's academic  
 6 medical centers, a wide array of leading integrated  
 7 health systems and pediatric hospitals, and more  
 8 than 20 percent of ambulatory providers in the U.S.  
 9 Vizient has focused its array of expertise  
 10 of supporting health systems evaluation and  
 11 adoption of biosimilars to lower pharmaceutical  
 12 expenditures and to maintain or improve patient  
 13 care. Still more work is required to alter the  
 14 trajectory of pricing growth for many biologic  
 15 drugs. Therefore, Vizient would like to offer  
 16 three key insights and recommendations to advance  
 17 the desired competitive landscape related to the  
 18 approval process, education, and payer decisions.  
 19 First, Vizient would like to thank the FDA  
 20 for its efforts at improving the understanding of  
 21 the approval process through the publication of  
 22 regulations and guidance documents. The additional

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1 clarity is essential for perspective manufacturers,  
 2 as well as the population of providers that will  
 3 ultimately be prescribing these medications.  
 4 Vizient would like to note the FDA's  
 5 decision regarding the clinical immunogenicity  
 6 considerations for biosimilar and interchangeable  
 7 insulin products, specifically the decision not to  
 8 require comparative clinical immunogenicity studies  
 9 in the approval of these agents, and scientifically  
 10 substantiated efficiencies and approval will  
 11 decrease the investment expense required to develop  
 12 competing molecules.  
 13 We encourage FDA to continue evaluating the  
 14 opportunity for similar decisions to be applied to  
 15 other biologics. For example, the European  
 16 community has identified certain molecules and/or  
 17 product classes where comparative effective studies  
 18 have been or could be waived, and we would ask that  
 19 FDA continue to evaluate additional opportunities  
 20 to streamline approval requirements up to, and  
 21 including, and eliminating the need for comparative  
 22 effectiveness studies where scientifically

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1 justified.  
 2 We would also like to commend the FDA for  
 3 increasing the level of education provided to  
 4 improve the understanding of foundational concepts  
 5 of biosimilar licensing. We especially thank FDA  
 6 for increasing the timeliness of access to approval  
 7 documents for approved biosimilars, even those not  
 8 subject to an advisory committee hearing.  
 9 This information, even the more detailed  
 10 aspects of analytical characterization, has been  
 11 invaluable as we have worked to educate pharmacists  
 12 and physicians on the fundamental differences  
 13 between the approval methodology of biosimilars as  
 14 compared to new molecular entities.  
 15 Vizient would ask FDA for additional  
 16 information concerning biologic production. Right  
 17 now, given the tremendous desire for increased  
 18 transparency in pharmaceutical manufacturing,  
 19 including the origination source of API due to our  
 20 lingering history of drug shortages, as well as the  
 21 concerns about coronavirus outbreak, while these  
 22 issues are not primarily impacting biologics, there

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1 is additional transparency that would be helpful  
 2 addressing any lingering concerns about biosimilar  
 3 quality and safety.  
 4 One of the biggest gaps we found regarding  
 5 biologic manufacturing understanding is the fact  
 6 that all biologics, originator or biosimilar,  
 7 demonstrate variability. In Europe, where this  
 8 information is disclosed, the content referring to  
 9 the clinical literature has been very informative  
 10 in educating pharmacists and physicians.  
 11 Therefore, we would ask if the FDA could provide  
 12 information on manufacturing changes related to  
 13 U.S. biologics. It would further the understanding  
 14 that the monitoring of biologic variation through  
 15 analytical means is not novel to the biosimilar  
 16 experience.  
 17 As has been discussed today, there are  
 18 challenges associated with payer reimbursement  
 19 decisions, which impact providers and most  
 20 importantly patients. Beyond educational issues  
 21 and messages questioning the validity of the  
 22 approval mechanism, biosimilar adoption continues

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1 to be delayed due to variable coverage and payment  
 2 policies. It is one of the most substantial  
 3 hurdles facing the market and will continue to  
 4 require appropriate attention and focus, and we  
 5 would appreciate any guidance from either agency on  
 6 ways to further conversation regarding this hurdle  
 7 with the appropriate audiences.  
 8 We appreciate FDA's and FTC's leadership and  
 9 working collaboratively to support a more  
 10 competitive approval landscape for biosimilars.  
 11 Thank you.  
 12 MS. IKENBERRY: Thanks, and sorry for the  
 13 mix-up.  
 14 Next is Kathleen Arntsen.  
 15 MR. GREENBLATT: Hello. My name is Corey  
 16 Greenblatt, and I'm representing Kathleen Arntsen  
 17 from LADA and ASBM. Before I begin, I just want to  
 18 say I have no disclosures to make today regarding  
 19 my comments on behalf of Lupus and Allied Diseases  
 20 Association.  
 21 Good afternoon and thank you for the  
 22 opportunity to provide our unique patient

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1 viewpoint. Biosimilars hold tremendous promise and  
 2 therapeutic advantages for people like us, just as  
 3 biologics have revolutionized treatment for  
 4 millions of individuals living with life-altering  
 5 diseases.  
 6 Lupus is an extremely complex, chronic  
 7 inflammatory autoimmune disease affecting virtually  
 8 any organ system of the body with few approved  
 9 drugs, no known cause or cure, and a challenge to  
 10 live with and treat. There is no cookie-cutter  
 11 approach to treat intricate patients like us, and  
 12 it requires access to the entire arsenal of  
 13 treatments and open and transparent communication  
 14 between us and our providers.  
 15 In order for biosimilars to reach their  
 16 potential and improve stakeholder engagement,  
 17 education, and access, we need to ensure confidence  
 18 that biosimilars are as safe and as effective as  
 19 the reference biologic products among patients,  
 20 healthcare providers, pharmacists, payers, and  
 21 other stakeholders while prioritizing patient  
 22 safety and affordability.

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1 We are pleased that the agency has finalized  
 2 guidance for interchangeable biologics by  
 3 clarifying safety, efficacy, and immunogenicity  
 4 methodologies by requiring manufacturers to conduct  
 5 vigorous multiple switching studies that alternate  
 6 between a biosimilar and its reference product. We  
 7 are also thrilled that the FDA supports robust  
 8 pharmacovigilant mechanisms for postmarketing  
 9 safety monitoring of an interchangeable in order to  
 10 not diminish efficacy and patient safety.  
 11 Developing an aggressive postmarketing tracking  
 12 system will also help to guarantee stakeholder  
 13 confidence and facilitate market uptake while  
 14 establishing a longitudinal electronic medical  
 15 record.  
 16 We suggest that you consider adopting  
 17 methods such as apps on electronic devices and  
 18 patient-reported outcomes to monitor real-world  
 19 events. Engaging patients and teaching them to be  
 20 more proactive in their care will be empowering and  
 21 can help diminish any lack of trust.  
 22 Biosimilars have the potential to promote

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1 greater price competition among biologics, and we  
 2 hope that they are more affordable, but the  
 3 variance in terminology when referring to  
 4 biosimilars is both confusing and a hindrance.  
 5 Stakeholder adoption of more uniform language such  
 6 as the FDA's would foster more confidence.  
 7 One of the biggest impediments to the  
 8 advancement of innovative therapies is the  
 9 overabundance of egregious payer utilization  
 10 management policies such as step therapy and  
 11 non-medical switching protocols. These  
 12 cost-containment measures impact provider ethical  
 13 obligations by requiring them to follow a set  
 14 course of care regardless of their best personal  
 15 judgment.  
 16 As an individual who is harmed by step  
 17 therapy, I am concerned that patients who are  
 18 stable on any drug will be switched for non-medical  
 19 reasons, and in particular those doing well in a  
 20 biologic will be switched to a biosimilar that has  
 21 not been determined to be interchangeable.  
 22 We urge you to establish robust patient

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1 safeguards by applying strong scientific safety  
 2 standards, stating that switching of stable  
 3 patients should only be determined by the treating  
 4 provider and the patient, and facilitating dialogue  
 5 among multistakeholders, including payers. We ask  
 6 you to reach out to other federal agencies and work  
 7 with them to develop sound policies that address  
 8 such issues.

9 In closing, I want to reiterate that we are  
 10 unwavering in our belief in the sanctity of the  
 11 doctor-patient relationship and that only providers  
 12 who are familiar with an individual's personal  
 13 medical history should be making treatment  
 14 decisions. Patient safety must be first and  
 15 foremost in choosing the most appropriate therapies  
 16 for any person with complex medical conditions.

17 We have faith that we can advance  
 18 biosimilars while still allowing physicians to make  
 19 decisions in the best interest of their patients.  
 20 Sometimes that decision is to keep a patient on a  
 21 successful biologic throughout their therapy;  
 22 sometimes it is switching to a biosimilar or

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1 starting a naive patient on a biosimilar.

2 There are millions of people who could  
 3 benefit from access to innovative therapies now and  
 4 many more in the future who are yet to be  
 5 diagnosed. We need to work together to make that  
 6 happen. We thank you for the opportunity to share  
 7 our perspective and applaud the FDA for continually  
 8 recognizing the importance of the patient voice  
 9 during the regulatory process. Thank you.

10 MS. IKENBERRY: Thank you.

11 Our next speaker is Ian Orekondy,  
 12 AdComplyRx.

13 MR. OREKONDY: Hello. Thank you for the  
 14 opportunity to comment today. My name is Ian  
 15 Orekondy. I'm the founder of AdComplyRx. We work  
 16 with industry to monitor prescription drug  
 17 advertising and identify ads that appear to  
 18 inadvertently infringe on FDA guidance so that  
 19 firms can fix them. Currently, we have a focus on  
 20 digital ads and search engine marketing.

21 My input is specific to the draft guidance  
 22 for promotional labeling and advertising

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1 considerations for prescription biological  
 2 reference products and biosimilar products.  
 3 Earlier we heard about Dr. Google and the  
 4 importance of patient education and healthcare  
 5 professional education around biosimilars.  
 6 Dr. Google is often the number one driver of  
 7 traffic to a prescription medication's website  
 8 where patients can learn about a specific  
 9 biosimilar or biosimilars in general.

10 We also note that there was an FDA warning  
 11 letter issued last month that was specific to  
 12 search ads on Google, so our request is that the  
 13 final guidance documents specifically get into how  
 14 this biosimilar guidance would apply to internet  
 15 marketing platforms with character space  
 16 limitations; for example, Google and Twitter.  
 17 Additionally, how would this guidance apply to,  
 18 quote/unquote, "brand-connected ads," that is ads  
 19 that do not mention any brand within the ad itself  
 20 but then link directly to a brand.com website.

21 These are important questions that impact  
 22 virtually all prescription biologic and biosimilar

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1 brands. We can elaborate on the specific scenarios  
 2 where we believe more specific guidance would be  
 3 useful when we submit our comments via the public  
 4 docket, and we thank you again for the opportunity  
 5 to comment in person today. Thank you.

6 MS. IKENBERRY: Thank you.

7 Our next speaker is Gregory Schimizzi,  
 8 Coalition of State Rheumatology Organizations.

9 DR. SCHIMIZZI: Yes, hello. My name is  
 10 Gregory Schimizzi, and I'm a board-certified  
 11 rheumatologist with 39 years of experience in  
 12 private practice. I'm speaking on behalf of the  
 13 CSRO, which is a national organization composed of  
 14 state and regional rheumatology societies in the  
 15 U.S. and Puerto Rico.

16 To date, some rheumatologists have  
 17 experienced occurrences of adverse effects or  
 18 decreased efficacy of biosimilars, but the vast  
 19 majority of rheumatologists do not believe that  
 20 biosimilars are inferior. We also have not  
 21 observed noticeable deceptive marketing practices  
 22 or received disparaging information on biosimilars

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1 in our offices, at educational meetings, or seen  
 2 them in journal advertisements. Therefore, we do  
 3 not believe that these are responsible, to a  
 4 meaningful degree, for the impaired patient access  
 5 to these products. We do see significant access  
 6 issues developing as a result of other marketplace  
 7 player activities.

8       Increasing patient access to these  
 9 medications can only be achieved if cognitive  
 10 distortions in the marketplace are addressed.  
 11 Developing remedies that disregard and ignore  
 12 manipulations designed to maximize profits from  
 13 fees, rebates, and other schemes that greatly  
 14 impede access may not be successful. We believe  
 15 these activities, which are at the core cause of  
 16 formulary design, far outweigh the impact of  
 17 deceptive marketing on patient access.

18       Formulary changes are rarely, if ever, based  
 19 on comparative clinical outcomes, or studies, or  
 20 safety, or tolerability, or even wholesale  
 21 acquisition costs, but rather on profitability to  
 22 the insurer, the large pharmacy, and PBM entities.

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1 The preeminent access barrier to address is the  
 2 control of an overly consolidated industry of  
 3 unregulated middlemen with unfettered power,  
 4 demanding ever-increasing tolls from patients,  
 5 community pharmacists, and manufacturers, almost  
 6 always to the detriment of patients' and  
 7 physicians' therapeutic options and the quality of  
 8 health care. Described earlier as one of the bad  
 9 barriers, these are also a major driver of rising  
 10 medication costs.

11       This should not be allowed to continue. It  
 12 is gratifying to hear that the FDA and FTC are  
 13 aligned with our own goal here. We urge addressing  
 14 these reprehensible and egregious insurance and PBM  
 15 behaviors, much of which exists due to  
 16 overconsolidation. These abuses need to be  
 17 addressed either through existing authority or by  
 18 requesting additional authority where needed and/or  
 19 petitioning statutory solutions.

20       We must end the profiteering inherent in the  
 21 current formulary design process by insurers, large  
 22 pharmacy, and PBM conglomerates. These are the

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1 main barriers to a fair, robust market of biologic  
 2 medication access and indeed to all medications.  
 3 Thank you very much.

4       MS. IKENBERRY: Thank you.

5       Next, Laura Brand, Biosimilars Global  
 6 Commercial Lead, Amgen.

7       MS. BRAND: Good afternoon. My name is  
 8 Laura Brand, and I'm the biosimilars global  
 9 commercial lead at Amgen. Thank you for allowing  
 10 me to share Amgen's perspective on a topic of  
 11 critical importance to the future of our nation's  
 12 healthcare system.

13       As a manufacturer of both innovator and  
 14 biosimilar products, Amgen shares a deep commitment  
 15 to the FDA's and FTC's goal of promoting a  
 16 robust-to-competitive marketplace for biological  
 17 products, including the adoption of biosimilars.  
 18 Although the U.S. market for biosimilars is still  
 19 maturing, it is competitive.

20       The FDA has approved significantly more  
 21 biosimilar products in the first nine years since  
 22 the U.S. pathway was established compared to other

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1 regions such as Europe, and there are currently  
 2 over 80 biosimilar programs enrolled in the FDA's  
 3 biosimilar product development program. Amgen  
 4 believes this reflects robust manufacturer interest  
 5 in the current market opportunity under current  
 6 payment and coverage systems.

7       Patients in the U.S. healthcare system have  
 8 benefited from considerable cost savings as a  
 9 result of biosimilar products already in the  
 10 market. Competition in the marketplace is likely  
 11 to yield additional savings as more biosimilars are  
 12 launched throughout 2020 and the coming years.

13       Cost savings are just one benefit of  
 14 biosimilars. Biosimilar manufacturers can also  
 15 benefit the market by offering improved patient  
 16 choice by competing on delivery devices and improve  
 17 reliability of supply. With this portfolio of  
 18 10 biosimilar products and development, including  
 19 four approved by the FDA, Amgen is committed to  
 20 delivering potential savings and expanded treatment  
 21 options to patients.

22       In Amgen's experience, a level playing field

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1 that encourages competition, not only with  
 2 innovator products but also among biosimilars,  
 3 creates a robust and sustainable marketplace. This  
 4 head-to-head competition drives meaningful cost  
 5 savings and also supports continued innovation to  
 6 expand biologic treatment options for providers and  
 7 patients. Our experience demonstrates that the  
 8 current regulatory and reimbursement policies for  
 9 biosimilars are working to promote competition.

10 Amgen has faced competition from biosimilars  
 11 for innovator products since 2015. Currently,  
 12 three of our innovator products, Neupogen,  
 13 Neulasta, and Epogen, compete against multiple  
 14 biosimilars. Biosimilars of Amgen's Neupogen  
 15 product together sell more units than Amgen, and a  
 16 Neupogen biosimilar competitor has obtained  
 17 preferred status over Neupogen with several  
 18 formularies, even though this competing biosimilar  
 19 does not have an interchangeability designation.

20 In 2019, Amgen launched the first  
 21 therapeutic oncology biosimilars in the U.S. The  
 22 list prices for both products are markedly lower

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1 than the average sales price of the respective  
 2 reference products, generating significant cost  
 3 savings for patients and payers. Amgen's two  
 4 biosimilars are gaining adoption quickly, having  
 5 each secured approximately 20 percent share of the  
 6 market in just over six months as recently reported  
 7 by the Bernstein report.

8 These examples demonstrate the current  
 9 policies, for example separate coding, are  
 10 supporting biosimilar uptake and encouraging price  
 11 competition. At Amgen, we believe the long-term  
 12 viability of industry depends on a competitive  
 13 marketplace in which patients, providers, and  
 14 payers have a real understanding of and confidence  
 15 in biological products, including biosimilars.

16 We share the FDA's and the FTC's goal of  
 17 promoting stakeholder confidence in biosimilars  
 18 through scientifically accurate educational  
 19 outreach. Such educational initiatives are crucial  
 20 to preserving patient choice, driving uptake of  
 21 biosimilars, and supporting a sustainable  
 22 marketplace.

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1 In summary, competition is robust,  
 2 biosimilar market share is increasing, and prices  
 3 are coming down. Amgen remains fully committed to  
 4 the success of biosimilars within the U.S.  
 5 healthcare marketplace. Thank you.

6 MS. IKENBERRY: Thank you.

7 Our next speaker is David Balto, Coalition  
 8 to Protect Patient Choice.

9 MR. BARLOW: Hi. Good afternoon. This is  
 10 Andre Barlow on behalf of David Balto, a public  
 11 interest attorney and the founder of the Coalition  
 12 to Protect Patient Choice, an entity that  
 13 advocates on behalf of consumer and patient  
 14 advocacy groups. We're also speaking on behalf of  
 15 consumer action.

16 We are appreciative of the opportunity to  
 17 provide comments today and we commend the FTC and  
 18 FDA's efforts to work together to promote  
 19 biosimilar competition, which will hopefully result  
 20 in patients having increased access to more  
 21 affordable drugs. Biologics are essential for the  
 22 treatment of serious debilitating and

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1 life-threatening diseases.

2 While fewer than 2 percent of all  
 3 prescriptions are for biologic drugs, they account  
 4 for almost 40 percent of all drug spending. In  
 5 other words, biologics are extremely expensive, and  
 6 they are the fastest growing segment of drug  
 7 spending in the United States. The expectation 10  
 8 years ago was that a robust biosimilar market would  
 9 substantially lower the price of biologic drugs.

10 It has been estimated that biosimilars can save  
 11 U.S. consumers \$54 billion by 2026.

12 In Europe, where biosimilars have entered  
 13 the market, biologics such as AbbVie's branded  
 14 blockbuster Humira has been discounted by  
 15 80 percent. Unfortunately, biosimilars have faced  
 16 numerous obstacles in obtaining commercial success  
 17 in the United States. There are a number of  
 18 anticompetitive behaviors, or shenanigans,  
 19 including sample blockage, patent thickets,  
 20 pay-for-delay agreements, and rebate walls. We  
 21 would like to highlight rebate walls because we do  
 22 not believe that they're getting enough attention.

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1 We believe the agencies need to use their  
 2 enforcement muscle to prohibit rebate contracting  
 3 practices that block biosimilars from competing on  
 4 drug formularies. There is increasing evidence  
 5 that rebates actually raise the cost of  
 6 prescription drugs.

7 What is important to understand about these  
 8 rebates is that they are not discounts for  
 9 patients. Because the rebates go to PBMs and plans  
 10 rather than to consumers, payers have perverse  
 11 incentives to negotiate higher list prices so they  
 12 can secure higher rebates without regard to patient  
 13 well-being or patient cost. These rebates actually  
 14 increase patients' cost because the patient's  
 15 coinsurance is based on the inflated list price of  
 16 the branded drug. If the patients had access to  
 17 lower cost biosimilars, their co-insurance costs  
 18 would go down.

19 How does a rebate wall work? A rebate wall  
 20 or trap is erected when an incumbent manufacturer  
 21 uses existing market power to secure preferred  
 22 formulary access for its drug by offering

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1 volume-based rebates to PBMs and plans on the  
 2 condition that they deny or limit the formulary  
 3 access of rival drugs.

4 The rebate is bundled across multiple  
 5 products, indications, and/or therapeutic  
 6 specialties, the breadth of which cannot be matched  
 7 by a new rival. The rebate wall, a manufacturer  
 8 with a dominant incumbent drug, can prevent entry  
 9 of a newly approved biosimilar even if the  
 10 biosimilar is offered at a greater rebate or for  
 11 free. That's because the new biosimilar has few  
 12 prescriptions, if any, so even a larger rebate will  
 13 not overcome the potential loss of the rebate  
 14 dollars from the market-leading product.

15 Biosimilars lose because they can't get on a  
 16 formulary. Patients lose because they do not have  
 17 access to lower cost drugs.

18 A related practice that keeps patients from  
 19 detaining access to biosimilars is step therapy,  
 20 also known as fail-first policies, whereby patients  
 21 are forced to try a drug preferred by the payer  
 22 before being approved to use a drug originally

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1 prescribed by their doctors.

2 Remarkably, most health plans have  
 3 instituted fail-first policies for new biosimilars,  
 4 meaning that a patient must fail on a more  
 5 expensive branded product before the plan will  
 6 cover a biosimilar of that same branded product.

7 This is noteworthy because, historically, generics  
 8 which are less expensive than branded drugs have  
 9 been the first option on the fail-first policy.

10 One explanation for discrimination against  
 11 biosimilars is that PBMs and health plans secure  
 12 significant rebates from branded drugs.

13 In short, the FTC needs to prioritize  
 14 investigations of rebate walls and step therapy  
 15 rules, which can be used to foreclose biosimilar  
 16 competition, which limits patients choices and  
 17 raises patients costs. Thank you.

18 MS. IKENBERRY: Thank you.

19 Our next speaker is Jocelyn Ulrich, deputy  
 20 vice president at PhRMA.

21 MS. ULRICH: Hello. Thank you. My name is  
 22 Jocelyn Ulrich, deputy vice president of medical

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1 innovation policy at PhRMA. I appreciate the  
 2 opportunity to represent PhRMA and our member  
 3 companies at today's Workshop on a Competitive  
 4 Marketplace for Biosimilars.

5 PhRMA represents the country's leading  
 6 innovative biopharmaceutical research companies,  
 7 which are devoted to discovering and developing  
 8 medicines that enable patients to live longer,  
 9 healthier, and more productive lives. Consistent  
 10 with that mission, PhRMA is dedicated to advancing  
 11 policies that promote innovation and competition in  
 12 the biologics and biosimilars marketplace.

13 While the BPCIA is less than a decade old  
 14 and biosimilar development is significantly more  
 15 complex and expensive than generic drug  
 16 development, the benefits of the BPCIA on  
 17 innovation and competition are already being seen.

18 As of today, there are 15 biosimilars on the market  
 19 competing against 7 innovator biologics, with an  
 20 additional 10 approved by the FDA coming to the  
 21 market over the next several years.

22 In addition, the upcoming transition of some

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1 products to licensure as biologics and the recently  
 2 enacted change to the definition of biologic will  
 3 provide additional opportunities for more  
 4 biosimilar applications and patient choice.  
 5 Publicly available data on the current U.S.  
 6 market has shown that in every case where a  
 7 biosimilar has entered the marketplace, both the  
 8 average sales price of the biosimilar and the  
 9 innovator biologic have decreased, and as noted by  
 10 the FTC, basic economic principles support that  
 11 this indicates the competition is indeed leading to  
 12 lower prices, increased consumer access and choice,  
 13 and innovation.  
 14 PhRMA supports FDA's efforts to implement a  
 15 science-based approach to regulating biosimilars  
 16 that both ensures patient safety and facilitates a  
 17 robust biosimilars market, and we believe it is  
 18 critically important to ensure the long-term  
 19 stability of the BsUFA through financial  
 20 transparency, efficiency, and accountability.  
 21 We also support many aspects of the FDA's  
 22 biosimilars action plan. In particular, we concur

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1 address barriers to appropriately structured  
 2 alternative payment models, particularly in  
 3 Medicare, that have the ability to increase  
 4 competition among innovator and biosimilar  
 5 products. And finally, policymakers must advance  
 6 meaningful rebate reform that would remove barriers  
 7 to biosimilar uptake and promote access and  
 8 competition.  
 9 In enacting the BPCIA a decade ago, U.S.  
 10 policymakers rightly sought to balance increased  
 11 competition with policies that support the United  
 12 States' leading role in finding new treatments for  
 13 patients. By allowing the market to continue to  
 14 evolve and enacting policies that support this  
 15 evolution, we'll continue to see biosimilars'  
 16 benefits for patients and society. Thank you.  
 17 MS. IKENBERRY: Thank you.  
 18 Next we have Corey Greenblatt, manager of  
 19 policy and advocacy, Global Healthy Living  
 20 Foundation. Hi, again.  
 21 MR. GREENBLATT: Hello, again. Before I  
 22 begin, I just want to disclose I have no

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1 with FDA that physician education and experience  
 2 with biosimilars will be critical for fostering  
 3 biosimilar uptake, and we applaud continued efforts  
 4 to develop effective communications to improve  
 5 understanding of biosimilars among patients,  
 6 clinicians, and payers.  
 7 PhRMA believes that FDA and FTC have a  
 8 robust set of authorities available to them to  
 9 continue to foster competition and encourage the  
 10 maturing biosimilars market. To further support  
 11 the market, we believe policymakers and  
 12 stakeholders should take the following additional  
 13 steps. First, we should increase transparency for  
 14 certain patents on biologic products consistent  
 15 with what is currently available in the FDA Orange  
 16 Book for drug products.  
 17 Second, to the extent there were issues with  
 18 access to samples, the recent enactment of what had  
 19 been previously referred to as the CREATES Act may  
 20 facilitate access to samples, which in turn will  
 21 facilitate biosimilars entering the market.  
 22 Third, we believe that policymakers should

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1 disclosures to make regarding my travel here today.  
 2 The Global Healthy Living Foundation accepts grants  
 3 and charitable contributions from pharmaceutical  
 4 companies, the federal government, private  
 5 foundations, and individuals. The organization has  
 6 received scientific briefings from pharmaceutical  
 7 companies as well as our independent medical  
 8 advisory board.  
 9 Good afternoon. My name is Corey  
 10 Greenblatt, and I'm the manager of policy and  
 11 advocacy for the Global Healthy Living Foundation.  
 12 On behalf of GHLF, I want to thank this committee  
 13 for allowing me to speak. GHLF is a 20-year-old  
 14 501(c)(3) organization representing chronically ill  
 15 patients and their caregivers across the country.  
 16 GHLF works to improve the quality of life for  
 17 patients living with chronic disease by ensuring  
 18 their voices are heard and advocating for improved  
 19 access to care.  
 20 The barrier for entry in the U.S. biosimilar  
 21 market has been too high for too long. Despite the  
 22 Biologics Price Competition and Innovation Act, the



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1 U.S. is about seven years behind Europe. Not  
 2 having a robust biosimilar market is a failure in  
 3 U.S. health care. Patient and provider education  
 4 is one reason for this failure; economics is  
 5 another.  
 6 Patients understand generic versus branded  
 7 drugs, but they do not understand biosimilars,  
 8 especially in the aggressive context in which they  
 9 are presented by insurers. Even many healthcare  
 10 professionals don't understand when to use  
 11 biosimilars and what the positives and negatives of  
 12 biosimilar use are. They are instead instructed  
 13 when to use them by insurers.  
 14 Switch biosimilar patients are required to  
 15 abandon a medication that works with little or no  
 16 explanation, education, or counseling. The  
 17 healthcare provider gets a letter in the mail  
 18 telling them to switch the patient or the patient  
 19 will pay the full retail price of their current  
 20 drug. This is obviously not the way to sell the  
 21 benefits of biosimilars to patients or physicians.  
 22 Government is being asked to favor one group

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1 adjusters, and step therapy.  
 2 Non-medical switching needs to be defined.  
 3 Patients and physicians should be able to  
 4 voluntarily non-medically switch drugs when it  
 5 benefits the patient, not only the insurer and the  
 6 PBM. If a patient can save money and their  
 7 healthcare professional does not object, they  
 8 should be allowed to switch brands, whether it's a  
 9 biologic or a biosimilar.  
 10 Forced non-medical switching, which occurs  
 11 now, offers no quantifiable financial benefit to  
 12 patients, only profits to insurers. The patient is  
 13 the only one who shows up to the table with a  
 14 checkbook but no power. Everyone else shows up  
 15 with varying degrees of power that are used to  
 16 protect profits. It is nearly impossible to  
 17 identify any other market where the person paying  
 18 the bills has so little influence on the price of  
 19 the product or the product itself.  
 20 You can change this by recognizing the need  
 21 for strict regulation of insurance practices and  
 22 market-based price lowering incentives to

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1 of manufacturers making biosimilars over another  
 2 which doesn't, with complete opacity to the  
 3 patient. Our hope is that the agencies will work  
 4 to create a transparent environment for the  
 5 patient, one that does not show a bias for  
 6 biosimilars or biologics, allows the patient to  
 7 directly benefit from generic-like lower price, and  
 8 feel positive about switching to or starting on a  
 9 biosimilar. We believe that only then will a  
 10 robust biosimilar market emerge for chronically ill  
 11 patients.  
 12 GHLF, the FDA, and other patient groups can  
 13 handle the education issues around biosimilars if  
 14 you can clear up the economic inequalities. To the  
 15 patient, biosimilars are generic biologics. Your  
 16 job is to create the market that allows them to be  
 17 priced this way. We need a system that allows  
 18 therapies to compete based on clinical outcomes and  
 19 costs to the patient, not a system that allows  
 20 anticompetitive practices such as rebates, rebate  
 21 walls, favorable pricing to physicians,  
 22 access-restricting formularies, co-pay accumulator

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1 biopharmaceutical companies. If there's no  
 2 financial relief for patients from what to them is  
 3 a generic drug, then biosimilar growth will  
 4 continue at its slow pace compared to other  
 5 generics and biosimilars in other countries.  
 6 We thank the FDA and the FTC for emphasizing  
 7 the value of the patient perspective through public  
 8 meetings, and we will continue to mobilize our  
 9 patient communities and create a better life for  
 10 those who will benefit from biosimilar therapies.  
 11 Thank you for your time and attention. It is  
 12 greatly appreciated.  
 13 MS. IKENBERRY: Next is Fouad Atouf.  
 14 DR. ATOUF: Good afternoon. My name is  
 15 Fouad Atouf. I'm vice president of global  
 16 biologics at the United States Pharmacopeia, USP.  
 17 I appreciate the opportunity to present on behalf  
 18 of USP our comment on the competitive marketplace  
 19 for biosimilars. USP is an independent scientific  
 20 non-profit organization dedicated to improving  
 21 health through the development and dissemination of  
 22 public standards for medicines, foods, and dietary

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1 supplement.

2 Through a long-standing collaboration with  
3 the FDA, we have worked continuously to benefit  
4 public health by facilitating broader access to  
5 quality medicines. USP supports FDA's and FTC's  
6 effort to foster access to biosimilars and to  
7 pursue initiatives that facilitate increased  
8 competition to biological products. Furthermore,  
9 we believe that our public standards serve an  
10 important role in fostering a competitive  
11 marketplace.

12 First and foremost, USP public standards  
13 help ensure quality medicines. For example, USP's  
14 quality standards for insulins have been used by  
15 manufacturers for a decade to meet quality  
16 expectations. Additionally, USP standards provide  
17 valuable information to biological manufacturers to  
18 support early development of new or biosimilar  
19 products and address common quality issues. These  
20 standards can add flexibility by offering choices  
21 of analytical approaches.

22 Furthermore, studies indicate that public

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1 standards help foster a more competitive  
2 marketplace for medicines because the standards  
3 provide transparency on the quality expectation for  
4 medicine, which helps new manufacturers bring new  
5 products to the marketplace.

6 USP standards are developed in an open  
7 transparent process. They're established by  
8 independent experts and scientific experts, and  
9 development of the standards takes into account  
10 public input. The expert who works with USP will  
11 collaborate closely with stakeholders and  
12 government agencies such as the FDA.

13 USP is committed to ensuring that our  
14 approach evolves with the science of biologics and  
15 the needs of stakeholders by developing solutions  
16 that support the adoption of emerging analytical  
17 tools for biological product innovation and  
18 competition. We are currently developing standards  
19 that are broadly applicable to classes and families  
20 of biological products and also working on tools to  
21 address quality of raw materials with an overall  
22 goal to support analytical testing throughout the

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1 product life cycle.

2 USP is a convener and will continue to  
3 convene stakeholders to identify areas of needs and  
4 improvement for development of biological products.  
5 In recent years, we hosted a series of roundtables  
6 to address and discuss with the stakeholders the  
7 common quality challenges and to develop together a  
8 set of solutions that address biological products  
9 throughout the product life cycle.

10 We will continue that convening role and we  
11 plan to hold in the next coming month a series of  
12 roundtables to address topics like ensuring quality  
13 of biologics globally, but also ensuring quality of  
14 insulins and other topics such as the role of  
15 genomics analysis and personalized medicines.

16 We are very much interested in hearing from  
17 the FDA and FTC any additional topics you would  
18 like to discuss with stakeholders and would be  
19 happy to facilitate those discussions. Thank you  
20 again for the opportunity to present, on behalf of  
21 USP, our perspective. Thank you.

22 MS. IKENBERRY: Thank you.

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1 Laura McKinley, director of regulatory  
2 policy, Pfizer.

3 DR. MCKINLEY: Hello. Thank you. I am  
4 Laura McKinley as she said, director of regulatory  
5 policy at Pfizer, and we appreciate the opportunity  
6 to present here today and applaud the FDA-FTC  
7 collaboration to support appropriate adoption of  
8 biosimilars.

9 The introduction of biosimilars in the U.S.  
10 was intended to increase competition by providing  
11 additional safe and effective biologic treatment  
12 options, thereby reducing healthcare costs. This  
13 goal will not be realized if patients and  
14 healthcare professionals receive incomplete or  
15 misleading information.

16 In August 2018, Pfizer filed a citizen  
17 petition requesting that FDA issue guidance to help  
18 ensure communications by sponsors concerning the  
19 safety and effectiveness of biosimilars are  
20 truthful and non-misleading.

21 In this regard, Pfizer appreciates the  
22 important steps FDA has taken to address

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1 misinformation, including the publication of draft  
 2 guidance that specifically notes that reference  
 3 product promotional materials should avoid  
 4 representing or suggesting that a biosimilar  
 5 product is less safe or effective than its  
 6 reference product because it has not been studied  
 7 in all clinical indications and/or is not licensed  
 8 as interchangeable.

9 The Federal Register notice seeks input on  
 10 promotional materials for interchangeables. Pfizer  
 11 believes it is essential to avoid inaccurate  
 12 perceptions of the safety and effectiveness of  
 13 biological products based on their licensure  
 14 pathway. Therefore, we encourage FDA to also  
 15 address interchangeable biosimilar labeling and  
 16 promotional materials to help ensure these to avoid  
 17 representing or suggesting that a biosimilar  
 18 product is less safe or effective because it has  
 19 not been licensed as interchangeable.

20 Pfizer fully supports the rigorous  
 21 evaluation standards that FDA applies to all  
 22 products, including biosimilars, but believes

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1 consistent with the risk information in the  
 2 reference product labeling as a CBE-0 submission.  
 3 Treating such updates as CBE-0's will help ensure  
 4 important risk information is being disseminated to  
 5 healthcare providers and patients in a timely  
 6 manner.

7 Finally, Pfizer is concerned about  
 8 anticompetitive contracting practices by which a  
 9 biologic manufacturer undertakes systemic efforts  
 10 to maintain unlawfully a monopoly in connection  
 11 with its reference products. The practice of  
 12 withholding significant rebates for both current  
 13 and future patients, unless insurers agree to  
 14 biosimilar exclusion contracts, effectively block  
 15 coverage of biosimilars. Without such coverage,  
 16 providers are reluctant to stock biosimilars.

17 Further, anticompetitive contracts  
 18 effectively conditioned on the providers not  
 19 purchasing biosimilars in exchange for discounts on  
 20 the reference or other products prevent physicians  
 21 from trying and patients from accessing  
 22 biosimilars. Pfizer again thanks FDA and FTC for

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1 further opportunities exist to optimize the  
 2 approval process for biosimilars without  
 3 compromising scientific standards.

4 For example, FDA has indicated they intend  
 5 to review and act upon supplement-seeking licensure  
 6 for an additional condition of use in a 6-month  
 7 review time as opposed to the 10-month review time  
 8 frame outlined in the BsUFA II goals letter.

9 However, the BsUFA II goals letter is limited to  
 10 supplements with clinical data.

11 We think consideration should be given to  
 12 reduce even further the review time for supplements  
 13 seeking licensure for additional indications  
 14 supported by scientific justification of  
 15 extrapolation in the absence of additional clinical  
 16 data. This would avoid unnecessary delays in  
 17 patient access to biosimilars.

18 It would also be beneficial to have further  
 19 guidance regarding the post-approval process for  
 20 adding safety information to biosimilar labels. In  
 21 particular, Pfizer urges the agency to consider  
 22 biosimilar safety labeling updates that are

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1 convening this workshop and for the opportunity to  
 2 speak.

3 MS. IKENBERRY: Thank you. That was our  
 4 last registered commenter. So with that, I will  
 5 turn it over to Caty for final remarks.

6 Closing Remarks - Catherine Gray

7 MS. GRAY: I have the best job of the day.

8 On behalf of FDA and FTC, I'd like to thank  
 9 all the speakers and panelists and everyone in the  
 10 audience for participating in today's workshop.  
 11 Whether you attended in person or via webcast, we  
 12 greatly appreciate your attention and your interest  
 13 in today's sessions and presentations. I'd like to  
 14 also send out one last acknowledgment to the many  
 15 folks at FTC and FDA who worked tirelessly in  
 16 preparing for this meeting. Thank you for your  
 17 persistence.

18 As a reminder, we strongly encourage you to  
 19 submit your comments to the docket, which will be  
 20 open until April 9th. If you would like any  
 21 details on how to submit your comments to the  
 22 docket, we have placed copies of the Federal

1 Register notice announcing this meeting at the  
2 registration table just outside the meeting room.  
3 A transcript from the workshop should be  
4 posted to the workshop website within 30 days. We  
5 will provide copies of today's presentations upon  
6 request and contact information about getting those  
7 copies is also available at the registration table.

8 On that note, I'm closing the workshop.

9 Thank you again for participating and have a safe  
10 trip home.

11 (Applause.)

12 (Whereupon, at 4:18 p.m., the workshop was  
13 concluded.)

14

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<p style="text-align: center;"><b>\$</b></p> <p><b>\$1044 (1)</b> 130:1</p> <p><b>\$12 (1)</b> 185:22</p> <p><b>\$125.5 (1)</b> 25:3</p> <p><b>\$144 (1)</b> 129:12</p> <p><b>\$2 (1)</b> 184:16</p> <p><b>\$291 (1)</b> 130:4</p> <p><b>\$3 (1)</b> 54:6</p> <p><b>\$3,000 (1)</b> 190:2</p> <p><b>\$344 (1)</b> 129:4</p> <p><b>\$4.8 (1)</b> 286:10</p> <p><b>\$40 (1)</b> 133:3</p> <p><b>\$435 (1)</b> 130:3</p> <p><b>\$54 (1)</b> 308:11</p> <p><b>\$85 (1)</b> 129:11</p>	<p>195:15;197:4;209:5; 236:4;239:2;244:11; 245:3;319:3</p> <p><b>absence (1)</b> 326:15</p> <p><b>absolute (1)</b> 179:13</p> <p><b>absolutely (4)</b> 20:13;201:12; 205:19;246:21</p> <p><b>abundance (1)</b> 269:2</p> <p><b>abused (1)</b> 161:2</p> <p><b>abuses (2)</b> 42:13;302:16</p> <p><b>ACA (3)</b> 147:15;148:1,4</p> <p><b>academic (2)</b> 58:4;289:5</p> <p><b>acceleration (1)</b> 16:16</p> <p><b>accept (3)</b> 63:4;77:10;275:5</p> <p><b>acceptance (5)</b> 169:5;171:15; 172:5;202:13;209:6</p> <p><b>accepted (1)</b> 95:19</p> <p><b>accepts (1)</b> 316:2</p> <p><b>access (46)</b> 6:21;7:13;15:21; 28:21;30:13;38:16,18; 40:2;73:7;75:8;126:9; 152:3;155:5;176:3,4; 184:5;185:13;207:18; 274:15;284:2;289:1; 291:6;294:12,17; 298:3;301:4,5,8,14, 17;302:1;303:2; 307:20;309:16,22; 310:3,17,19;313:12; 314:18,20;315:7; 316:19;321:4,6; 326:17</p> <p><b>accessed (2)</b> 9:19;208:2</p> <p><b>accessibility (1)</b> 19:4</p> <p><b>Accessible (4)</b> 32:20;134:1; 180:17;203:3</p> <p><b>accessing (1)</b> 327:21</p> <p><b>access-restricting (1)</b> 318:22</p> <p><b>accompanied (1)</b> 86:16</p> <p><b>accomplish (2)</b> 102:16;238:5</p> <p><b>accomplished (2)</b> 136:17;284:6</p>	<p><b>accomplishes (1)</b> 81:3</p> <p><b>accordance (1)</b> 84:9</p> <p><b>according (2)</b> 89:7;223:12</p> <p><b>account (8)</b> 18:13,16;48:19; 56:4;104:19;146:5; 308:3;322:9</p> <p><b>accountability (1)</b> 313:20</p> <p><b>accounted (1)</b> 149:15</p> <p><b>accumulator (1)</b> 318:22</p> <p><b>accurate (8)</b> 10:2;15:17;75:11; 110:7;112:1;113:4; 114:1;306:18</p> <p><b>accurately (4)</b> 106:17;112:20; 117:6,21</p> <p><b>ACE (2)</b> 178:20;180:17</p> <p><b>achieve (5)</b> 42:2;74:13;139:10; 165:15;281:19</p> <p><b>achieved (1)</b> 301:9</p> <p><b>achieving (2)</b> 279:14;284:13</p> <p><b>acknowledge (4)</b> 12:10,14,16;145:9</p> <p><b>acknowledgment (1)</b> 328:14</p> <p><b>acquisition (1)</b> 301:21</p> <p><b>across (19)</b> 12:20;16:5;19:13; 34:11;52:3;60:15; 72:13,15,22;86:4; 152:21;160:6;197:6; 208:21;262:18;273:2; 276:11;310:4;316:15</p> <p><b>Act (39)</b> 17:9;26:8,11,16; 34:2;37:7;53:20;79:6; 81:10,18,21;85:6,18, 22;93:22;97:3;104:5, 13;119:13;217:14; 218:14,19;219:5,9; 223:6,7;224:5;225:12; 226:19;227:20;229:7; 241:19;248:4,19,21; 252:2;314:19;316:22; 326:5</p> <p><b>Actavis (1)</b> 27:6</p> <p><b>acting (4)</b> 6:9;23:5;253:1; 256:15</p> <p><b>action (26)</b></p>	<p>27:18;30:8;45:1,6; 62:10;164:19;213:7; 218:10,15;219:5; 223:8;225:17,20; 226:8,17;238:2; 239:21;242:22; 248:21;251:19;253:6; 271:8;279:9;280:16; 307:15;313:22</p> <p><b>actionable (1)</b> 219:9</p> <p><b>actions (6)</b> 21:11;26:22;85:17; 98:4;225:12;240:7</p> <p><b>active (4)</b> 54:20;72:16; 110:19;113:15</p> <p><b>actively (3)</b> 49:18,19;270:20</p> <p><b>activists (2)</b> 27:9;236:21</p> <p><b>activities (7)</b> 15:8,20;21:10,16; 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