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U.S. FOOD & DRUG ADMINISTRATION
THE HATCH-WAXMAN AMENDMENTS:
ENSURING A BALANCE BETWEEN INNOVATION AND ACCESS

Keith Flanagan, Moderator
Office of Generic Drugs
Center for Drug Evaluation and Research

Tuesday, July 18, 2017
9:02 A.M. - 5:28 P.M.

Food and Drug Administration
White Oak Campus
10903 New Hampshire Avenue
Silver Spring, Maryland

Reported by: Michael Farkas,
Capital Reporting Company

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P R O C E E D I N G S

MR. FLANAGAN: Good morning, and welcome. My name is Keith Flanagan. I'm the Director of the Office of Generic Drug Policy, in the Office of Generic Drugs, and I'll be serving as today's moderator. I'd like to thank you all, whether you're attending in person or watching via webcast, for joining our public meeting on the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access.

We're holding this meeting to provide an opportunity for the public to make your views known on how to maintain the balance between a steady pipeline of innovative drug development while speeding access to lower cost alternatives to innovator drugs. If you were unable to register in advance to speak today, you can share your view by submitting a written comment to the docket, which will remain open until September 18th. For your reference, the docket number is FDA-2017-N-3615. And the docket can be accessed at www.regulations.gov.

We have a full day today. Before getting

1 started, I'd like to briefly go over some logistics
2 that will help keep the meeting running efficiently.
3 As to logistics, if you haven't already done so please
4 sign in at the registration desk, especially if you are
5 presenting, so we can send any follow-up information
6 after this meeting. Today's agenda includes a ten-
7 minute break this morning, a one-hour lunch break, and
8 a ten-minute break in the afternoon. We ask that you
9 return promptly from the breaks and lunch, so that the
10 39 speakers are able to fully utilize their allotted
11 time.

12 For any members of the media present, FDA
13 press officer Sandy Walsh is available to help you.
14 Sandy, please stand up and raise your hand to identify
15 yourself. Please direct all media questions to Sandy.
16 The Wi-Fi network name and password are available at
17 the registration desk.

18 With respect to the agenda, the times listed
19 on the agenda are approximate. If we finish one
20 session ahead of schedule, we'll move right into the
21 next part of the agenda. We'll try to end the meeting
22 by 5:00.

1 Following our opening remarks and introduction
2 of the panelists, we will have public presentations
3 that represent the perspectives of those in academia
4 and research, payers and providers, pharmaceutical
5 product developers and patients and consumers. After
6 each presentation, today, the panel will have an
7 opportunity to ask questions. No participant may
8 interrupt the presentation of another participant.
9 Only the panel may ask questions after the
10 presentations. I'll announce the first speaker of each
11 set of speakers, but not each subsequent speaker. So,
12 please approach the podium when the slide that lists
13 your name and affiliation appears on the screen.

14 After presentations from the
15 academic/researcher perspective, we'll take a ten-
16 minute break. The payer/provider group will then
17 present. Those presentations will be followed by lunch
18 from noon to 1:00. After lunch are presentations from
19 pharmaceutical product developers. Those presentations
20 will be followed by the afternoon break, and then
21 presentations from the patient/consumer perspective. I
22 ask that each presenter remain at the podium after your

1 remarks, to allow the panel an opportunity for
2 questions. After today's presentations, have
3 concluded, I'll make brief closing remarks and adjourn
4 the meeting.

5 Concerning the transcript and written
6 comments, the record of this meeting will be
7 transcribed. So, please remember to use the microphone
8 when speaking. The transcript will be accessible
9 through regulations.gov and the website for this public
10 meeting in about 30 days. Any comments that aren't
11 presented today can be submitted through
12 regulations.gov using docket number, again, FDA-2017-N-
13 3615.

14 And with that, I'd like to thank Commissioner
15 Gottlieb for his leadership, activism and support, and
16 invite him to make some opening remarks.

17 DR. GOTTLIEB: Thank you. Thank you all for
18 coming today, and thank you for having me here. I want
19 to discuss how we can make sure that, in places where
20 Congress intended for there to be vigorous drug
21 competition, such competition actually reaches the
22 market. This is especially true as it relates to the

1 generic drug approval process, because generic
2 medicines deliver so much value to consumers, and price
3 competition to the marketplace.

4 The fact is that in too many places people
5 can't afford the medicines that they need. Now, I know
6 there are complex reasons for this. The structure of
7 health insurance and formularies has changed, at times
8 leaving some patients underinsured for the drugs they
9 use. The pharmaceutical supply chain has also become
10 more complex, and at times, more costly. A long series
11 of middlemen sometimes extract premiums as drugs pass
12 from manufacturers to patients, while adding uncertain
13 value.

14 FDA doesn't have a direct role in how drugs
15 are priced. But at FDA, we do play a key role, if
16 indirect role, in the eventual cost of medicines. For
17 one thing, our regulatory requirements impact the cost
18 of drug development. On some level, drugs are
19 ultimately priced to some measure of the cost of the
20 capital needed to create them. These costs aren't just
21 a reflection of the direct cost of drug development,
22 but also the indirect costs. They include the cost of

1 scientific and regulatory risk. They also include the
2 costs associated with the time it takes to develop a
3 drug and gain its regulatory approval, and the costs
4 associated with the research and development of
5 experimental products that ultimately do not make it to
6 market.

7 To the extent that FDA can make sure its own
8 regulatory requirements are efficient, predictable, and
9 science-based, we can also help reduce the time and
10 uncertainty of drug development for both generic and
11 branded drugs -- and ultimately impact the cost of
12 these endeavors.

13 But there's another important way FDA can have
14 an impact on drug costs. That's by encouraging
15 competition. Consumers derive greater value when they
16 have access to more choice and competition. This is
17 especially true when it comes to new drug categories.
18 Novel drugs that are therapeutically similar, or can be
19 used interchangeably, can provide price competition.
20 In other instances, they offer important clinical
21 differentiation for patients who might not respond to
22 one particular drug, but benefit from a medicine that

1 works through a slightly different mechanism.

2 The benefits of competition are equally
3 obvious when it comes to generic drugs. But in some
4 cases, we know that branded companies are using our
5 rules that are intended to protect consumers, or meant
6 to make the regulatory process more predictable, and
7 taking advantage of these rules in order to
8 deliberately forestall the entry of expected generic
9 drug competition.

10 In other words, they're gaming our system.
11 Let me give you some examples. In some cases, this
12 takes the form of activities meant to make it hard for
13 generic drug makers to physically purchase the branded
14 drug that generic firms need in order to develop their
15 own generic versions of these medicines. In other
16 cases, it may take the form of raising scientific
17 objections with us that are timed to maximize the
18 potential for delaying the approval of a generic drug
19 application. In other cases, it may take different
20 forms entirely. This sort of gaming is wrong. It
21 undermines the careful balance Congress struck between
22 access and innovation.

1 We have a system that supports market-based
2 pricing for innovation, as a way to provide proper
3 incentives to entrepreneurs for taking on the
4 uncertainty of these costly and high risk endeavors.
5 But that means we also have to have a system that
6 allows for vigorous competition once the patent and
7 exclusivity rights have lapsed on these new inventions.
8 This is the careful balance that Congress crafted when
9 it created the modern generic drug framework in 1984.
10 This careful compromise worked well for many years. We
11 need to make sure it continues to support patients.

12 At FDA, we want to hear from the public today,
13 about the ways we can continue to make sure that this
14 system is benefiting consumers. We want to know how we
15 can prevent a select few from disadvantaging many, by
16 exploiting loopholes in our rules in ways that upset
17 the careful balance between access and innovation.
18 Ultimately, this sort of activity undermines the
19 market-based incentives needed to attract the sort of
20 entrepreneurship that supports new innovation.

21 It's part of our public health mission to
22 ensure access to safe and effective medicines. It's

1 part of our public health mission to help make sure,
2 within the scope of our legal authorities, that new
3 technology can be more affordable. It's also part of
4 our public health mission to address the gaming and
5 abuse of our rules by a small number of actors bent on
6 taking advantage of consumers.

7 We also need to make sure people can't use our
8 approval process as another way to take advantage of
9 consumers. In some cases, we've seen speculators
10 purchase niche products that are not protected by
11 patent or exclusivity but still face little
12 competition, often because these drugs are infrequently
13 used. These speculators then undertake very large and
14 seemingly gratuitous price increases that appear
15 untethered to any market condition or other practical
16 consideration. They do this knowing that it can take
17 years before another generic drug can enter the market
18 to compete with them and force down their price.
19 They're exploiting a regulatory arbitrage, born of the
20 growing complexity of our regulatory system, and its
21 occasional slowness.

22 We've already taken steps to address some of

1 these issues as part of our drug competition action
2 plan. That plan has three major elements, each focused
3 on places where I believe there are barriers to
4 intended competition when it comes to the market entry
5 of generic drugs.

6 Our goal, in each case, is to find ways we can
7 adapt or change our own rules and practices, to make
8 sure that in places where Congress intended for there
9 to be vigorous competition -- and yes, lower prices --
10 these kinds of benefits are being realized on behalf of
11 consumers.

12 So, let me tell you about the key components
13 of our Drug Competition Plan, and some of the new steps
14 that we're announcing today as part of this broader
15 effort.

16 First, we're looking for places where this
17 sort of gaming is happening, and we will change our
18 rules where we can, to make sure that the competition
19 that Congress envisioned is taking place. It's these
20 sorts of scenarios that we hope to learn more about
21 from this meeting today.

22 For example, we undertook an effort in 2014 to

1 facilitate access for generic drug applicants seeking
2 quantities of branded drug products covered by REMS in
3 order to perform the bioequivalence testing they need
4 to do. We published a guidance that describes a
5 procedure by which generic applicants can obtain a
6 letter from FDA stating that their proposed study
7 protocols contain sufficient protections such that the
8 sale of the medicine to the generic applicant by the
9 branded manufacturer would not be considered by FDA to
10 be a violation of the branded drug's REMS.

11 In other words, FDA sends a letter to the
12 company saying it's OK for the branded company to sell
13 the drug to the generic manufacturer for these
14 purposes. We're now taking a close look at that
15 guidance and actively considering whether it achieves
16 its goals or whether we could and should do more.
17 One of the things we're considering is whether we make
18 these letters from FDA publicly available, to make more
19 widely known the instances where generic drug makers
20 may be having trouble getting access to branded drugs.
21 These letters could contain important information that
22 can help inform the broader discussion about access and

1 competition. Their public release could be one-step to
2 help ensure that unnecessary hurdles to generic drug
3 development are removed.

4 Second, we're looking for places where the
5 scientific and regulatory obstacles to the entry of
6 generic medicines exist. In these cases, our aim is to
7 address these obstacles by ensuring that our own
8 regulatory processes are in line with the most current
9 advances in science. We also are taking steps to
10 further improve our scientific knowledge and enhance
11 communication with product developers.

12 These obstacles can arise, for example, when
13 it comes to complex drugs. In many cases, the
14 traditional requirements used to demonstrate sameness
15 may not be appropriate when it comes to complex drugs
16 that can't be easily measured in the blood, or where
17 the drug's therapeutic effect is delivered locally to a
18 particular organ, rather than systemically, through the
19 blood.

20 We've made significant progress on these
21 fronts in the last few years. But we believe there
22 continue to be additional steps we can take to improve

1 our own regulatory framework, to make it easier to
2 demonstrate sameness in these settings, and to bring
3 new generic competition to the market for complex drugs
4 where relevant patents and exclusivities have lapsed.

5 And finally, we're going to be focusing on our
6 own efficiency and throughput of the overall generic
7 drug approval process, and the program. We need to
8 make sure we are evaluating new generic applications in
9 an efficient way, and making sure we keep the costs of
10 filing generic applications low. By making sure the
11 barriers to market entry are not unnecessarily inflated
12 through the regulatory process, it helps keep costs
13 low, and promote competition. So, we're taking new
14 steps to build on the generic program's many successes
15 and to continue to make sure its efficiency improves,
16 and that our own review times continue to come down.

17 I want to close by describing some of these
18 new efforts. The generic program has made substantial
19 progress over the past several years. Thanks to the
20 first generic drug user fee program, GDUFA I, beginning
21 in 2012, FDA hired and trained more than 1,000 new
22 staff, reorganized key offices, made significant

1 business process improvements, and we've also
2 implemented a new Generic Drug Review information
3 platform.

4 Last month, we fully approved 88 ANDAs and
5 tentatively approved 12. That is a new record for full
6 approvals in a month, breaking several other such
7 records set since the start of GDUFA I. Working
8 together, we're increasing the speed at which generic
9 drugs can enter the market.

10 The biggest remaining challenge is that it has
11 taken on average about four review cycles for an ANDA
12 to reach approval. That's highly inefficient. It
13 entails a greater deal of re-work by FDA and industry
14 alike. It can needlessly delay consumer access to
15 affordable medicines and raise costs.

16 The GDUFA II proposal, currently pending
17 before Congress, is designed to reduce the number of
18 review cycles for an ANDA to reach approval. It would
19 expand the frequency and scope of communication between
20 FDA and ANDA filers, giving applicants more
21 opportunities to cure deficiencies and get ANDAs
22 approved more quickly, including within their first

1 review cycle. It would also create a pre-ANDA program,
2 with a special focus on complex generics. Applicants
3 would obtain regulatory clarity earlier in product
4 development, so they can submit ANDAs that are right
5 the first time. Moreover, the program size envisioned
6 under GDUFA II would be commensurate with the overall
7 generic drug workload. Right-sizing the program will
8 help us manage our workload and optimize resources for
9 generic drug review and approval.

10 All of this is very good. But we can do more
11 to build on the success that we have experienced in the
12 generic program. So, we will be taking some additional
13 steps I'd like to announce today.

14 By the end of this year, FDA will develop and
15 issue two key documents to streamline the ANDA review
16 program. First, we will issue a "Good ANDA Assessment
17 Practices" MAPP. MAPP stands for Manual of Policies
18 and Procedures. These documents are internal CDER
19 policies that are posted on our website for
20 transparency. This particular MAPP will outline ways
21 that we intend to streamline the ANDA review process
22 inside FDA, by, among other things, eliminating

1 unnecessary, duplicative procedures and greatly
2 increasing the efficiency of our review.

3 This efficiency doesn't mean lowering our
4 standards. In the United States, approximately 90
5 percent of the drugs that are dispensed are generics.
6 That's because when consumers go the pharmacy, they can
7 be confident that a generic drug will work the same as
8 its branded equivalent.

9 FDA will continue to be the gold standard for
10 review and approval of all drug applications, and we
11 will make sure that consumers continue to trust that
12 gold standard. It also doesn't mean altering GDUFA II
13 review goals or program enhancements. One lesson that
14 we learned from GDUFA and PDUFA alike is that
15 truncating review prevents applicants from fixing their
16 submissions and getting them approved. The result is
17 additional review cycles, not faster approval. The
18 goal of the MAPP is to help make sure that we work
19 smarter.

20 The primary ANDA assessment should focus on
21 "need to know" regulatory requirements. Supervisors
22 should validate, not re-do, assessments. And the level

1 of supervisory scrutiny should vary according to the
2 experience level of the primary reviewer and the risk
3 and complexity of the product. At the end of the
4 review cycle, if the ANDA is not approved, the complete
5 response letter should clearly say what needs to be
6 fixed. If the written communication is unclear, FDA
7 should follow up and explain it over the phone in a
8 direct, scientist-to-scientist exchange.

9 These improvements will increase efficiency
10 and output, benefitting industry and consumers alike.
11 These changes will also free up program staff to
12 communicate more with applicants. It will also give us
13 more time to engage in strategic, value-added policy
14 and scientific initiatives. This includes, for
15 example, initiatives concerning complex generics.

16 We hire and train talented, extremely
17 dedicated staff to engage in critical thinking on
18 behalf of the nation's public health, not to administer
19 unnecessary paperwork. I'm proud of the staff's hard
20 work and resilience, especially over the past five
21 years. I'm strongly committed to supporting their work
22 and enhancing their professional growth.

1 The MAPP and its related improvements are
2 critical to the continued success of the generic drug
3 program. However, at the end of the day, FDA can only
4 approve submissions that are approvable. Industry must
5 also do its part too, by submitting complete
6 applications that are ready to be approved. Towards
7 these ends, FDA will also issue a second key document.
8 This "Good ANDA Submission Practices" guidance will
9 also issue by the end of this year. It will set forth
10 common, recurring deficiencies that we see in
11 applications, and provide advice on how these problems
12 can be avoided in the first place, so applicants can
13 send us ANDAs that are "right the first time".

14 Neither our internal MAPP nor the guidance
15 alone can ensure that ANDAs will be approved more
16 efficiently. But taken together, I believe they will
17 help effectuate real and measurable change. So, that's
18 why I am delighted about these two new efforts. While
19 we're here to discuss the broader goals of Hatch-Waxman
20 Amendments -- because at the heart of the law is an
21 effort to ensure access to lifesaving medications. The
22 efficiency of the review process is central to this

1 effort.

2 I'd like to close by thanking each of you for
3 coming today. I'd also like to thank our staff for
4 organizing and working to put this meeting together.
5 My colleagues and I look forward to hearing from you
6 today and considering your thoughts in connection with
7 the drug competition action plan and our ongoing
8 implementation of these efforts.

9 And I'd like to also close by taking this
10 opportunity to introduce the next speaker, Dr. Janet
11 Woodcock. I'm extremely grateful for the work that she
12 has done, not just leading our drug program but also
13 leading these initiatives, and extremely grateful and
14 delighted to be back at FDA working with her again, and
15 look forward to her remarks today. Thank you.

16 (Applause.)

17 DR. WOODCOCK: Thank you, Dr. Gottlieb, and
18 good morning, everyone. Good to see you. Thank you
19 for coming to this very important meeting. What we're
20 talking about today is the balance set by Hatch-Waxman
21 between innovation and access to affordable medicines,
22 both of which are extremely important to the patients

1 in this country, as you know. And FDA's job is not to
2 set that balance -- to decide where that balance lies -
3 - but to preserve the balance that is established by
4 Congress, and make sure that that weighing is actually
5 instantiated out in the public. And part of the
6 subject of this meeting is "have there been ways to
7 actually subvert that balance, and actually tip it in
8 one way or another not in favor of the public."

9 We really here at FDA believe in innovation.
10 And actually, I've spent a lot of my professional
11 career trying to advance innovation by lowering the
12 barriers to innovative products, through science, to
13 improve the science of translational drug development
14 and improve the success rate, actually, of innovations
15 reaching the market.

16 FDA has a lot of expedited pathways, as you
17 know, that are intended to help promising therapies get
18 into the hands of doctors and patients as quickly as
19 possible. And they include things like the
20 breakthrough designation, fasttrack designation,
21 accelerated approval, priority review, and so forth.

22 We also have worked over the past four or five

1 years to really enhance manufacturing and modernize
2 manufacturing. And that's both in the innovator space
3 and the generic space. And I think we're beginning to
4 see the fruits of that. Actually, manufacturing, say,
5 for a breakthrough drug, can be a tremendous delay in
6 market access, due to the rapidity of development. And
7 continuous manufacturing other newer technologies can
8 actually overcome that barrier. So, there's a lot of
9 work to do there, and we know that the newer products
10 we're approving both can extend or save lives, or
11 mitigate suffering in many cases. And so, patients are
12 really depending on a robust pipeline of innovative
13 products.

14 But at the same time, we don't want this to
15 subvert the balance. And I think there's a fair
16 balance there. Innovators can get rewarded for
17 innovation. But at the same time, we can have a broad
18 availability of affordable medicines.

19 Now, when you think about competition in the
20 drug space there are really many paths to competition.
21 The (b)(1) path itself we often approve additional
22 drugs in a class. And although this is often

1 disparaged as "a me too" product, actually this can, in
2 fact, introduce both choice and competition for
3 consumers. In addition, in that area we have the
4 (b)(2) -- the 505(b)(2) pathway, which can introduce
5 micro innovations, so to speak -- not a new molecular
6 entity, but some improved dosage form or route of
7 administration and so forth, that can also provide both
8 competition and choice for patients.

9 And now, under the generic program, with the
10 success of GDUFA I, we have really stabilized and
11 modernized the ANDA review program. This program was
12 really the victim of its own success, and the rise of
13 generics and the tremendous number of applications we
14 began receiving had actually, five years ago, swamped
15 the program. And we -- with GDUFA I, with the
16 cooperation of industry and with Congress, this program
17 has undergone deep and foundational restructuring to
18 meet the current needs of the robust generic industry,
19 that actually is sending in ever increasing number of
20 generic drug applications every month, it seems like.
21 Which is good news for consumers. And so, I'd really
22 like to adjoin Dr. Gottlieb in congratulating the

1 staff, both in OGD, OPQ, and CDER and the staff in the
2 field, ORA, all of whom really gave it their all over
3 the past five years as the program underwent an amazing
4 transformation that we've all -- we all worked just
5 incredibly hard on. But, I think this program is
6 really ready to deliver on the promise.

7 Now, at the same time there are new
8 challenges, some of which have already been alluded to.
9 We're working on things like chemical sameness for
10 nontraditional kind of drugs -- for complex drugs.
11 Drug device combinations are increasingly becoming the
12 norm in some areas, and we need to figure out the
13 standards for that in the ANDA world. And there are
14 many other regulatory expectations that we need to work
15 on. We also still have issues with labeling, that we
16 hopefully will continue to improve our approach to
17 that.

18 So, we also, a number of years ago, got
19 authority to approve biosimilars. We just had an
20 advisory committee this week where two biosimilars were
21 discussed. And there have been significant legal
22 policy and organization challenges to setting up this

1 new pathway, but I think this new pathway, which
2 introduces competition for biological molecules, is
3 established. We've had the first few approvals, but
4 there are literally tens and tens of additional
5 products under development over 50 programs going on,
6 and I think we will see a flourishing of competition in
7 this area as some of these begin to reach the market.

8 So, that's sort of the landscape of what we
9 have. But, in addition to the issues that Dr.
10 Gottlieb alluded to of gaming the Hatch-Waxman kind of
11 balance that we have, the general issue of competition
12 is one where FDA is just one piece of the puzzle. And,
13 of course, drugs are distributed and marketed in the
14 incredibly complex U.S. health care system, where it's
15 not just complex distribution and so forth. The
16 reimbursement situation is almost impossible,
17 sometimes, to comprehend.

18 But, one of the things that we can't
19 understand very well, and we'd like to hear input
20 about, is what is the cause of so many of the market
21 failures that we see where we don't see competition for
22 either a single source innovator drug or a single

1 source generic drug. These lead to a lot of problems.
2 They lead to shortages, where -- if you have a single
3 source, where problems occur. Then we have a perhaps
4 long-lasting drug shortage, sometimes of a lifesaving
5 medicine. This is a terrible situation that the
6 healthcare folks contact us constantly about.

7 Or, we see what Dr. Gottlieb alluded to,
8 where we see price spikes of these sole source drugs,
9 because getting competition onto the market takes a
10 while. You have to have a plant, and you have to
11 develop -- do some small studies, and submit an
12 application. And this takes some time. So, we don't
13 understand why when we may have robust competition at
14 some time then the competitors will drop off. We do
15 understand, and I've testified on this, that sometimes
16 a month's supply of a generic drug costs a consumer
17 less than a cup of coffee. Right. And there's
18 something, you know -- I'm sure that's very satisfying
19 for people who take a lot of drugs. That's very
20 helpful for them. But, there may be some point where
21 this -- is this one of the factors that's leading
22 generic manufacturers to switch to a new line of

1 products, where they can get a higher reimbursement
2 for. For example, new opportunities arise. The
3 companies pursue them. They can't make everything.
4 So, why are we losing competition?

5 It's unclear, also, the effect of mergers and
6 acquisitions on competition, and how that is playing
7 out. So, we have recently posted a list of off-patent
8 off-exclusivity products with no approved generics.
9 And if we get applications for those, we'll expedite
10 them. But we realize there is an energy and cost and
11 so forth that must go into developing a product and
12 submitting an application for that product.

13 But, this is just a start of the conversation.
14 I think you all collectively in this room, and
15 hopefully on the webcast, there's much more diverse
16 experience and knowledge about some of the root causes
17 of this lack of competition, both the ability to delay
18 entry of generics but also the problem of lack of
19 competition in the marketplace.

20 And so, the purpose of this meeting is for us
21 to hear from you, to a great extent, what the root
22 causes are and what might be done about them so that we

1 can continue to maintain for the benefit of the
2 patients of this country a proper balance between
3 innovation on one hand and access to affordable drugs
4 on another. Thank you very much, and look forward to
5 your input. Thank you.

6 (Applause.)

7 MR. FLANAGAN: Now, I will introduce our
8 panelists. The panelists are here to listen to the
9 views of the public. They will be in listen only mode.
10 However, they may ask clarifying questions following
11 each presentation. Maryll Toufanian is Deputy Director
12 of the Office of Generic Drug Policy in the Office of
13 Generic Drugs.

14 I'd like to thank Markus Meier from the
15 Federal Trade Commission (FTC) for joining us today.
16 Markus is Acting Director of the Bureau of Competition
17 at FTC, and I'll ask you to make some brief remarks
18 after I introduce the rest of the panel.

19 Liz Dickinson is Senior Deputy Chief Counsel
20 in the Office of the Commissioner. Dr. Peter Stein is
21 Deputy Director of the Office of New Drugs. Dr. Cook
22 Uhl is Director of the Office of Generic Drugs. Grail

1 Sipes is Director of CDER's Office of Regulatory
2 Policy. And Anna Abram is Deputy Commissioner for
3 Policy, Planning, Legislation and Analysis in the
4 Office of the Commissioner.

5 I thank all of today's panelists for their
6 participation. Now, Markus, if you have some opening
7 remarks.

8 MR. MEIER: First, I'd like to say thanks,
9 Keith, and thanks to the FDA for inviting me to be
10 here. I'm a bit of the odd man out in this room. I'm
11 certainly the odd man out on the panel, because I'm a
12 law enforcer. I'm not a sector regulator. I'm not a
13 policy maker. I work at the Federal Trade Commission,
14 where we enforce the antitrust laws which are supposed
15 to promote competition, one of the topics we're talking
16 about today.

17 At the FTC, we're charged with promoting
18 competition for the benefit of consumers. The laws we
19 apply apply broadly across all sectors of the economy.
20 They're not solely limited to pharmaceutical industry.
21 I personally, however, happen to have worked on lots
22 and lots of pharmaceutical cases over the years. I've

1 been doing it for about 27 years. And the way we try
2 to enforce competition policy is by challenging certain
3 types of business practices that might violate the
4 antitrust laws, in the hope that by challenging those
5 business practices we will actually promote competition
6 -- the type of business practices we're concern about
7 are things like price-fixing cartels, monopolization,
8 and mergers and acquisitions that substantially lessen
9 competition.

10 Now, one of the things that's very hard for
11 people to understand, and something that we have to
12 explain constantly at the FTC, is we don't have a
13 federal law that goes against high prices. We don't
14 have an anti-price gouging law. We don't have the
15 power to just go after high prices for the sake of high
16 prices. And in fact, if one really thinks about it it
17 probably makes a fair amount of sense. As a famous
18 judge in America, in a famous antitrust case once said
19 -- and this is a bit of a paraphrase -- you can't ask
20 people to run a race and then punish the winner for
21 winning. If you want to have competition, sometimes
22 there are winners and sometimes there are losers, and

1 sometimes people come out on top.

2 And I think when we think about this in the
3 context of the pharmaceutical industry, it becomes even
4 more important. We have a regulatory system that's
5 designed to incentivize innovation through patents and
6 through exclusivities, and one shouldn't be surprised
7 when a company that has market power exercises that
8 market power. And when you couple those issues
9 together with the fact that there clearly are high
10 barriers to entry into these industries, it gives
11 companies a lot of market power. And when given that
12 opportunity, they exercise the market power.

13 It's important to also point out that there is
14 really limit on the ability for us to do our
15 enforcement job. And some of these limits are that it
16 takes a lot of time. So, we can never turn around
17 something really quickly. Sorry, but we can't. It's
18 often costly. And it's really uncertain, because we go
19 through the courts. I have to be prepared, and my
20 staff has to be prepared, to present cases in court and
21 to win cases in court, and that can be very uncertain.
22 So, let me give you one quick example, just for a

1 moment. I think most people in this room may have
2 heard of pay for delay by now. These are agreements
3 that branded companies enter with generic companies to
4 settle patent litigation, and in that settlement the
5 generic agrees to stay out for some period of time,
6 despite the fact that they have final FDA approval to
7 enter, and in return we allege that the branded company
8 has made a payment to that generic company for that
9 agreement to stay out.

10 Now, that seems to be pretty obviously anti-
11 competitive. Yet, I personally have been working on
12 this issue for 17 years, going on 18 now, together with
13 a handful of other people who have been through it
14 since the very, very beginning, in the late 1990s, and
15 we got a great decision from the Supreme Court in 2013
16 and we're still fighting out these issues and we're
17 still doing litigation all across America. This makes
18 smart regulation and smart legislation imperative. And
19 I think that's what we're really talking about here
20 today.

21 I'd also like to say that the -- make sure
22 everybody knows that the FTC and the FDA have enjoyed

1 for many years a really strong and good cooperative
2 working relationship. We all know about Hatch-Waxman
3 1984, and we've all heard of drug substitution laws.
4 But how many people in this room actually realize that
5 states adopted drug substitution laws in large part
6 because of an initiative by the Federal Trade
7 Commission, working together with the FDA. Did a big
8 report, did a big study, created a model state law that
9 was adopted by many of the states across America -- and
10 this was before Hatch-Waxman. So, just to give a sign
11 of one thing that we can do together is that kind of
12 work. We've obviously over the years done a lot of
13 other collaboration and information sharing. And I
14 think it's been a great relationship and I look forward
15 to that relationship continuing to build and grow.

16 And then in sum, I want to say I'm really
17 looking forward to hearing from the speakers today and
18 learning additional ideas on ways that we can think
19 about -- intelligently about these issues. Thank you
20 very much.

21 (Applause.)

22 MR. FLANAGAN: It's now time to begin the

1 public presentations. We will start with the
2 academic/researcher perspective. Again, I'll announce
3 the first speaker, but not subsequent ones. So, please
4 approach the podium when the slide that lists your name
5 and affiliation appears on the screen. The first
6 speaker is Michael Carrier, of Rutgers Law School.

7 MR. CARRIER: Thank you. My name is Michael
8 Carrier. I'm a Distinguished Professor at Rutgers law
9 School, and I'd like to present four proposals to
10 enhance generic competition. This is an important
11 exercise. Brand innovation has gotten a lot of
12 attention. Generic access has not. I have
13 comprehensively studied the issue as co-author of the
14 leading treatise on IP and antitrust law. I've written
15 more than 90 articles on IP and antitrust law,
16 including 40 on pharmaceutical antitrust law. I've
17 written many amicus briefs to courts on behalf of
18 hundreds of professors, and I'm frequently cited in the
19 media and courts, including the U.S. Supreme Court.

20 In a nutshell, the balance has tilted away from
21 generic access. As Commissioner Gottlieb mentioned,
22 Hatch-Waxman was all about a balance -- about brand

1 firm innovation as well as fostering generic
2 competition. And brand firm innovation has been
3 upheld. If you look at Hatch-Waxman, the mechanisms to
4 promote brand firm innovation have been in effect.
5 Things like patent term extensions, nonpatent market
6 exclusivity, automatic 30 month stays -- there's no
7 problem with any of that stuff.

8 On the other hand, generic competition has not
9 always worked as meant to. So, if you look at the
10 Hatch-Waxman Act, certainly there are a ton more
11 generics than there were before. But, some of the
12 provisions have been twisted far beyond how they were
13 initially intended to be used. Start with the 180-day
14 period of exclusivity. This was designed to promote
15 challenges to invalid patents. Instead, it has been
16 twisted so that the brand firm settles with the first-
17 filing generic -- there's a rush to be the first-filing
18 generic, because then you get paid to stay off the
19 market. And so, this is the first way in which Hatch-
20 Waxman has not worked as intended. There are easy
21 fixes for that. Congress always thinks about or has
22 legislation introduced that would open up the 180-day

1 period. So, it's not just the first filer who gets 180
2 days, but the first to win District Court litigation,
3 or generics that are not sued -- let's have a race to
4 be first to the market, rather than just a race to be
5 the first filer.

6 In addition, REMS patents can be used to block
7 generic competition. And so here, by just filing a
8 patent in the Orange Book you get an automatic 30-month
9 stay, but it seems like REMS patents are not the type
10 of patents that should be listed in the Orange Book.
11 They don't cover a drug or a method of using a drug.
12 Rather, it's just a method of distribution. So, if you
13 look at the REMS patents that have been listed, they
14 don't seem to fall into the listable category -- the
15 Xyrem patent dealt with a method of distribution using
16 a central pharmacy. The Entereg patent dealt with
17 providing hospitals with literature regarding the
18 proper use of the drug. The thalidomide drugs dealt
19 with the method of distributing a drug to avoid
20 exposure to a fetus. These patents should not be
21 listed in the Orange Book, and this is one potential
22 thing that the FDA could do.

1 At the same time, these patents are not needed
2 for innovation. Any time we hear about patents, we
3 hear they're needed for innovation. This is a category
4 that is not needed for innovation. For starters, after
5 the Supreme Court decided the Alice case it's not clear
6 that these patents are patentable anyway. The Court
7 raised the bar significantly, and I don't think these
8 patents would be awarded today.

9 In addition, my empirical study -- and this is
10 all quoted in the slides -- found that of 60 NDAs
11 covering REMS programs, only 5 were patented. And so,
12 if brand firms have no problem patenting every aspect
13 of the drug, the fact that they're not patenting the
14 vast majority of elements of the REMS program shows
15 that this is not crucial for innovation. And it's just
16 one example of harm.

17 You look at Jazz Pharmaceuticals that argued
18 against a waiver of the shared REMS program for
19 generics that were utilizing multiple pharmacies. And
20 the brand said, "Oh, you can't use multiple
21 pharmacies." Sure enough, there was a patent that
22 covered a central pharmacy. So, the brand is saying

1 one thing to FDA in order to sweep the generics into
2 the web of their patents.

3 Another way in which the balance is tilted
4 away from generic access involves reformulations.
5 Brand companies reformulate drugs all the time, and one
6 empirical analysis several years ago, found that the
7 vast majority do not present competitive concern. This
8 study found that 80 percent of reformulations were done
9 at a time that generic entry was not expected. And
10 so, most of the reformulations are fine.

11 However, some are absolutely not fine. And
12 the -- those that have been the subject of court cases
13 have been those that make no economic sense at all,
14 other than harming generic competition. So, why would
15 in the Namenda case the brand firm pull a \$1.5 billion
16 drug off the market? Makes no sense. Why would, in
17 the Suboxone case, the brand company disparage its own
18 drug -- say there are safety concerns with its own
19 drug, but then leave its drug on the market for another
20 six months. Why in the Doryx case and the Tricor case
21 do we have the brand company destroying its own
22 inventory, changing the code to obsolete in the

1 database. This makes no sense at all, other than
2 harming generic entry. So, in short, even though the
3 vast majority of reformulations are fine, there are
4 some that are a perversion of the state substitution
5 laws, of the Hatch-Waxman Act, where the change is made
6 only to stifle generic entry.

7 The fourth category involves citizen
8 petitions. I have conducted two empirical studies of
9 citizen petitions. In 2011, I looked at every petition
10 filed between 2001 and 2010, and I found that the FDA
11 denied 81 percent of these petitions. Last year, I
12 updated my study, looking at every 505(q) petition.
13 Those are the most concerning ones. They target a
14 pending generic. Looking at all of those between 2011
15 and 2015, and I found that the FDA denied 92 percent of
16 these petitions.

17 I then parsed it even more closely, to look at
18 the types of petitions that showed the even greater
19 concern. And so, there are some petitions that are
20 late filed, within six months of the expiration of a
21 patent or data exclusivity period. The FDA denied 98
22 percent -- 49 out of 50 of these petitions. And then

1 there are the simultaneous petitions. Those were the
2 FDA makes a decision on the petition at the same time -
3 - either same day or, extrapolating further, same month
4 -- that the ANDA is approved. And 100 percent of those
5 petitions were denied, when there was a simultaneous
6 determination. So, in short, the figures are very
7 concerning.

8 Then you look at actual examples. Those are
9 even worse. So, the FTC filed its first case
10 challenging citizen petitions against Shire ViroPharma,
11 which had 46 regulatory and court filings. Teva had
12 multiple petitions on the Copaxone drug. Bayer filed a
13 petition against Mirena one day before patent
14 expiration. And then the EpiPen has gotten a lot of
15 attention for price increases, but there is a citizen
16 petition angle there as well in which you have a
17 delayed petition coming on the heels of the settlement
18 that it entered into which delayed competition even
19 further.

20 So, in short, there is a real tilt away from
21 generic access. What can the FDA do? Well, I have
22 four proposals. The first is to clarify the Orange

1 Book listing. It seems like REMS patents are not drugs
2 or methods of using drugs. Rather, they're just how
3 the product is distributed. This is a really simple
4 fix. You look at 23 C.F.R. § 314.53(b)(1). You have
5 certain categories there, that cannot be listed --
6 process patents, packaging, metabolites, intermediates.
7 Just add REMS to that list, and it will be perfectly
8 clear that you do not get an automatic 30-month stay
9 from filing this thing that has nothing to do with
10 innovation, that is just done to block generic entry.

11 My second proposal is a little more
12 complicated, because here we have shared REMS
13 negotiations. And here you don't have an on/off
14 switch, at which the brand's refusal to negotiate
15 automatically becomes something that is
16 anticompetitive. In day one it's not. In year 15, it
17 is. But what's the point in which it triggers over
18 that line. We don't know. But we have seen certain
19 examples where there has been delay, where the brands
20 have slow-walked negotiations -- and I mention the
21 Suboxone, the Xyrem case as potential examples. In
22 Suboxone, for example, the FDA contemplated a quick

1 development of a shared REMS program, given that the
2 brand already had a REMS that was there and all you had
3 to do was add the generics. But, according to the
4 plaintiffs in that case, the brand turned down numerous
5 invitations to participate in meetings, refused to
6 share information until its demands were met, and
7 refused to cooperate until the generic gave the brand a
8 veto or supermajority power.

9 So, what can the FDA do given this slow-
10 walking of negotiations? For starters, the FDA could
11 more quickly allow waiver. In theory, it's great to
12 have shared REMS programs but in practice it's better
13 to get the generic on the market. And when the brand
14 is using the shared REMS process in order just to delay
15 the generic from entering the market, perhaps we could
16 be quicker to allow waiver. Relatedly, there could be
17 expectations discussed during a kickoff meeting, in
18 which it's made clear what the norms are and how the
19 waiver would be granted. Additionally, the FDA could
20 develop guidance on when the burden outweighs the
21 benefit, and therefore a waiver would be allowed.

22 So, we could look at things like the number of

1 ANDA applicants. As the number of applicants
2 increases, we would expect the process to take a longer
3 time. The complexity of the ETASU restrictions -- if
4 we're talking about a complex restriction, like a
5 distribution restriction, we should expect more time
6 than a simpler restriction, something like patient or
7 physician enrollment. The potential delay in generic
8 approval is something else to look at, and finally
9 perhaps a history of unsuccessful negotiations could
10 lead to a quicker waiver. Again, all of these shedding
11 guidance on the factors that will be considered in
12 granting a waiver.

13 In addition, we could think about templates
14 that would shoehorn part of the process, or at least
15 short-circuit it, by which the brand would make clear
16 upfront what it would accept in terms of governance
17 terms, NDAs, IP licenses, diligence, indemnity and
18 insurance.

19 And finally, perhaps even think about a time
20 frame. The CREATES Act, being considered in Congress,
21 set a 120-day period. That's something to think about
22 as well.

1 Before I get to proposal 3, perhaps I could
2 offer proposal 2-A, based on something that
3 Commissioner Gottlieb said in his introductory remarks.
4 And that is making these letters publicly available in
5 the REMS process. And so, the thought was that we --
6 if we have these letters, then they would give the
7 consolation to brands that they wouldn't be on the
8 hook. The letters have not been used in that way. The
9 brand company basically throws the letter in the trash,
10 in some of these cases, and says thanks but no thanks.
11 And so, in the Cornell Law Review article that I have
12 forthcoming that I quote on the previous slide, on page
13 49, note 370, I give examples of how the brand company
14 ignores the letter.

15 And so, in the In Re Thalidomide and Revlimid
16 case, the Court talked about that. In the Actelion
17 case, the brand company said it would sell to the
18 generic if it got a letter. And then it got the letter
19 and said, quote, this changes nothing, you still don't
20 get the sample. And so, if the letter really does mean
21 nothing, when the brand company will always say forget
22 the letter, I still have safety concerns, then let's

1 make the letters publicly available. Let's shed some
2 more light on this issue.

3 To proposal 3, we can loosen the distribution
4 restriction bottleneck. The statute says that REMS
5 should not be used to block or delay generics. But,
6 that is how REMS have been used. And so here, these
7 are changes that Congress could make. Perhaps the FDA
8 could support them in the first one with block or
9 delay, make clear that a patent is not a defense here.
10 In the second one, where we talk about shared REMS,
11 let's remove patents as an excuse for switching to a
12 waiver, just because that is not needed for all the
13 reasons I've mentioned before.

14 Along similar lines, you could do what was
15 done in the America Invents Act, with tax-strategy
16 patents. Those were not the strongest patents in the
17 world. You could something similar with REMS patents,
18 and say that they constitute prior art and therefore
19 should not be able to be patented.

20 The final proposal is to address the harms
21 from citizen petitions. And so, here I would start
22 off by saying that the FDA should include a

1 comprehensive list of 505(q) petitions in its annual
2 report to Congress. There is a report every year. It
3 includes some information, but there is a ton of
4 information that researchers like myself and others
5 would really find useful. So, as someone who has gone
6 through all the citizen petitions, there is no simple
7 answer to where we find the information. For my first
8 study, I went to regulations.gov. That's really
9 difficult to navigate.

10 For my second study, I had the benefit of Kurt
11 Karst at FDA law blog that collects every citizen
12 petition. It overlaps with regulations.gov, so it
13 makes my life a lot easier. But why should we be
14 relying on Kurt? As great as his work is, this is
15 something that FDA has access to. Let's see a list of
16 every citizen petition. That would be very helpful.
17 In addition, let's see the timing of the petition in
18 relation to the patents in the Orange Book. How much
19 time was spent on each of these petitions, and how much
20 delay was caused by the petitioning. So, in these
21 reports it says, well, there's been almost no delay --
22 there were only nine petitions that were delayed

1 between fiscal year 2008 and 2015, and my sense is
2 delay there is determined by something that goes beyond
3 the initially 180, now 150, day period. But that seems
4 to be too strict a definition. It seems like there
5 still can be delay, even in the 150-day period. So,
6 maybe FDA does decide within 150 days, but the ANDA is
7 delayed because the FDA is dealing with a frivolous
8 citizen petition that takes an extra 100 days within
9 the 150-day period. So, let's get information on that
10 sort of situation.

11 The second proposal here is to focus on
12 summary disposition under 505(q)(1)(E). So, FDA in
13 theory has the power to use summary disposition. As
14 far as I can tell, it has not used that power.
15 Something is not right there. The standard seems to be
16 pretty high, when you say that there has to be a
17 primary purpose of delay as well as not on its face
18 raising valid scientific or regulatory issues.

19 For starters, how do we show a primary purpose
20 of delay? A lot of these petitions are frivolous. But
21 you can't tell that in an instant, by looking at it.
22 And you can never figure out the primary purpose of the

1 brand company when it's doing these things. And so,
2 the standard seems to be too high. I would think about
3 getting rid of the primary purpose of delay standard,
4 and then focusing on whether or not this is an
5 appropriate standard. Yes, I certainly see the concern
6 with summarily disposing of one of these, and then
7 having it come back to bite you later on if there
8 really is a safety concern. But on the other hand, if
9 you do have this power and it's never been used, what
10 good is it actually doing.

11 The next issue deals with simultaneous
12 determinations. So, again, getting to the point of
13 delay, it's possible that with all of these
14 determinations when an ANDA is approved at the same
15 time that a 505(q) petition is denied that it's
16 possible that the ANDA approval was delayed because you
17 were dealing with the petition. And if that's the
18 case, then that would be something that would be useful
19 to know.

20 We don't know. There's no transparency as to
21 the timing of all this. That would be very helpful.
22 Some others have raised concerns that maybe the

1 announcement of the FDA's decision was delayed under
2 ANDA approval -- if you delay that announcement on the
3 petition's denial, then you forestall a court challenge
4 until the ANDA is approved. And so, that's something
5 as well. Again, we don't see from the outside. So,
6 that's something that can be clarified.

7 The next point is how much time and money was
8 incurred in resolving these petitions. In the annual
9 reports, it talks about this. Let's see. This is not
10 a costless exercise. Yes, there's a freedom of speech
11 and a right to submit petitions. But as a practical
12 matter, these are wasted resources. Let's figure out
13 how much money and time that could raise the political
14 will to do something about the process.

15 And finally, the 505(q) in terms of the
16 certification of objections needs to be within a
17 reasonable time. So, in the EpiPen case this was years
18 after they were aware of the ANDA. Something is not
19 right there.

20 In conclusion, not one thing I have said would
21 rebut or get in the way of legitimately issued patents.
22 Not one thing I said would get in the way of

1 innovation. These are evasions of the system. This is
2 an evasion of the regulatory regime. And there's no
3 good reason at all, especially in all the citizen
4 petitions and REMS aspects that I talked about, that
5 FDA can do something about -- this is not about
6 innovation. It's about consumers getting the right to
7 generic drugs that they have every right to get. Thank
8 you so much for your attention to this crucial issue.

9 (Applause.)

10 MR. FLANAGAN: Thank you, very much. Any
11 questions from the panel?

12 MS. DICKINSON: So, Mr. Carrier, thank you.
13 I have one question. You did pose the challenge of
14 product hopping, and abandoning what are apparently
15 viable products for alternative products. But, you
16 didn't pose a solution to that particular matter. Is
17 that because solutions fall outside FDA's authority?

18 MR. CARRIER: So, it's difficult when a drug
19 is just a little bit different than the earlier drug
20 what FDA could do. And so, one thing that FDA could
21 do, which could be a very aggressive change, would be
22 to raise the standard when you have a me-too drug.

1 Should something get FDA approval when it's basically
2 the same thing as the old one, you're just adding a
3 second score or you're going from 50 milligrams to 100
4 milligrams or something like that. That would deal
5 with changing the standard for review. And so, that
6 would be one thing to think about. But, I recognize
7 that that is a bit of an aggressive approach.

8 DR. UHL: I appreciate your presentation this
9 morning. And although some of your recommendations are
10 obviously legislative, or regulatory, none of which are
11 rapid, I want to follow, though, on Liz's point.
12 Because that really struck me, this aspect of
13 reformulation. Are there ways that you can suggest
14 that FDA should be able to target or identify these
15 formulation changes prospectively, so that we can
16 target this product hopping? I believe most of your
17 analysis was, obviously, retrospective. It's kind of
18 easy to tell when it product hopped after the fact.
19 It's less easy when it's in the midst of a supplement
20 at the agency under review. So, do you have any
21 guidance or suggestions to us how to prospectively
22 identify that 20 percent for which you say are

1 problematic?

2 MR. CARRIER: So, perhaps we look at the
3 markets. When you have very large markets, like for
4 cholesterol drugs, it seems like there are a lot of
5 changes that are made that are not the most
6 revolutionary in the world. And so, perhaps a dosage
7 change or a formulation change -- I recognize some of
8 these might be legitimate, but perhaps the changes that
9 are less significant are worth more attention. So, I
10 would say where you have a large market -- where you
11 have something that's far away from the active
12 ingredient, dealing with something that is very small
13 in nature, like a dosage change or a line on a drug
14 that would allow it to be split, or something like
15 that, that would be something that would seem to deal
16 less with innovation.

17 MR. FLANAGAN: Any other questions from the
18 panel? Thank you.

19 MR. CARRIER: Thank you.

20 DR. SARPATWARI: Good morning. Hi. My name
21 is Ameet Sarpatwari, and I'm the Assistant Director of
22 the Program on Regulation, Therapeutics and Law at the

1 Department of Medicine at Brigham and Women's Hospital
2 and Harvard Medical School. I appreciate the
3 opportunity to present comments at this meeting. So, I
4 want to just quickly, in terms of summarizing my
5 presentation, give three respective ways problems in
6 which generic drug availability is hampered and generic
7 drug usage is hampered, and what possible solutions
8 could be.

9 So, just by way of background, between 2014
10 and 2016, net retail prices increased 10 percent
11 annually. These were driven by higher launch prices
12 and markups on existing brand-name drugs. These brand-
13 new drugs enjoy extensive market exclusivity. If
14 you're talking about widely used drugs you're talking
15 about 12.5 years; first-in-class drugs 14.5 years. And
16 the fact of the matter is that these price increases
17 are having a substantial impact on patients. 20
18 percent of 2,001 respondents in a 2016 survey did not
19 fill a prescription in the past year due to cost.

20 So, the gravity and the importance of timely
21 access to generic drugs and promoting generic drug
22 usage is important. And yet, it is being hampered, and

1 one of the reasons is restrictive distribution networks
2 and REMS. So, restricted distribution networks in
3 which you have a single specialty pharmacy or multiple
4 certified pharmacies, which can be independent or part
5 of REMS, companies have been exploiting in a way that -
6 - in a way to deny generic drug access for
7 bioequivalence testing. So, the FDA has testified last
8 year that it received 150 inquiries from generic
9 manufacturers unable to obtain brand-name samples
10 necessary for bioequivalence testing.

11 In addition to the component of access to
12 samples, there's the component of REMS with regards to
13 the patenting and shared REMS with elements to assure
14 safe use. So, that includes patenting REMS and also
15 refusing to engage in meaningful discussions in which
16 to have shared REMS. In addition, you have 11th hour
17 citizen petitions -- so, citizen petitions are
18 mechanisms that allow individuals, including companies,
19 to request that the FDA take or refrain from taking an
20 administrative action.

21 Between 2000 and 2012, 40 percent of citizen
22 petitions pertaining to generic drug -- pending generic

1 drug applications, were filed within a year of generic
2 entry. If we take a further look between 2011 and
3 2015, of the 124 citizen petitions pertaining to
4 pending generic drug applications, 87 percent were by
5 brand-name manufacturers, and only 8 percent were
6 granted. In one egregious case, you had a company
7 filing 24 citizen petitions to delay generic
8 vancomycin. And so, the FDA has stated that citizen
9 petitions delayed five generic drug approvals between
10 2013 and 2015.

11 I think it's important to also stress that we
12 need to be focused not just on timely availability of
13 generic drugs, but on timely usage of generic drugs.
14 And we can't ignore the problem that there still is
15 lingering skepticism about generic drugs -- safety and
16 effectiveness. And part of that is the fact that you
17 have \$24 billion of pharmaceutical marketing to
18 physicians. Now, that was in 2012, so obviously that
19 number has increased. About a third of physicians and
20 patients still harbor some generic drug skepticism, and
21 there is still a sizable way to go in terms of
22 achieving optimal both bioequivalent and therapeutic

1 substitution levels.

2 So, with regards to those problems, what can
3 we do? First, in terms of curbing restrictive
4 distribution and REMS misuse, I think the FDA can
5 compel sample deposit as a condition of drug approval.
6 So, for instance, compelling at least enough samples
7 being deposited as a condition of drug approval
8 sufficient to have bioequivalent testing done by three
9 generic manufacturers, and then conditioning receipt of
10 those samples for bioequivalence testing on a
11 commitment to market the product for a minimum period
12 of time -- say, for example, five years -- and on the
13 condition, that if that drug has -- is a REMS covered
14 drug, that you have a receipt of FDA safety
15 certification for the testing.

16 I think from a legislative standpoint a fix is
17 needed, and that fix is the CREATES Act, which would
18 authorize generic manufacturers to petition a court to
19 require sale of drug samples if a brand-name
20 manufacturer blocked access. It would mandate FDA
21 safety certification for REMS covered drugs, and it
22 would allow FDA to require shared programs or approve

1 separate REMS.

2 Separately, you could -- in terms of a
3 patenting issue, I think you could request Congress to
4 prohibit REMS patenting or, as Professor Carrier has
5 recently argued, to at least go to the extent that was
6 done in the America Invents Act to say that patenting
7 REMS would be -- would not meet the prior art standard.
8 So, in addition to that you could request Congress to
9 require government owned and operated REMS. I've
10 recently been doing a series of interviews with
11 stakeholders about physicians and patients with their
12 experiences with REMS, and one point that physicians
13 repeatedly made is why companies were running REMS, why
14 it wasn't the government actually in charge of running
15 these programs.

16 In terms of combating citizen petitions, a lot
17 of these petitions stem over complex generic products.
18 And so, providing early guidance early on on showing
19 bioequivalence for these complex drugs is important.
20 And in order to do that, and in order to promulgate
21 that guidance, you could levy user fees to conduct
22 necessary research and involve brand-name manufacturers

1 early in that province, in terms of the guidance
2 development.

3 In terms of this notion of still having these
4 manufacturers promote citizen petitions as a delaying
5 tactic, perhaps the FDA could adopt a rebuttable
6 presumption of delay for late-filled citizen petitions,
7 and presume that brand-name manufacturer petitions
8 pertaining to generic applications filed less than nine
9 months before the expiry of the primary patent on the
10 brand-name drug is a delaying tactic, which would
11 require a preliminary finding that the petition would
12 likely be granted based on compelling evidence in order
13 to proceed to a full review.

14 And finally, in terms of promoting evidence-
15 based decision-making and increasing physician
16 confidence and patient confidence in generic drugs, I
17 think it's important that the FDA continue to use
18 Sentinel to conduct generic drug safety surveillance to
19 support comparative safety and effectiveness research
20 and dissemination, and that this could be to recommend
21 that Congress specifically earmark funds from PDUFA for
22 this purpose, and recommend that the Department of

1 Justice earmark a proportion of, let's say, off-label
2 settlements for this activity.

3 In terms of addressing deficiencies in generic
4 direct labeling, I think it's important to issue annual
5 reports on generic drug safety and label changes and
6 create a central online repository of dynamic labels so
7 that physicians and patients have an easy to access
8 record. And in terms of stemming confusion about what
9 generic drugs are or whether or not they are somehow
10 inferior or different than brand-name drugs, requiring
11 generic drugs to have the same appearance as brand-name
12 versions is one possible additional step.

13 So, thank you.

14 (Applause.)

15 DR. SARPATWARI: Happy to take any questions.

16 MS. TOUFANIAN: Thank you for your comments.

17 I have two -- a two-part question related to the
18 skepticism concern that you referenced in your
19 presentation. The first is in your research, have you
20 identified specific therapeutic classes for which the
21 skepticism of the healthcare practitioner or the
22 patients is particularly high? And my second question

1 relates to your last comment requiring generic drugs to
2 have the same brand version as -- excuse me, have the
3 same appearance as the brand-name version. If you have
4 data to support that as a particular concern.

5 DR. SARPATWARI: Sure. So, in terms of
6 specific classes of drugs we do know that in particular
7 -- at least, our research has shown that for narrow
8 therapeutic index drugs there is a particular concern.
9 And we know specifically -- at least have -- are
10 building a body of evidence in terms of which
11 physicians and which patients are more skeptical. So,
12 targeted interventions with relationship to those
13 particular drugs to those populations is a viable
14 solution, in terms of increasing confidence overall.

15 As to the second question, I'm happy to share
16 with the group studies as to the decrease in adherence
17 as a result of a shifting pill color appearance -- and
18 so, size or shape, color -- and what the impacts are in
19 terms of patients stopping taking their medication.
20 And so, ultimately, it's that balanced with -- you do
21 hear generic companies say that if that change were to
22 result, it would result in an increased cost of

1 production. But, you've got to weigh that against the
2 potential increase in adherence that would result from
3 patients being less confused about their medications.

4 DR. UHL: If you have particular data, could
5 you please submit that to the docket? That would be
6 very helpful to us.

7 DR. SARPATWARI: I'd be happy to. Thank you.

8 DR. UHL: Thank you.

9 MR. MEIER: Okay. So, when I made my remarks
10 about the FTC I described us as a law enforcer. But,
11 we also have a unique aspect to our constitution, all
12 the way back to the 1914 -- when we were created,
13 Congress also gave us the right to do research and
14 original projects like that. And we've used those
15 authorities quite a bit, in fact, in the healthcare
16 area, where we've done a number of studies over the
17 years. So, we have some unique tools, including the
18 ability to subpoena companies and those kind of things.
19 As a researcher, yourself, what research would you
20 prioritize if you were in charge at the FTC?

21 DR. SARPATWARI: Oh, boy. That's a -- you're
22 asking a million-dollar question. And I am

1 particularly concerned right now -- at the FTC, you
2 said.

3 MR. MEIER: Yes.

4 DR. SARPATWARI: Yeah, okay. I would be
5 particularly interested right now in how the PTAB
6 process may be facilitating pay for delay settlements,
7 that may hindering timely availability to generic
8 drugs, as one possible concern. And I would be
9 interested in further studying the anticompetitive
10 effects of restricting -- of these restricted
11 distribution pathways, in particular. Those would be
12 two areas.

13 DR. UHL: In follow-up to your question -- I
14 mean, to your comments about promotion and skepticism,
15 and you mentioned the extent of pharmaceutical
16 marketing, and et cetera, that's typically brand-name
17 pharmaceutical marketing. So, do you have any
18 recommendations or suggestions to the generic drug
19 industry with respect to that?

20 DR. SARPATWARI: So, I mean, part of the
21 magic of generic drugs is that they don't engage in
22 that marketing, and thus those costs aren't going to be

1 incorporated into the cost of the generic product. So,
2 it's a difficult position for generic manufacturers to
3 be in. But, I think it's important to capitalize on
4 what existing research has been done in terms of how to
5 persuade physicians and how to show value to
6 physicians. And I think that there are scalability
7 issues with regard to things like academic detailing
8 that generic manufacturers should actively investigate,
9 to see that even if they can't compete on the same
10 level, in terms of the amount of promotion that's going
11 on, can they maximize the way in which they will put
12 out evidence that physicians and patients can use to
13 make more informed choices.

14 MS. SIPES: I had a quick question pertaining
15 to your suggestion -- one of your suggestions about
16 citizen petitions. You talked about on the second
17 bullet there the potential to require a preliminary
18 finding in some cases that the petition will likely be
19 granted, based on compelling evidence, in order to
20 proceed to a full review. Can you say a little bit
21 more about that, or maybe give an example of how that
22 might play out in terms of degree of review of the

1 actual evidence?

2 DR. SARPATWARI: Sure. So, in the case that
3 I think other scholars have mentioned, that there are
4 certain citizen petitions in which the substance of the
5 information presented does not really make -- it is
6 fairly apparent that this is a delaying tactic and not
7 really a substantive question of safety or efficacy,
8 that those are questions that could potentially be
9 weeded out in a preliminary review. And there are --
10 there's -- in the same way that you can get granted a
11 preliminary injunction, at a federal district court or
12 something of the sort, where the court is decided to
13 consider the likelihood of prevailing on the merits,
14 this would be a sort of similar way to weed out some of
15 those petitions to actually lessen the workload of
16 actually undertaking a full review. So, if that were a
17 possibility, I think that that could at least maximize
18 the resources that the FDA had and make sure that
19 they're not being spent on citizen petitions that
20 really don't warrant that much of resources.

21 MS. SIPES: I do hear what you're saying, but
22 I'm -- I guess I'm trying to dig in a little more, and

1 sort of get a sense of what the circumstances would be
2 in which this kind of preliminary finding would be
3 made. I mean, when is it apparent that full review is
4 not necessary, I guess is what I'm asking.

5 DR. SARPATWARI: So, there I think that you
6 could have -- and I -- you could convene a body of
7 experts who have significant experience with these
8 petitions. And actually, entrust them to make those
9 decisions based on expertise. And in terms of if
10 you're specifically asking what would be the reasoning
11 behind making those decisions -- so, I want to just
12 make sure I'm understanding.

13 MS. SIPES: I -- clearly, it would take, you
14 know, expertise to make these determinations. And I
15 guess this is a -- you've largely answered my question,
16 I think, in terms of your thinking. I guess it's just
17 that it's -- the degree of review of evidence that it
18 would -- that would be necessary to make this kind of
19 determination is not, kind of, I think immediately
20 clear.

21 DR. SARPATWARI: Yes. And so, the question
22 is it really is a matter of considering how many of

1 those citizen petitions that would undertake a rigorous
2 review -- how many of them could actually be on a more
3 superficial review, be cut out of the process. And
4 that's an empirical question which I honestly don't
5 have the answer to. Thank you.

6 MR. BRILL: Good morning. My name is Alex
7 Brill. I am a Research Fellow at the American
8 Enterprise Institute, and I'm also Principal at a
9 consulting firm, Matrix Global Advisors. I'm speaking
10 this morning on my own behalf. These views expressed
11 are mine and only mine, although I have provided
12 counsel to both brand and generic drug manufacturers in
13 the past.

14 I thank you for having this meeting today.
15 This is perhaps one of the most important topics in
16 pharmacoeconomics, this striking of the balance. It's
17 also one of the hardest questions for economists and
18 policy makers to wrestle with. I'll try to be brief in
19 the next few minutes, and not be redundant to comments
20 that were made earlier, all of which were appreciated.

21 I'll start with my key point, and then make a
22 few specific policy suggestions and observations. And

1 the key observation that I wanted to convey this
2 morning is that the objectives laid forth in this
3 meeting, the balance between innovation and access --
4 or, as I would suggestion, innovation and competition -
5 - is not a zero-sum game. But in fact, policies that
6 are intended at encouraging competition can also be
7 positive for innovation. In other words, innovation
8 does not always come at the cost of access, and
9 competition does not always come at the cost of
10 innovation.

11 This can be illustrated simply by looking
12 outside the pharmaceutical space and thinking about the
13 phones that each of us are carrying. Samsung is
14 spurring Apple, and the Samsung Galaxy is spurring the
15 iPhone, to innovate. The threat of that -- those
16 competitive pressures on each other is pushing forward
17 the technology in that industry, and leading to better
18 outcomes. Similarly, the threat of generic entry or
19 entry of a competing brand can also spur innovation in
20 the pharmaceutical industry. This isn't always
21 necessarily the case, as was mentioned earlier.
22 Sometimes those innovations or changes can be small, a

1 product hopping or evergreening. But, it does have the
2 potential to have a strong and positive innovative
3 effect through more competition.

4 It's tempting, I think, to look at the parties
5 in front of you in a dispute -- a brand versus a
6 generic -- and think of this in a sense as a zero-sum
7 game. And it is, of course, a game of winners and
8 losers in any particular challenge. But the proper
9 framework, I think, is one of a welfare perspective --
10 not about the two manufacturers that are seeking an
11 advantage over another, but rather of the customers --
12 the consumers. And whether those consumers may be
13 consumers seeking the advantages of a new and
14 innovative product, or those consumers may be seeking
15 the advantages of a more cost-effective product.

16 And the other large point I want to make is
17 simply that the marketplace is increasingly
18 sophisticated here. The Hatch-Waxman Amendments that
19 date back to the mid-1980s were enacted at a time
20 where, quite frankly, the industry was different, both
21 with respect to the generic industry as well as with
22 respect to the brand industry. And so, it's

1 appropriate to consider and reevaluate where these
2 balances may lie.

3 Let me also just touch -- and this was also
4 mentioned in the opening remarks -- when we think about
5 competition, we tend to think about them in the very
6 simple and -- manner of the competition between the
7 brand and the generic-- the generic entry as being the
8 quintessential example of competition in the
9 pharmaceutical industry. But in fact, I think there
10 are four straightforward and obvious types of
11 competition; three of them are related to the subject
12 at hand. Brand to generic, the one I just mentioned.

13 Generic to generic competition is also
14 critically important. Simply, it's not a binary choice
15 that -- in the marketplace that there either is or is
16 not generic entry for a given product, but in fact more
17 generic entrants result in different market dynamics.
18 And we know that in part due to some research from the
19 FTC.

20 And brand to brand competition, which was also
21 mentioned in the opening remarks. Brands can --
22 although not always, can compete with one another.

1 Brands in the same drug class can compete with one
2 another on price.

3 And the fourth part would be the
4 biologic/biosimilar competition dynamics. Most
5 economists consider this dynamic or expect this dynamic
6 to be similar to that in the brand to brand space, in
7 some respects, although perhaps it will be its own
8 unique dynamic, but, of course, outside the Hatch-
9 Waxman framework.

10 Thinking a little bit more specifically about
11 a few policies to consider, one that's been discussed
12 by the last two speakers, and I won't rehash these
13 remarks, but the restrictions that are imposed through
14 the use of REMS with ETASU and REMS-like programs that
15 block generic competition in my view is certainly not
16 something that was intended by Congress, and that does
17 upset some of the balance between competition and
18 innovation.

19 In work that I did earlier this year, I tried
20 to get an estimate -- admittedly, an upperbound -- on
21 the scope and scale of this marketplace, identifying
22 over 70 drugs with over \$20 billion in annual sales

1 that are potentially at risk of restrictions. And work
2 that I did back in 2014, looking at a sample of 40
3 products which there had been evidence of restricted
4 access, tried to estimate the potential lost savings,
5 at over \$5 billion a year economy-wide and almost \$2
6 billion a year to the federal government. This is an
7 issue not only of potential foregone savings in the
8 healthcare space, but one that will alter the balance
9 between innovation and competition.

10 Also, as Dr. Janet Woodcock mentioned in her
11 opening remarks, there are many brand products for
12 which there are no exclusivities or pending -- or
13 patent protections, yet no generic approval. I think
14 it would be misleading to think that we'll ever see
15 generic competition for all of these products. There
16 are natural market forces that may prohibit a generic
17 entry. But, I also would believe that an exclusivity
18 for the generics can be a positive policy change that
19 could encourage more entry of generics into this space.
20 And we saw in legislation passed by the House of
21 Representatives last week, I believe, that a policy in
22 this vein is likely to generate additional cost

1 savings, which suggests to me that it is likely to
2 generate additional generic competition.

3 With respect to the generic to generic
4 competition dynamic that I mentioned a moment ago, this
5 too is very important to think about. It's not -- we
6 should not think of this as simply a binary choice, but
7 rather we should be encouraging not only generic entry,
8 but robust generic competition. And the evidence
9 presented in Reiffen and Ward research that started at
10 the FTC clearly illustrates the importance of more
11 generic entrants into a market for driving down costs.

12 And then finally, the important brand to brand
13 competition. And again, I'll reiterate that brands do
14 not necessarily always compete on price with one
15 another. But they can. And that in the given -- the
16 current framework that we have, where we -- where the
17 FDA prioritizes -- expedites various approval pathways
18 -- given the fact that there's resource constraint at
19 the agency, the additional emphasis on these expedited
20 pathways necessarily means, I think, that there are
21 more limited resources available for these "me too"
22 products. But, these me-too products can also be

1 procompetitive in many respects.

2 And I'm out of time, so that just details my
3 earlier comments.

4 MR. FLANAGAN: Thank you. For you -- how
5 would exclusivity for generics for sole source markets
6 incentivize product development, since there are no
7 competitors to exclude?

8 MR. BRILL: I think in the current landscape,
9 absent that incentive, generic manufacturers may
10 hesitate to enter out of fear that a competitor is
11 similarly engaged in the same process. And so, it's
12 about -- a bit of a prisoner's dilemma, in a sense.
13 Two generics both -- either one willing to enter, but
14 fearful that the other one is entering simultaneously.

15 MS. DICKINSON: You mentioned that there have
16 been a number of changes in the marketplace and in the
17 industry since 1984. Are there particular developments
18 that are salient for the agency's implementation of the
19 statute that you would direct us to?

20 MR. BRILL: Just in the broadest terms, we
21 see both very high share of the market captured by
22 generics. Nearly 90 percent of all prescriptions are

1 generic prescriptions. And we see the generics can
2 capture large market shares relatively quickly,
3 particularly for large product classes. On the other
4 hand, on the innovative side, as we all know we see
5 prices for brand products at launch significantly
6 higher than they had been historically, even adjusting
7 for overall inflation and other dynamics. So, the pull
8 is in both directions. How it nets out, it's hard to
9 speculate.

10 MS. TOUFANIAN: Thank you. On your second to
11 last slide, you noted that there's a lack of a
12 sufficient number of ANDAs to maximize the competitive
13 market dynamic. I would surmise that some of that is
14 attributed to the pay for delay settlements that Markus
15 is interested in. But, in addition, are there other
16 market forces that inform generic drug entry when there
17 is no legal impediment that intersects with FDA's
18 regulatory space in a way that FDA could look at more
19 closely.

20 MR. BRILL: I'm sorry, you're referring to
21 multiple generics in a space, or generics when there is
22 no generic?

1 MS. TOUFANIAN: When there are less than the
2 number of generics that you identified. We know that
3 some are precluded from entering into the market due to
4 the exclusivity of those first applicants. In other
5 scenarios, we may have seven, eight, ten generics
6 approved and yet only two are marketing at any given
7 time.

8 MR. BRILL: Yeah. So, some of it is what I
9 would call natural to the market. For small products -
10 - for small product classes, the market can only
11 withstand a relatively small number of competitors.
12 And so, we shouldn't always expect the five, six number
13 of generics in a market. It depends on the
14 particulars. But, in other cases there could be
15 regulatory barriers. And I can't say with certainty,
16 but we should think of the application process as a
17 hurdle for entry.

18 And to the extent that those hurdles -- and
19 they're barriers, in other words, and to the extent
20 that there are costs associated with those, whether the
21 direct literal cost or the time and risk associated are
22 large, that will deter generic competition. And in

1 particular, it will deter additional generic
2 competition in these smaller products. And so, for,
3 you know, a billion-dollar product firms would be happy
4 to shell out a few million dollars for an ANDA. As the
5 products get smaller, those hurdles and burdens become
6 potentially more binding.

7 DR. STEIN: The point you had made with
8 regard to brand to brand competition, and the need to
9 have more within a class for stimulating competition,
10 did you have specific suggestions? You commented on
11 the approval pathways for breakthrough medications,
12 priority review. Specific suggestions for how FDA
13 would address this issue?

14 MR. BRILL: To be honest, I think it's a true
15 challenge. Many of these expedited pathways are
16 legislated. There's a political desire, and a
17 reasonable and appropriate one, to direct resources
18 into certain types of pathways to unmet needs, which is
19 an appropriate and reasonable area for which the agency
20 should be working diligently, and is. But it comes at
21 that cost. And so, you know, in the simplest terms
22 additional resources -- or, at least, an awareness of -

1 - within the agency of how resources may be -- are
2 perhaps being diverted to the expedited pathways that
3 are set by Congress, at the expense of standard
4 reviews.

5 MS. ABRAM: Going back to your evergreening
6 comments, are there specific examples of types of
7 evergreening that you believe are disrupting the
8 balance that Hatch-Waxman sought to strike?

9 MR. BRILL: No. I think that we -- again,
10 it's more of a scientific question, I think, and
11 outside my scope of expertise. The -- this question of
12 what is a significant change versus what is an
13 incremental change is extremely difficult for policy
14 makers, and certainly difficult for those who are -- of
15 us who are not from the hard sciences, to wrestle with.
16 I think, though -- I would note that some of this issue
17 could be -- some of the burden here should not be
18 attributed solely to the agency, and that the industry
19 -- and that the marketplace itself can potentially
20 resolve some of these challenges. And what I mean here
21 is that the payers should be aware of the differences
22 in products, and how those products are tiered and

1 whatnot can influence the outcomes at the end of the
2 day as well.

3 DR. UHL: I just want to follow up on the
4 question from Peter, about the brand to brand. Do you
5 have particular examples that you could provide us
6 where the -- that demonstrate the -- your second bullet
7 here, the expense of approving brand products that
8 offer the opportunity to compete directly. Are there
9 particular circumstances or examples of product
10 development meetings that didn't happen, IND meetings
11 that didn't happen, NDAs by which we missed goal dates,
12 or whatever? I just -- I think it would be -- I
13 intuitively understand your point. But do you have
14 data to substantiate that?

15 MR. BRILL: I think it's virtually impossible
16 measure empirically. And I don't have -- if I had an
17 anecdote, I would share it. I'm not close enough to
18 the process to be able to share an anecdote. But
19 empirically, to demonstrate this -- a meeting that
20 would have happened or something -- the but for cases
21 is hard to imagine. I think it is -- as you said, it's
22 intuitive in the sense that given the fact that there

1 is a fixed amount of resources that are available, and
2 there is a pull on those resources into a particular
3 direction, that necessarily means that there can be
4 other activities that lag. The extent to which this is
5 a concern, or empirically, I think would be very
6 difficult to measure. Perhaps it's measurable
7 internally. But even then, I think there would be
8 challenges. Okay. Thank you.

9 DR. POLLI: Good morning. My name is James
10 Polli. I'm a faculty member of the University of
11 Maryland. I'd like to talk with you about
12 pharmaceutical quality. Pharmaceutical quality is a --
13 I have some slides. Yeah. Okay. So, in any event,
14 pharmaceutical quality is an area where Hatch-Waxman
15 Amendments have had a favorable impact on the
16 development of both brand and generic products.
17 Pharmaceutical quality is an interest to all
18 pharmaceutical companies throughout entire product
19 lifecycles. I intended to show a schematic of how
20 pharmaceutical quality is designed into products, with
21 time progressing from the beginning of development to
22 subsequent development.

1 Innovators learn about formulation risks and
2 sensitivities during development, often through
3 failures. When development efforts are successful,
4 product formulation, manufacturing and quality control
5 tests are arrived at as clinical development proceeds,
6 even after phase 3 studies are completed. There is a
7 reliance on the bioequivalence standard during
8 innovator development. A typical NDA has four to six
9 bioequivalent studies. After NDA approval, CMC experts
10 remain busy throughout subsequent product lifecycle
11 stages. After patent expiration, generics enter the
12 market employing the same bioequivalence standard.

13 The notion and availability of generics has
14 brought about a public interest in and public discourse
15 of pharmaceutical product quality. Questions include
16 who, where and how is medication made. What nondrug
17 ingredients go into the medication, and what is their
18 impact. What quality control tests are used, and what
19 do they assure. What is the bioequivalence standard
20 and is it good? Is this the same product that was made
21 last month? Is this a narrow therapeutic index drug?
22 These are not always easy questions, particularly for

1 drugs that are difficult to formulate and for complex
2 formulations. Innovator companies have substantially
3 contributed to pharmaceutical science that underpins
4 the answers to these questions.

5 However, there is little doubt that Hatch-Waxman has
6 had the effect of greater public interest in and public
7 discourse of pharmaceutical product quality, which has
8 benefited everyone, including both innovator and
9 generic companies.

10 FDA-sponsored research to examine
11 pharmaceutical quality and manufacturing standards. I
12 have two examples -- actually, maybe I don't. This
13 first example is a study designed to address questions
14 from pharmaceutical scientists, from both innovator and
15 generic companies. We examined whether large amounts
16 of common excipients impact bioequivalence for so-
17 called BCS Class III drugs. Excipients are nondrug
18 ingredients in medicines, like fillers and binders, and
19 are typically present in quantities larger than the
20 drug itself. We found that a dozen of the most common
21 tablet and capsule excipients do not impact
22 bioequivalence.

1 So, we've developed a list of common
2 excipients that we concluded that need not exhibit
3 qualitative and quantitative sameness between pre-and
4 post-change products, including brand and generic, for
5 tablets and capsules. Hence, human testing is not
6 necessary to bioequivalence of BCS Class III drugs
7 involving these excipient changes. FDA has since
8 provided regulatory relief. Innovator and generic
9 companies are utilizing these new guidelines. In 2010,
10 we had conservatively estimated that such regulatory
11 relief would directly save \$62 to \$71 million each
12 year.

13 A second example is a study designed to
14 address concerns from neurologist and epilepsy
15 patients. The American Epilepsy Society was opposed to
16 generic substitution, since it had questions about the
17 bioequivalence standard, which is typically performed
18 in healthy volunteers and not in patients.
19 Neurologists were most concerned about the anti-
20 epileptic drug lamotrigine. We performed a switching
21 bioequivalent study of the brand lamotrigine and the
22 most common generic in patients with epilepsy under

1 clinical conditions. We've published this work, where
2 one can see that bioequivalence was observed.

3 A second similar study showed bioequivalence
4 between two generics. Last year, the American Epilepsy
5 Society rescinded its 2007 position statement that
6 opposed generic substitution, indicating "These studies
7 confirm that the U.S. FDA standards for bioequivalence
8 are appropriate for patients with epilepsy."

9 Again, Hatch-Waxman Amendments have had a
10 favorable impact on the development of both brand and
11 generic products through greater public interest in and
12 public discourse of pharmaceutical product quality.

13 MR. FLANAGAN: Sorry we disrupted your flow.
14 Your very excellent slides will be part of the public
15 record.

16 DR. POLLI: Okay. All right.

17 DR. UHL: Jim, thank you very much. Are you
18 making the recommendation to us that that list of
19 common excipients -- if there's a product that includes
20 that list of excipients, that we waive bioequivalence?
21 Or are you making different recommendations?

22 DR. POLLI: No, I don't think I have anything

1 to add beyond what we have already published. Which is
2 more -- which provides more relief than what I
3 understand the current -- what the agency currently
4 does. Just through -- I was just really saying that
5 through competition there's been a greater focus on
6 pharmaceutical quality, and that has elevated the game
7 of all formulation scientists throughout the world,
8 regardless of who their employer is.

9 And in that one particular case that you're
10 asking about, it sort of inspired questions about,
11 well, what should the standard be, is there ways to
12 relax the standard, should it be tightened. So, I
13 think that sunshine has been helpful in this space.
14 It's also -- I would also say that it's also helpful in
15 that it's also helped recognize that some products are
16 in fact more complex than others. So, it's just a
17 sunshine issue.

18 MR. FLANAGAN: Thank you.

19 DR. BERNDT: Good morning. My name is Ernst
20 Berndt. I'm a Professor at MIT. I'd like to speak
21 today about some recent research results. If you could
22 -- the research is our own. It's sponsored by the NIH,

1 and it's joint with a professor at the University of
2 Chicago named Rena Conti, and my postdoctoral fellow,
3 Steve Murphy. Two more slides down, please -- or no, I
4 -- oh, here we go.

5 The research I'll talk about this morning is
6 not yet published. It's currently being submitted as
7 working papers to the National Bureau of Economic
8 Research. We expect they will be available publicly in
9 a few weeks.

10 I'll talk about two study questions. One is
11 how competitive are product markets in the U.S.
12 generic industry, how do we quantify that, and what are
13 trends in that over time. And the second thing I want
14 to talk about is to what extent has GDUFA, the first
15 authorization of the Generic Drug User Fee Act,
16 exacerbated certain concentration trends and hindered
17 competition in the generic drug industry.

18 Let me just start by defining what we mean by
19 a product market. This is an important issue in
20 antitrust economics. What I'm going to do here is
21 define a product market by the combination of the
22 active pharmaceutical ingredient and the root of

1 administration. That is to say, if we take a drug like
2 -- brand-name drug like Pepcid, which is famotidine,
3 oral versions -- all oral strengths of famotidine and
4 Pepcid would be in the same product market. However,
5 injectable would be a different product market. And
6 similarly, ranitidine, which is Zantac, would be in a
7 different product market than Pepcid. The data that we
8 use is for 12 years. It was from QuintilesIMS, and
9 it's through all drug channels, not just the retail
10 channel. Let me skip ahead here. There are four
11 regulatory regimes we distinguish. One is pre-MMA.
12 That's before passage of the MMA implementation --
13 before implementation. After 2006 until the beginning
14 of 2010 is we call the MMA era. That's MMA was
15 implemented. Then passage of the Affordable Care Act
16 in the second quarter of 2010, until third quarter of
17 2012. And finally, the GDUFA era, which was after
18 GDUFA was implemented, which is beginning in the fourth
19 quarter of calendar year 2012 -- not fiscal year,
20 calendar year.

21 What we do is rather conventional, in terms of
22 methodology. There's no real innovation here. What

1 makes the study quite useful, I think, is the level of
2 detail -- very disaggregated -- by product market.

3 Let me start, then, with revenues. On the
4 vertical axis, here we have revenues in thousands of
5 dollars per quarter. We have time on the horizontal
6 axis. And what we do is we do the interquartile range
7 and the mean. That is to say, if you look at the very
8 bottom line there that tells us that 25 percent of
9 these product markets have quarterly sales of \$100
10 million or less. That's \$400 million per year. If you
11 look at the red line just above that flat line on the
12 bottom, that's the median revenues. What the median
13 revenues are at the beginning of the samples are around
14 150 -- sorry, about \$100 million per quarter, and at
15 the end of the sample it's up to about \$150 million per
16 quarter. So, rather quite a small market. If we look,
17 however, at the mean -- which is way up on top -- we
18 see that means are very, very much larger than even the
19 75th percentile, suggesting that there's a very small
20 number of very large revenue drugs. Probably
21 authorized generics, or perhaps even some branded
22 generics. But, for the most part I think it's

1 important to characterize this industry as consisting
2 of a lot of products that have small revenues.

3 A second thing to look at is entry and exit.
4 The -- what we define as an entrance is a product for
5 which for two quarters -- at least for the last two
6 quarters there's been zero sales, zero units sold. And
7 then we see positive thereafter. That's called an
8 entrance. And an exit is when we don't see any product
9 sales in revenues, dollars or in units, for two
10 quarters. What you see here is on the top you have two
11 lines. One is the absolute number, and on the right
12 vertical axis a percent -- 1, 2, 3 and 4 percent. What
13 you see, therefore, in the top is that over time, for
14 the most part, there's been more entry than there's
15 been exit. The top two lines. And that the total
16 churn rate is about 5 percent a quarter. What you also
17 see is that towards the end of the sample, on the
18 right-hand side, you see that there's a convergence
19 between entry and exits.

20 Following passage of GDUFA, the entrance rate
21 actually fell. I'm not attributing it, necessarily, to
22 GDUFA. There may be many other things going on, like

1 patent cliffs and things like that, and consolidation.

2 But you also see the number of exits increasing quite
3 substantially towards the end of the sample.

4 How many manufacturers are there in a typical
5 product market? What this tells you is that for the
6 most part the median there is between two and three.
7 It means that 50 percent of all generic product markets
8 have two to three competitors, no more. The 75th
9 percentile is the line on the top, which says between
10 five and six. The mean here is between four and five.
11 So, what this tells you basically is that most generic
12 markets not only are small revenue markets, but they
13 have a small number of competitors. So, they're highly
14 concentrated.

15 This is probably the most important slide of
16 this set, and this is -- let's take a look at all these
17 product markets, and see how many of them have only one
18 competitor, only one ANDA actively being marketed, how
19 many have two, how many have three and how many have
20 four or more. What you see here is a couple of things.
21 One is the lines are all pretty flat. So, this is a
22 steady state sort of thing. This is not abrupt

1 changes. They're pretty flat lines. But, what you
2 see, for example, is that blue line on top says 40
3 percent of all generic markets have only one supplier.
4 Dr. Gottlieb's data from the other day talked about
5 the number that have no generics at all. We're looking
6 at just those markets where there is a generic, and 40
7 percent of those markets have only one supplier.
8 Another 12 to 15 percent have two suppliers. So, that
9 means that more than half of all markets have two or
10 fewer suppliers. On the other hand, there's about 40
11 percent that have four or more suppliers.

12 I won't present regression results here, other
13 than to show that during -- if you look at what happens
14 to exit rates, you see that during the GDUFA era they
15 are higher than in the pre-MMA era, and that they're
16 higher typically for orals than they are for
17 injectables or other routes of administration. If you
18 look at entry shares, you see the opposite happening.
19 Whereas there's increased exit over time, there's
20 decreased entry. And the entry -- the decreased entry
21 is particularly notable amongst injectables. This is a
22 slide that looks at what happens to the price per

1 standard unit in QuintilesIMS parlance, as a function
2 of how many competitors are there. And as you'd
3 expect, the larger the number of competitors the lower
4 the price, other things equal. And they find an
5 elasticity here that's about $-.75$, and it's robust to
6 how you measure the number of competitors. In other
7 words, whether they use a corporation or a manufacturer
8 count.

9 So, three takeaways from that. First is the
10 quarterly sales revenue for a manufacturer/molecule are
11 surprisingly small. Generics product markets generally
12 have a small number of competitors. Median is two.
13 And while there's -- entry was outnumbering exits
14 through most of the sample, since 2013 these churn
15 rates have converged to one another. Could reflect
16 many things -- patent cliff, consolidations, barriers
17 to entry and inducements to exit from GDUFA I.

18 Okay. One comment that's more of an economics
19 sort of issue, in this country we have legislation that
20 called Hart-Scott-Rodino legislation, which requires
21 any merger and acquisition that exceeds some threshold
22 to be publicly reported so it can be scrutinized by the

1 DOJ or the FTC. That current threshold is \$81 million.
2 Given how small the revenues are for a lot of these
3 generic manufacturers, that tells us that there can be
4 mergers and exits, and that would not exceed the Hart-
5 Rodino threshold but could still be very important in
6 terms of public health, for making the concentration
7 even higher and supply more vulnerable.

8 Let me just comment for a few minutes on GDUFA
9 and PDUFA. And I mean -- by PDUFA, I mean, the
10 Prescription Drug User Fee Act for brands that was
11 originally implemented in 1992, and GDUFA will be the
12 one from 2012, whose authorization is now being
13 considered. Similar to PDUFA, GDUFA had a one-time
14 application fee. But GDUFA had annual facility fees,
15 that were larger for fixed final dosage forms than for
16 API -- actual pharmaceutical ingredient -- facilities,
17 and it was \$15,000 larger for a foreign than for a
18 domestic applicant.

19 In PDUFA, there were no foreign domestic
20 distinctions. And annual establishment fees but not
21 annual facility fees. Because of importance of
22 contract manufacturing, primarily in the generic drug

1 industry, but not as much, apparently, in the brand-
2 name drug industry -- although there is some there --
3 GDUFA had a one-time drug master file fee that ANDAs
4 could reference, but there wasn't a separate contract
5 manufacturing organization fee from facility fee. And
6 there's no analog to that in PDUFA.

7 Quite importantly, unlike for PDUFA, with
8 GDUFA, the annual facility fees were due at the time
9 the ANDA was submitted, rather than after the ANDA was
10 approved. For PDUFA, the annual establishment fees are
11 not assessed until the product is actually approved.
12 What this means, then, is for those generic
13 manufacturers having a backlog, which for a while was
14 as much as 48 months -- that means for those four years
15 you have to pay facility fees even though you don't
16 have a product on the market. Okay. I might note that
17 GDUFA II plans to address that issue, and I'll talk
18 about that in a minute. But, in terms of just seeing
19 how large are these fees, here are the various fees of
20 one-time ANDA fees, product -- prior approval
21 supplement fees and drug master file are all in the
22 \$35,000 to \$70,000 range. The annual program fees are

1 quite a bit higher. If you look at the final two
2 columns, for a final dosage form, it's -- domestic it's
3 \$258,000 at the end of the sample, and for foreign it's
4 \$15,000 more, at \$274,000. And I might note, so that
5 generic manufacturer submitting an ANDA, with having to
6 wait for years, has to pay \$1 million during that
7 interval before it has any revenues. That discourages
8 entry.

9 I might also note that the growth rates of all
10 these fees are considerably higher than the growth rate
11 of prescription drug prices. So, what did GDUFA do to
12 try and address this. One thing that the FDA noticed,
13 and industry agreed with, was that the revenues were
14 highly volatile -- how could they be made more
15 predictable. And here an important change, I think, is
16 that the -- instead of assessing them annually on the
17 stock of approved ANDAs, they'll now be addressed on
18 the -- sorry, instead of addressing on the flow of new
19 ANDAs, they're now going to be assessed on the stock of
20 all approved ANDAs, which is a much more stable and
21 predictable number. And the supplement fees are
22 entirely abandoned.

1 Finally, there are some small business
2 concerns. There will now be an annual program fee for
3 -- that will depend on how many ANDAs is held by a firm
4 and its affiliates. For small ANDA holders -- that is,
5 from one to five ANDAs -- they will have a 10 percent
6 of the full fee assigned. For medium -- that is,
7 holding a portfolio of 6 to 19 ANDAs -- that will be a
8 40 percent of a full fee, and then the full fee would
9 be for those that have a portfolio of 20 or more ANDAs.

10 The FDA estimated that in 2016, there were
11 about 10,000 approved ANDAs, but they also recognize
12 that there were a lot of ANDAs that were not being
13 marketed anymore. And so, part of the issue of the
14 whole GDUFA funding IT support, and so forth, and
15 enabling the FDA to monitor the industry was to try and
16 find out more carefully just how many of these products
17 are actually being marketed.

18 The actions that the FDA took was to use the
19 Orange Book to identify the apparent ANDA owners, ask
20 them as of November 14th, to inform the FDA by February
21 what ANDAs they owned and whether they were being
22 manufactured and marketed. Only 7 percent of the

1 identified ANDA holders responded to that request.
2 However, they were very disproportionately large ANDA
3 holders. The average portfolio size of a respondent to
4 that was about 15 ANDAs, but some of them were much,
5 much larger. For example, Teva holds, as of that date,
6 1,609 ANDAs; Mylan, 662; Novartis, 647; and then, a
7 fair number as well. Ten largest of those responders
8 claimed 70 percent of all the claimed ANDAs.

9 Why do I raise this issue? Well, Dr.
10 Gottlieb proposed recently that there would be
11 expedited review for all those markets in which -- for
12 any ANDAs submitted in a market in which there were
13 three or fewer ANDA holders. By our count here, that's
14 60 some percent of all markets. It's not a very
15 discriminating sort of tool. It's a very -- and most
16 of those markets are probably extremely small, and the
17 reason they're small is probably because they're very,
18 very old drugs, for the most part. Now, some of those
19 very old drugs are very important -- standard of care.
20 But many are not, and there's probably good reason why
21 they're obsolete. We've got some better products now
22 in turn to address those needs. But, what -- the point

1 we want to make here is that the FDA could burden
2 itself enormously if it had to do expedited review of
3 60 percent of all ANDA holders -- of all product
4 markets. Now, the -- it's very unlikely that there
5 will be that many applicants. But this suggests to us
6 that there might be a more focused way of trying to
7 find what are those product markets which have very few
8 competitors, but are really important, in terms of the
9 public health. How that would be done I don't know.
10 There may be room for patient advocacy groups here, for
11 rare disease orphan drug groups, or there may just be
12 other ways in which the economists at the FDA can
13 collaborate with their medical staff colleagues on
14 identifying what those markets are.

15 Thank you.

16 DR. UHL: Thank you very much. In your
17 earlier slides, with the analysis of entry and exit --

18 DR. BERNDT: Yes.

19 DR. UHL: -- where -- because you looked at,
20 if I recall correctly, 2004 to 2016.

21 DR. BERNDT: '16.

22 DR. UHL: So, over that 12-year period, did

1 your analysis also take into effect the mergers and
2 acquisitions? Because there were a substantial number
3 of mergers and acquisitions during that time period.

4 DR. BERNDT: The way in which the
5 QuintilesIMS data handles mergers and acquisitions is
6 rather tricky, in the sense that they always attribute
7 the manufacturer as combined when postmerger. So, we
8 didn't explicitly look at the role of consolidation and
9 M&A activity. But, we do very much expect, and from
10 press releases we're led to believe that a lot of M&A
11 activity resulted in the closing of redundant plants.
12 The -- I might add that the number of API and final
13 dosage form facilities has actually declined quite a
14 lot -- by about 20 percent. So, it's not just a --
15 some products exiting. It's actually plants exiting as
16 well.

17 DR. UHL: So, did you do anything in your
18 analysis to control for that?

19 DR. BERNDT: Not yet.

20 DR. UHL: Okay. Thank you.

21 DR. BERNDT: We hope to do that soon.

22 MR. FLANAGAN: Thank you.

1 DR. BERNDT: Thank you.

2 MS. SIPES: I'm sorry. I'm so sorry. I
3 actually had a question. Sorry about that. Thank you
4 very much for this presentation. I'm just wondering --
5 I see your point in the second part of the presentation
6 about the impact of fees on entry and exit. Did your
7 work lead you to any other insights into factors that
8 strongly affect generic entry and exit beyond the fee
9 structure, in terms of what companies look at when they
10 make their decisions?

11 DR. BERNDT: Well, we do know as well that
12 for very good reason is the FDA increased its
13 monitoring of both domestic and foreign manufacturing
14 sites, for quality control and sterile manufacturing,
15 things like that. And we have noticed that a number of
16 firms withdrew their products after getting their Form
17 483 complaints. So, it's not just GDUFA. It's other
18 regulatory activities, which are very important to
19 maintain so that we have an assurance of high quality
20 manufacturing. But, that probably -- again, because
21 some of these markets are so very small, with small
22 revenues, the cost implications of upgrading so that

1 you're up to date with current good manufacturing
2 practices can be quite substantial, and can lead to
3 exit that way as well.

4 In the academic literature on generic drugs,
5 we've studied very, very closely the first 24 months
6 after loss of exclusivity, but we haven't really looked
7 at what happens to mature markets. And there's not
8 been much work at all on factors affecting the exits.

9 So, I -- the answer to your -- long answer to
10 your short question is that there is some work on this,
11 but very little has been done. And I think it would be
12 an important area to follow up on.

13 MS. SIPES: Thank you.

14 MR. FLANAGAN: Thank you. Now we'll take a
15 ten-minute break, which means we'll return at 11:13 and
16 kick off right then. There's a kiosk serving coffee in
17 the lobby. Restrooms and vending machines are out
18 there. If you'd like to preorder lunch, you can do so
19 at the kiosk.

20 (Off the record at 11:03 a.m.)

21 (On the record at 11:16 a.m.)

22 MR. FLANAGAN: As with previous presentations,

1 I'll announce the first speaker but not subsequent
2 ones. So please approach the podium when the slide that
3 lists your name and affiliation appears on the screen.
4 And after your remarks, please remain at the podium to
5 allow the panel an opportunity for questions. Sir.

6 MR. EBERT: Thank you. And good morning, and
7 than you for the opportunity to be here today and to
8 give our perspective on increasing access and
9 competition in the generic drug market. And thank you
10 to the FDA for its leadership on this critical issue.
11 My name is Todd Ebert. I'm a registered pharmacist.
12 I'm a former CEO of one of the nation's leading GPOs,
13 and I am now currently the President and CEO of the
14 Healthcare Supply Chain Association, HSCA. I have no
15 slides today. Our comments have been submitted in more
16 detail to the docket.

17 HSCA represents the nation's leading health
18 group purchasing organizations, or GPOs. GPOs are the
19 sourcing and purchasing partners to virtually every
20 hospital in the country, as well as the vast majority
21 of long-term care facilities, surgery centers, home
22 healthcare providers and clinics. We help healthcare

1 providers leverage their purchasing volume to negotiate
2 competitive prices on their healthcare products and
3 services, which lowers costs for patients, providers,
4 payers, Medicare and Medicaid, and taxpayers. GPOs
5 deliver the cost savings that allow providers to focus
6 on their core mission, providing first-class care to
7 their patients.

8 Given the unique line of sight that GPOs have
9 over all aspects of the healthcare supply chain, HSCA
10 submits for your consideration the following
11 administrative and policy solutions that we believe
12 will help lower costs and increase competition and
13 innovation in the healthcare market. It is important
14 to note that much of the information that I'll share
15 with you comes from our customers -- our members and
16 the customers they serve, the pharmacists out in the
17 field.

18 Generic drug shortages and price spikes.
19 Price spikes are commonly used generic drugs -- price
20 spikes for commonly used generic drugs and ongoing
21 prescription drug shortages are jeopardizing patient
22 access to care. As you know, generic drug price spikes

1 often occur when a lack of competition among drug
2 manufacturers allows high prices to go unchecked.
3 Research and experience indicates that the introduction
4 of at least one competitor reduces drug prices, but
5 only modestly. But when there are at least three
6 competitors, the price drops precipitously by more than
7 40 percent. Increased competition engenders even more
8 favorable drug pricing for consumers and providers. We
9 applaud the FDA's recent action to increase generic
10 drug competition by giving priority review approval --
11 priority review to abbreviated new drug applications
12 for which there are three or fewer alternatives.

13 HSCA also supports your recent action. We
14 also support similar legislative efforts, including
15 S.1115, the Making Pharmaceutical Markets More
16 Competitive Act, a bipartisan piece of legislation from
17 Senators Collins, Franken, McCaskill and Cotton. The
18 language drawn from this bill is in the most recent
19 Senate draft of the User Fee reauthorization bill, and
20 similar language was included in the House version,
21 which unanimously passed on the House floor last week.

22 As the FDA takes additional steps to further

1 increase competition, we suggest that you consider
2 implementing more specific timelines for these
3 expedited reviews. Generic injectable drugs are the
4 workhorses of acute care facilities, and shortages of
5 these drugs create significant challenges for patients
6 and providers alike. Shortages are often exacerbated
7 by the backlog of ANDAs at the FDA, which can delay
8 product review for up to four years -- product delay
9 and introduction. To help resolve these issues, we
10 recommend that the FDA utilize its current authority to
11 fast-track applications for generic injectable drugs as
12 well.

13 Working closely with manufacturers to maintain
14 a supply of generic medications. The nature of generic
15 injectable drugs requires rigorously-maintained
16 manufacturing processes. Manufacturers of these drugs
17 sometimes shut down plants or specific lines for FDA-
18 mandated CGMP improvements or 483 observations, even in
19 instances where only small issues need improvement or
20 where the remaining areas are functioning successfully.
21 These shutdowns can lead to price spikes and to
22 shortages for drugs ranging from saline to chemotherapy

1 treatments. We believe that improved coordination
2 between divisions at the FDA, as well as more rapid
3 review of manufacturer corrective actions, would help
4 to moderate supply and price fluctuations for these
5 drugs.

6 Pay for delay tactics. HSCA opposes so-called
7 pay for delay tactics. Tactics are the practice by
8 which some brand-name pharmaceutical manufacturers
9 attempt to pay the manufacturer of generic drug
10 alternatives to not to enter the market. Pay for delay
11 can give rise to lack of market competition and delay
12 patient access to cheaper alternatives, and we urge the
13 FDA to take action within its authority to end this
14 practice.

15 Now, as noted by Alex Brill, biosimilar
16 products were -- aren't part of Hatch-Waxman. But,
17 this is something we feel very strongly about, and that
18 is the biosimilar nomenclature. HSCA is also concerned
19 about the impact on competition of the FDA's rule on
20 biosimilar nomenclature. Current FDA guidelines call
21 for a unique four-digit suffix for biosimilar names.
22 We are concerned that an arbitrary suffix may lead to

1 clinician confusion and hinder the adoption of
2 biosimilars. We encourage the FDA to eliminate the
3 four-digit suffix to help promote competition and
4 eliminate possibility of confusion for clinicians and
5 patients.

6 In conclusion, I would like again to thank the
7 FDA for allowing us to provide our perspectives and
8 recommendations today. HSCA looks forward to
9 continuing to serve as a resource to the FDA for the
10 FDA to continue working with the agency to increase
11 generic drug competition.

12 Thank you.

13 DR. UHL: Thank you for your comments. I
14 have two questions, based upon some of your
15 recommendations. One was if we could implement more
16 specific timelines. Do you have a recommendation to us
17 about what that would look like?

18 MR. EBERT: Yes. Eight months.

19 DR. UHL: Eight months. As opposed to ten
20 months, the standard GDUFA.

21 MR. EBERT: Right.

22 DR. UHL: Okay.

1 MR. EBERT: We are supporting the legislation
2 by the Senators, S.1115, which calls for eight months.

3 DR. UHL: Okay. That would be for which
4 specific kind of products?

5 MR. EBERT: These would be for the generic
6 products in the express lane. Those that had three or
7 fewer manufacturers.

8 DR. UHL: Three or fewer.

9 MR. EBERT: Uh-huh.

10 DR. UHL: Okay. And then another comment
11 that you made is to fasttrack generic injectables. Is
12 that a recommendation to fasttrack all generic
13 injectables, or specific injectables?

14 MR. EBERT: Only those in which there is
15 limited competition, and where there are opportunities
16 or there's something out in the queue that is waiting
17 to be reviewed and approved, that they would receive a
18 fasttrack.

19 DR. UHL: And what do you mean by fasttrack?
20 Do you mean --

21 MR. EBERT: Meaning that they --

22 DR. UHL: -- the same thing as the specific -

1 - the other specific timelines?

2 MR. EBERT: Yes, ma'am.

3 DR. UHL: Okay. Thank you.

4 MR. EBERT: Thank you.

5 MR. RUSSELL: Good morning. My name is Wayne
6 Russell. I'm the Vice President of Pharmacy for
7 Premier, Incorporated. Premier is a healthcare
8 alliance, serves approximately 3,700 hospitals in the
9 United States and about 130,000 other provider
10 organizations in the nonacute markets. We're a leading
11 healthcare improvement company. We unite the alliance
12 of hospitals and other providers to lead the
13 transformation of high quality cost-effective
14 healthcare.

15 A key component of our alliance is our
16 pharmacy program, which combines clinical data with
17 purchasing power to deliver reduced costs, improve
18 quality and safety and increase knowledge sharing
19 amongst healthcare professionals. I am responsible for
20 a team in Charlotte, North Carolina, that contracts
21 with major manufacturers in the pharmaceutical
22 industry, including both brand and generic

1 manufacturers, distributors, wholesalers, pharmacy
2 technology suppliers, service companies, plasma drive
3 products, vaccines and biosimilars. We have sourcing
4 committees made up of clinical experts from our member
5 hospitals, who also assist us in the evaluation of
6 current emerging pharmaceuticals for contracting and
7 patient care.

8 Because of the disparity in the FDA approval
9 standards between 1938 and 1962, Congress required that
10 drugs approved in the time frame be reviewed again for
11 updated safety and efficacy requirements. The FDA
12 carries out these requirements through a process called
13 drug efficacy study implementation, or DESI. While the
14 FDA's efforts to obtain safety and efficacy data on all
15 drugs in the marketplace is laudable, many of these
16 drugs have a long history of safety and efficacy.
17 Because of the length of time they've been on the
18 market, and also the competitive nature of many of
19 these drugs and number of manufacturers that were
20 making them, most of these products had relatively low
21 prices.

22 Premier recommends several things for the FDA

1 to consider in changing the process to allow more
2 notice for manufacturers and providers regarding the
3 FDA action on these older drugs when immediate removal
4 from the market we consider to be not necessary.

5 First, we recommend that the FDA announce in the
6 federal register the first NDA approval for an older
7 medication currently manufactured by several companies.

8 Second, we recommend that the FDA allow 18 to 24 months
9 after that notice before requiring the current
10 manufacturers to exit the market. This would give
11 providers, purchasers and consumers time to engage with
12 manufacturers on their decision-making regarding
13 seeking FDA approval of a drug that is under this
14 designation. Third, if a manufacturer already has an
15 application at the agency, they should not be required
16 to leave the market when the other manufacturers are
17 instructed to do so.

18 The disruption to the marketplace when other
19 products are required to exit as a result of the FDA's
20 policies should not be underestimated. When
21 manufacturers of these older drugs leave the market --
22 examples include guaifenesin, levothyroxine, digoxin,

1 morphine, colchicine -- providers have experienced
2 significant drug price increases due to the lack of
3 competition, and in some cases, it's created drug
4 shortages.

5 I have several slides that show examples of
6 what I'm talking about. This is an example of
7 potassium chloride, which in 2014 sold for
8 approximately \$40.86 for a 20 milliequivalent per 15 ML
9 liquid product. When other manufacturers were required
10 to leave the market, the price jumped to \$236.93 in
11 2016. Epinephrine -- which, by the way, is currently
12 on the drug shortage list -- sold of \$69.16 a vial in
13 2015. It jumped 352 percent, to \$312.50, in 2016 --
14 one year -- when other manufacturers were required to
15 leave the market. The price has continued to go up
16 another 20 percent this year, on a drug that's been in
17 the market with no new indications or therapy
18 improvement for many years. As you know, again, this
19 is a drug on the drug shortage list. The third example
20 is norepinephrine. This drug was priced at \$33 for ten
21 vials in 2009. When the brand Bloxiverz was approved
22 by the FDA -- same package size -- it jumped to \$150 in

1 2013. It continued to go up to \$938.12 in 2015, and
2 then you'll see that there were two other products --
3 two other manufacturers that came onto the market and
4 the drug now has dropped down to about \$580. But
5 again, the point being that it started out at \$33 and
6 now it's at \$580. So, there's still a significant
7 increase in price, even though we now have three
8 suppliers.

9 So, again, on behalf of our hospitals,
10 physicians and patients, we request that the FDA
11 seriously reconsider the administration of this program
12 and its impact it's having on cost of care and product
13 availability. Thank you.

14 MS. TOUFANIAN: Thank you for your comments.
15 Could you give a little bit more detail on the benefit
16 that you see resulting from permitting those products
17 who are not approved to market within the 18 to 24-
18 month period you described?

19 MR. RUSSELL: Well, these are products that
20 would be currently on the market, that the FDA has
21 targeted to take out of the market. So, it's not like
22 they haven't been around for many, many years. The

1 benefit would be it would give organizations like
2 myself and the hospitals and physician community that I
3 represent time to talk to manufacturers to see if
4 somebody is going to remain in the market, submit an
5 NDA or ANDA, or everybody is going to exit the market.

6 The other dynamic that it would allow us to do
7 is talk to the manufacturer that theoretically has
8 filed the NDA, is going to stay in the market, and
9 quite honestly determine can they supply the market.
10 That's a real problem we have today. Epinephrine is a
11 great example. The manufacturer that stayed in the
12 market couldn't supply the demand that existed in the
13 market, when all the vial manufacturers got out of the
14 market, and then we had a problem with quality for a
15 syringe manufacturer of that product. So, now we have
16 a drug shortage. So, we have price escalation and a
17 drug shortage to deal with, of a very critical drug.

18 DR. STEIN: So, one issue I'd be interested
19 in your comments on -- the process is intended to allow
20 us to assure the quality of the product that's approved
21 by going through the application and the approval
22 process. How do you figure that into the

1 considerations? Obviously, there's value in having as
2 much competition in the market as there can be. But
3 how do we fold in the consideration of the product
4 quality that we can assure through the application
5 process with the importance also of assuring
6 competition in the market?

7 MR. RUSSELL: We're not saying that we should
8 subvert that process. We're not saying that that
9 process that exists shouldn't be ignored. All we're
10 saying is that there needs to be consideration for --
11 and due time given for when manufacturers are told to
12 exit the market because, basically, data on a drug that
13 could be 50 or 60 years old, and been in the market for
14 50 or 60 years, hasn't gone through the process that
15 exists today. So, we're not saying do away with that.
16 We're saying give everyone time to make some
17 determinations.

18 Number one, if somebody did file an NDA and go
19 through the expense and the data process, can they
20 supply the market yes or no. That's something that
21 organizations like mine are very uniquely able to
22 establish, and we would welcome the communication with

1 the FDA to determine that thing.

2 Secondly, we know who other suppliers are in
3 the market of those products. I assume the FDA does
4 too. We could have conversations with them. We could
5 encourage them to stay in the market, and hopefully
6 lead to a market, given some adequate time, where
7 everybody understands what's about to happen -- that we
8 would still have two or three or four competitors, not
9 just one. Or maybe none. Okay.

10 MR. EITING: Good morning. My name is Paul
11 Eiting, and I'm the Senior Manager of Value-Based
12 Policy at Blue Cross Blue Shield Association (BCBSA).
13 I'm happy to be here. I have oral comments, but I do
14 not have slides today. So, as many of you know, BCBSA
15 represents 36 independent and locally based plans
16 providing coverage to over 106 million Americans. And
17 I'm here presenting the opinions of the association on
18 the topic today.

19 First, we applaud the FDA's launch of its Drug
20 Competition Action Plan, as mentioned today by the
21 Commissioner, and efforts to remove barriers of
22 competition to generics. We look forward to learning

1 more about the initiative, as we did this morning, and
2 as they are rolled out in the future.

3 BCBSA is committed to making sure people have
4 timely access to safe and effective and affordable
5 cutting edge prescription medicines when they need
6 them. We share the FDA's concern about methods by
7 which the agency's regulatory structure is being gamed
8 to the detriment of consumers. Currently, there are
9 significant barriers that hinder patients' timely
10 access to generic and biosimilar medicines. We believe
11 that promoting competition and consumer choice will
12 make prescription medicines more affordable.

13 Specifically, the emerging biosimilar market
14 in the U.S. provides great promise to further the goal
15 of providing consumers with access to lower cost
16 medicines. BCBSA supports a robust biosimilar market
17 that ensures providers and patients have unbiased
18 information available to them about the benefits of
19 biosimilars. We recommend that the FDA and Congress
20 address anticompetitive strategies and tactics aimed at
21 delaying the availability of biosimilars, and that FDA
22 ensures that policies for labeling and naming and

1 interchangeability provide the clarity and safety and
2 avoid unnecessary regulatory hurdles.

3 With both the biosimilar market and the small
4 molecule market, Congress enacted patent and
5 exclusivity laws that create monopoly markets for new
6 drugs, followed by the introduction of generic
7 competitors. We have seen activity in the prescription
8 drug market that has tipped the scales and upset this
9 balance. BCBSA recommends the following steps to allow
10 market forces to work more effectively and efficiently.

11 The first recommendation addresses the limited
12 distribution systems and/or the use of REMS program to
13 block generic manufacturers from accessing brand-name
14 products. As we've heard today, some brand-name drug
15 companies claim that providing adequate supplies of a
16 drug to prospective drug manufacturers in the generic
17 market would violate their REMS program. And other
18 brand manufacturers use limited or restricted
19 distribution systems for drugs, even for those drugs
20 without a REMS, to the same effect. We encourage the
21 FDA to recommend to Congress changes that will address
22 these anticompetitive behaviors. BCBSA supports the

1 Fast Generics Act and the CREATES Act, which discourage
2 companies from using restricted access programs to
3 avoid generic competition.

4 Second, the success of a generic market is
5 dependent on the ability to substitute generic products
6 for brand products at the doctor's office and at the
7 pharmacy. The practices of evergreening and product
8 hopping are direct challenges to the generic market,
9 and lead to increased spending on prescription drugs
10 without any measurable improvements in quality or
11 outcomes. Preventing such tactics will bring generic
12 options and lower costs to consumers more quickly. We
13 recommend that the FDA monitor activity that may be
14 deemed anticompetitive, such as when an originator
15 product is removed from the market and is replaced by a
16 reformulated version. And also, to work with the
17 appropriate federal agencies if antitrust laws have
18 been violated.

19 Our last recommendation to rebalance the
20 Hatch-Waxman scales is for legislation to ban pay for
21 delay agreements, where brand drug manufacturers pay a
22 generic drug manufacturer, or make other financial

1 arrangements, to not bring lower cost alternatives to
2 the market. The FTC estimates that these
3 anticompetitive arrangements cost taxpayers and
4 consumers up to \$3.5 billion in higher drug costs.
5 Given the FDA's interest in seeing generic products
6 reach consumers in a timely manner, we encourage the
7 agency to assist the FTC in its review of such cases,
8 and advise Congress on legislative solution.

9 I have two final comments. The first is
10 BCBSA's support of the FDA's efforts to reduce the
11 generics backlog and expedite approval of generics. We
12 are encouraged that the resources of GDUFA II, once
13 approved, will assist the FDA in this herculean task.

14 And second, we request that the FDA examine a
15 policy that would prioritize the review of brand-name
16 applications where there is little or no competition,
17 similar to the FDA policy that was announced for
18 generics last month and was mentioned by Alex Brill
19 this morning. The FDA drug application review process
20 could be improved to prioritize branded products where
21 there are no competitors in the therapeutic class.
22 With the right solutions that increase competition,

1 choice and promote value, we can deliver affordable
2 prescription drugs while protecting and supporting the
3 essential innovations to deliver new treatments and
4 cures to patients. Thank you for your time and
5 consideration.

6 MS. DICKINSON: Thank you. I have a question
7 about whether BCBSA or other entities have actually
8 studied what we've been characterizing as product
9 hopping -- that is, changes to formulations or other
10 characteristics of drugs that have changed dosing
11 regimens, et cetera, to determine whether they have, in
12 fact, made a difference in patient compliance or
13 clinical effect.

14 MR. EITING: So, reformulations that have
15 intent -- with the intent to improve adherence? We
16 haven't studied that to my knowledge. I know some
17 reformulations are created with that intent, to
18 increase adherence by reducing from three pills three
19 times a day to one pill one time a day. We haven't
20 examined that exactly, no.

21 MS. DICKINSON: Thank you.

22 DR. UHL: Could I just seek a little bit of

1 clarity to your very last recommendation, which was
2 something around brand-name policies -- to prioritize
3 those for which there is no competition with that
4 class. What -- could you be a little more specific
5 there? Are you talking about the indication for which
6 there's no competition, or are you talking about the
7 pharmaceutical class, molecule? I'm -- you know, it
8 would help to better understand what it is you're
9 driving at.

10 MR. EITING: Sure. Looking at the molecular
11 level -- so, instances where you could have potentially
12 two or three applications moving through the FDA at the
13 same process, or same time, and where -- or, even a
14 year down the road, where a -- granted, a priority
15 review of a drug would bring that drug to market more
16 quickly. So, especially in cases where you would have
17 a first in class drug hit the market, and then you
18 would have manufacturers catching up to try to get
19 their market into the same molecular class.

20 DR. UHL: Okay. But, you wouldn't
21 necessarily be driving towards indication. So, for
22 example, there's a first in class that treats -- pick

1 something -- MS, for example. You would want to
2 prioritize similar in class molecules.

3 MR. EITING: That's right. Yes.

4 DR. UHL: Okay.

5 MR. BANKOWITZ: Good morning. I'm Richard
6 Bankowitz. I'm the Executive Vice President for
7 Clinical Affairs at America's Health Insurance Plans,
8 or AHIP. I have no slides, but we'll submit detailed
9 comments to the docket.

10 America's Health Insurance Plans is the
11 national association whose members provide coverage for
12 healthcare and related services to millions of
13 Americans every day. We're committed to market-based
14 solutions and public/private partnerships that improve
15 affordability, value, access and well-being for
16 consumers. We appreciate this opportunity to comment
17 on issues surrounding high costs of prescription drugs,
18 and the need for market-based solutions. And we
19 applaud the FDA for focusing on this critical issue.

20 Prescription drug prices are out of control.
21 When drug companies are granted extraordinary
22 protections through the patent system or market

1 exclusivity protections, they have a monopoly and can
2 set any price they choose and raise prices at any time
3 for any reason, as we have seen in the well-publicized
4 example of the EpiPens. We recognize that
5 manufacturers who take large risks in developing new
6 therapies should be fairly rewarded. However, when
7 monopoly power is abused, everyone overpays, from
8 patients, businesses, taxpayers, hospitals, doctors and
9 pharmacists.

10 A study recently published in the Annals of
11 Internal Medicine highlights specific examples of
12 generic drugs that were subject to dramatic price
13 increases, including hydrocortisone acetate, lidocaine
14 hydrochloride, which increased from 92 cents per
15 application in 2008 to \$42.27 per application in 2013.
16 The study found that generic drugs with monopoly levels
17 of competition were associated with price increases of
18 25 percent to 73.2 percent. By contrast, generic drugs
19 with relatively high levels of competition were
20 associated with price reductions of -34 percent to -28
21 percent.

22 Rising prescription drug costs impose a heavy

1 burden on all Americans. A recent AHIP study concluded
2 that 22 cents of every premium dollar goes to pay for
3 prescription drugs, outpacing the amount spent on
4 physician services, inpatient hospital services, and
5 outpatient hospital services.

6 I have several recommendations for reducing
7 prescription drug prices. Our recommendations for
8 effective market-based solutions include, number one,
9 delivering real competition; number two, ensuring open
10 and honest pricing; and, number three, delivering value
11 to patients.

12 First, delivering real competition. Reducing
13 rates of -- reducing rules, regulations and red tape.
14 The FDA should be provided the necessary resources to
15 clear the backlog of generic drug applications,
16 particularly for classes of drugs with no or limited
17 generic competition. We strongly support the FDA's
18 efforts in this area.

19 Stopping REMS abuse and other tactics. We
20 applaud the FDA's new focus on the abuse of risk
21 evaluation mitigation strategies -- REMS -- and other
22 restricted distribution systems which have effectively

1 allowed brand manufacturers to form artificial
2 monopolies to halt the development of generic
3 alternatives. Anticompetitive tactics such as pay for
4 delay and product hopping should also be prohibited.

5 If we're serious about promoting competition,
6 there are other important steps FDA should consider.

7 For example, creating a robust biosimilars market.

8 Some of the costliest and the most expensive and widely
9 used biologics have been on the market for decades
10 without biosimilar competition. In order for
11 biosimilars to generate promised cost savings for
12 consumers, FDA regulations must promote a robust
13 market, ensure that providers and patients have
14 unbiased information about the risks and benefits, and
15 do not allow pharmaceutical manufacturers to delay the
16 availability or limit access to biosimilars by taking
17 advantage of regulatory loopholes, or exploiting the
18 patent system.

19 Two, targeting orphan drug abuse. The Orphan
20 Drug Act is being exploited. AHIP has data for 45
21 orphan drugs available from 2012 to 2014 which shows
22 that almost half of the utilization of these drugs --

1 that's 44 percent -- was for indications that were not
2 orphan indications. So, we must make sure that we
3 support manufacturers who are developing drugs to treat
4 rare diseases, and that this process is not being used
5 as a gateway for premium pricing and blockbuster sales.

6 I'll conclude by saying that the FDA should
7 also look at open and honest pricing, publishing the
8 prices. As part of the FDA approval process, we
9 believe manufacturers should be required to disclose
10 information regarding the intended launch prices.
11 Also, evaluating the effect of direct to consumer
12 advertising. We strongly support FDA's focus on the
13 impact of direct to consumer advertising, especially
14 given that many companies spend nearly twice as much on
15 sales and marketing as they do on R&D. We urge FDA to
16 assess the impacts of the growth of direct to consumer
17 advertising, particularly broadcast advertising, and
18 evaluate the best approaches for conveying information
19 to consumers.

20 We have some other recommendations on
21 informing patients about the value and effectiveness of
22 therapy, and also on looking at outcome-based formulary

1 programs, which we will include in our written remarks.

2 Thank you.

3 MR. FLANAGAN: Thank you.

4 MS. SCHLAIFER: Good morning. I'm Marissa
5 Schlaifer, a pharmacist representing the Pharmaceutical
6 Care Management Association, or PCMA. I appreciate the
7 opportunity to appear at this public meeting to provide
8 PCMA's suggestions on ways to better balance access and
9 innovation under the Hatch-Waxman framework. PCMA is
10 the national association representing America's
11 pharmacy benefit managers, or PBMs. PBMs administer
12 prescription drug plans for more than 266 million
13 Americans.

14 Generic drugs are important options that allow
15 greater access to healthcare for all Americans.
16 Through innovative utilization management tools, such
17 as lower cost-sharing generic incentive programs and
18 the use of mail service pharmacies, PBMs are continuing
19 to drive generic drug utilization rates. Increasing
20 the utilization of generic drugs saves money for
21 patients and plan sponsors, and allows greater access
22 to healthcare for all Americans. PBMs rely on generic

1 competition to provide the most cost-effective
2 medications for patients.

3 PCMA and our PBM member companies greatly
4 appreciate Commissioner Gottlieb's and the FDA's
5 efforts to clear the generic backlog, and to expedite
6 consideration of ANDAs when there are fewer than three
7 existing drugs. We agree that competition is best to
8 facilitated when at least three competitor products are
9 on the market. PCMA's recommendations focus on five
10 specific policy improvements to increase competition in
11 the drug market and bring down the cost of drugs. PCMA
12 will expand on these topics in our written comments, to
13 be submitted later this summer. Our recommendations
14 include ending the use of risk evaluation and
15 mitigation strategies, or REMS programs, to thwart
16 competition; ending the use of anticompetitive pay for
17 delay agreements; stopping anticompetitive product
18 adjustments, or evergreening; using accelerated
19 approval to generate needed competition; and changing
20 biosimilar naming practices to better encourage
21 competition.

22 So, first, reforming the use of REMS. As

1 you've already heard, manufacturers are misusing REMS
2 programs to prevent generic competition. While many
3 REMS programs restrict product distribution as a safety
4 measure, brand drug manufacturers have begun using
5 these required restrictions to deny access to samples
6 for generic manufacturers, who need the samples to
7 develop generic versions of brand products. Brand
8 manufacturers have also begun extending this practice
9 to drugs that are not under the REMS program. For
10 example, several brand manufacturers sell drugs under
11 tight controls through a limited number of pharmacies,
12 which have been used to prevent generic competitors
13 from acquiring samples to conduct bioequivalence tests
14 required for generic drug approval. One generic drug
15 manufacturer recently testified to Congress that it
16 took three years to execute a sample sharing agreement
17 for one drug limited by such restricted distribution
18 system. Through last year, the FDA received more than
19 150 reports from generic manufacturers unable to access
20 drug samples. The misuse of REMS delays timely filing
21 and approval of ANDAs, keeping drug prices higher than
22 they would otherwise be by preventing more cost-

1 effective generic alternatives. One recent study found
2 brand drug manufacturers used REMS programs to thwart
3 competition for \$5.4 billion in sales on 40 drugs.

4 PCMA supports efforts to stop the
5 anticompetitive use of REMS. The House of
6 Representatives is currently considering legislation,
7 the Fair Access for Safe and Timely Generics, or FAST
8 Act, that would make it easier for generic
9 manufacturers to obtain samples.

10 As an example of other ways to encourage brand
11 manufacturers to use REMS programs properly, one would
12 be to condition Medicare Part D coverage on any brand
13 drug on its manufacturer's proper use of REMS. There
14 is already a precedent in statute that brand
15 manufacturers must agree to provide Medicare a 50
16 percent discount in the Part D coverage gap to have
17 their drugs covered. Perhaps requiring an addition to
18 the pledge on the proper use -- an additional pledge on
19 the proper use of REMS programs would give brand
20 manufacturers a strong incentive to stop
21 anticompetitive behavior around REMS. We therefore
22 encourage the FDA and HHS to examine all regulatory or

1 administrative authorities available to limit these
2 kinds of abuses.

3 Second, eliminating pay for delay agreements.
4 As identified in the public notice of this meeting, the
5 drugs described in more than half of all FDA approved
6 ANDAs are never marketed, marketed following a
7 substantial delay, or marketed only intermittently.
8 Brand-name pharmaceutical companies can delay generic
9 competition by agreeing to pay a generic competitor to
10 hold its competing product off the market for a certain
11 period of time. These so-called pay for delay
12 agreements have arisen as part of patent litigation
13 settlement agreements between brand-name and generic
14 pharmaceutical companies. These types of agreements
15 are anticompetitive, and prohibiting them will lower
16 drug costs. The Federal Trade Commission, or FTC,
17 estimates these anticompetitive deals cost consumers
18 and taxpayers \$3.5 billion in higher drug costs every
19 year. PCMA supports efforts to prohibit or
20 significantly restrict such anticompetitive agreements.
21 Numerous proposals have been put forward to do so,
22 including Senate Bill 124, which would have authorized

1 the FTC to initiate proceedings against parties to any
2 agreement resolving or settling a patent infringement
3 claim in connection with the sale of the drug. In the
4 last Congress, the Congressional Budget Office scored
5 such a proposal as saving \$2.9 billion over ten years.

6 Under FDA regulations, when first filers delay
7 entering the market, other generic manufacturers cannot
8 enter, which can make these first filer patent
9 settlement deals particularly harmful to consumers. We
10 encourage the FDA to consider current regulations to
11 the furthest extent it can, to allow for increased
12 competition wherever possible, especially on patent
13 settlements.

14 Third, anticompetitive product adjustments, or
15 evergreening. Drug manufacturers use tactics such as
16 product hopping or evergreening, submitting
17 applications to the FDA for approval of a "new product"
18 that is essentially the same as the original product.
19 Examples can include extended release formulations,
20 combination therapies that combine two existing
21 medications into one pill. These product lifestyle
22 management tactics artificially extend drug exclusivity

1 periods and delay the take-up of lower cost generics.
2 We ask the FDA to continue to work with the Federal
3 Trade Commission, which has argued that such tactics
4 may be anticompetitive and unlawful, and to continue to
5 take actions when drug companies employ unlawful
6 tactics, that delay widespread use of lower generic
7 option, and, two, support plaintiffs who present legal
8 challenges regarding such anticompetitive behaviors.

9 Fourth -- also, as previously mentioned, allow
10 accelerated approval for brand drugs to generate needed
11 competition. The FDA grants accelerated review to new
12 drug applications that address unmet medical needs. We
13 believe unmet medical needs should encompass lack of
14 access when brand products are priced high and face no
15 or little competition. If the price of a drug is so
16 high that a patient who needs it cannot afford it, a
17 concept some call financial toxicity, the patient's
18 medical need is still unmet.

19 Economic data show that additional entrants
20 into a therapeutic class result in lower costs when
21 they generate head to head competition. For example,
22 the second entrant into the breakthrough hepatitis C

1 therapies resulted in price concessions of nearly 50
2 percent from the original manufacturer. As costs fell,
3 health plans offered the drugs to substantially greater
4 populations of patients, thus meeting existing medical
5 needs that had previously been unmet. We believe the
6 FDA should further interpret the Food, Drug and
7 Cosmetic Act in guidance to permit unmet medical need
8 to include unaffordability.

9 Finally, changing biosimilars' naming and
10 labeling practices to better encourage competition.
11 PCMA recommends that the FDA reconsider its current
12 guidance on biosimilars' naming and labeling. The FDA
13 has adopted a guidance on biosimilar naming that
14 requires the use of a nonmeaningful suffix attached to
15 the nonproprietary name. This approach is different
16 than that for small molecule drugs, where no such
17 suffix is used. We believe this confuses patients and
18 clinicians, and can promote the mistaken belief that
19 substitutable products are not. Substitutable
20 biosimilars should bear identical names and labels to
21 their innovator analogs. FDA should revise its
22 approach for biosimilars to be consistent with that for

1 small molecule generic drugs. Such a change is
2 necessary to promote development of a robust
3 biosimilars market.

4 Thank you for the opportunity to be here today
5 in this public forum. PCMA looks forward to working
6 with the agency and other stakeholders to address these
7 important issues.

8 MR. FLANAGAN: Thank you.

9 MS. SCHLAIFER: Thanks.

10 MR. FLANAGAN: Same question that other
11 panelists have asked other presenters. Often
12 reformulation produces a significant therapeutic
13 benefit. Other times it's pejoratively referred to as
14 evergreening. Can you offer additional detail or
15 thoughts?

16 MS. SCHLAIFER: I think as far as -- we don't
17 have official policy on that, but just as a pharmacist,
18 you know, as we've seen things go from tablets to
19 capsules we've seen the addition of aspirin or an
20 antacid to products. I think extended release and
21 sustained release products are definitely an
22 improvement in therapy, but when they happen close to

1 the end of a patent expiration the purpose of that
2 change becomes a little more suspicious.

3 DR. UHL: Okay. So, can I just follow up
4 Keith's question? How would you advise the agency to
5 identify that, or find ways to mitigate that or, you
6 know, something -- I mean, we understand the concern
7 about product hopping or evergreening, whatever --
8 whatever term you want to use.

9 MS. SCHLAIFER: Right.

10 DR. UHL: What advice can you give us, aside
11 from please don't let that happen, to -- in order to
12 help us do our job?

13 MS. SCHLAIFER: Yeah. I think -- that's a
14 great question, and I think as we go and submit our
15 comments to the docket we can definitely provide some
16 specific recommendations. I do think it's -- and it's
17 obviously the challenge that you're trying to address
18 with the question. Is there a substantial improvement
19 in medical need to the patient? You know, definitely I
20 think one where I personally would see a difference is
21 when you're combining two medications that are both on
22 the market -- one is available OTC, that's -- I think a

1 question will -- but, I think as far as what the
2 association's input is, we can go back and submit
3 details on that when we submit comments to the docket.

4 MS. McCASLIN: Good morning. My name is
5 Tiffany McCaslin, and I'm a Senior Policy Analyst at
6 the National Business Group on Health. Our
7 organization represents 413 primarily large employers,
8 including 73 of the Fortune 100, who voluntarily
9 provide group and other employee benefits to over 55
10 million American employees, retirees and their
11 families. We appreciate the opportunity to comment on
12 the administration of the Hatch-Waxman Amendments to
13 the Federal Food, Drug and Cosmetic Act, to ensure the
14 appropriate balance between encouraging innovation in
15 drug development and accelerating the availability of
16 lower cost alternatives to innovator drugs.

17 We agree with the position that the life cycle
18 of a pharmaceutical product as contemplated by the
19 amendments includes a patent for a branded product
20 followed by the expiry of said patent, followed by the
21 entrance of one or multiple generic versions of that
22 product to market, thereby increasing competition and

1 introducing downward pricing pressure on the branded
2 pharmaceutical marketplace. We are very pleased that
3 the agency has taken up this important issue, and
4 within the context of the notice in the federal
5 register our comments will focus on question number 1.

6 Current permissive patent and exclusivity
7 period protocols may unduly delay market entry of lower
8 cost alternatives to brand medications. After a
9 generic or biosimilar is approved by the FDA, in many
10 cases it may still take years for these less expensive
11 medications to come to market, often due to litigation
12 by the manufacturer of the original drug over
13 outstanding legal questions about whether patent
14 protection can be extended.

15 Employers and other members of the public have
16 trouble understanding why this happens. Meaning, how
17 can this claim of protection extend well beyond the
18 original intent of the underlying patent. There can be
19 multiple patents for one product covering different
20 indications, delivery methods and/or combinations of
21 the product. In fact, determining when a patent
22 expires often requires specialized legal expertise.

1 One publication by CDER states that patent and
2 exclusivity are the two most commonly searched terms on
3 the FDA website, underscoring both the complexity and
4 the value of these product protections to drug
5 manufacturers as well as the level of interest from
6 outside stakeholders. Beyond statutory extensions due
7 to delays by the Patent and Trade Office or the FDA,
8 the life of a drug's overall patent protection can be
9 extended by applying for secondary patents through new
10 formulations of the drug, new routes of administration,
11 new indications or uses of the drug in combination with
12 another drug. All of these lead to what we call patent
13 estates.

14 Unfortunately, what we sometimes see is
15 repeated and dubious use of the patent system to extend
16 periods of market exclusivity, which adds to the
17 growing unaffordability and unsustainability of pricing
18 and spending in the prescription drug market. The
19 costs of extended monopolies in the pharmaceutical
20 market are more than just financial. They reduce
21 patient access to needed medications and can serve to
22 threaten further innovation. Therefore, policies that

1 extend patent protection terms or exclusivity periods
2 should be revisited by policymakers and regulators. We
3 have attached an addendum to our comments, which
4 outlines specific patent abuses and other
5 anticompetitive practice in more detail.

6 While these practices do not in effect extend
7 original patents, they do create the patent estates I
8 mentioned earlier, which increase the probability of
9 litigation between brand and generic manufacturers.
10 Additionally, building patent estates tends to run
11 incongruence with the applications for additional
12 market exclusivity from FDA.

13 We have four specific recommendations for
14 policymakers, including eliminate or limit additive
15 patent extensions and exclusivity periods that serve
16 only to extend monopoly power, especially where there
17 is limited or no additional company investment or
18 patient value produced. Develop sound policy that
19 would discourage patent abuses such as evergreening and
20 product hopping. Eliminate pay for delay deals and/or
21 implement penalty provisions for companies that engage
22 in these types of arrangements, and finally reduce the

1 market exclusivity for biologics from 12 to 7 years.

2 Thank you for the opportunity to comment.

3 MR. FLANAGAN: 1 p.m. One hour lunch.

4 Return at 1 p.m., please. Thank you.

5 (Off the record at 12:04 p.m.)

6 (On the record at 1:04 p.m.)

7 MR. FLANAGAN: As with the previous
8 presentations, I'll announce the first speaker but not
9 the subsequent speakers. So, please approach the
10 podium when the slide that lists your name and
11 affiliation appears on the screen. And after your
12 remarks, please remain at the podium to allow the panel
13 an opportunity for questions.

14 Mr. Davis?

15 MR. DAVIS: Great. Thank you, and good
16 afternoon, everyone. On behalf of the Association for
17 Accessible Medicines (AAM), and our members, it's a
18 pleasure to be here today. And I want to start by
19 thanking the FDA and Commissioner Gottlieb for
20 convening today's discussion and for your commitment to
21 maintaining a balance between encouraging innovation in
22 drug development and accelerating the availability of

1 lower cost generic alternatives for America's patients.

2 We particularly appreciate the Commissioner's
3 initiative and leadership in advancing his recently
4 announced Drug Competition Action Plan that he spoke to
5 this morning to address regulatory issues that are
6 impeding competition. AAM is the nation's leading
7 trade association for manufacturers and distributors of
8 generic and biosimilar medications. Our core mission
9 is to improve the lives of patients by advancing timely
10 access to affordable generic and biosimilar therapies.

11 I want to take this opportunity at the
12 beginning to say that we are optimistic -- and there's
13 been discussion this morning about the possible soon
14 reauthorization of the GDUFA program -- and I want to
15 say that we are optimistic about the reauthorization of
16 GDUFA, and I want to thank the FDA for being such a
17 strong and constructive partner throughout the
18 negotiations to get to an agreement that will truly
19 benefit patients. As a result, we urge Congress to
20 swiftly pass this legislation.

21 The Hatch-Waxman Amendments truly represent a
22 model of successful bipartisan public policy. In over

1 its 30-plus year history, the amendments have produced
2 a thriving marketplace in which generic drugs now make
3 up 89 percent of all prescriptions filled in the U.S.
4 market, but account for only 26 percent of total
5 prescription drug costs to the U.S. healthcare system.
6 This has important positive effects on public health,
7 supports greater patient adherence, lower patient
8 abandonment rates, and leads to longer healthier lives.
9 In the request for comments, FDA described the balance
10 between encouraging innovation and accelerating the
11 availability of lower cost generic drugs as "critical
12 to the public health." For the record, the Association
13 for Accessible Medicines could not agree more.

14 There is abundant evidence that the innovation
15 side of this balance has been flourishing. It's only
16 July, and this year FDA has already approved more new
17 molecular entities than it did in all of 2016. And
18 that is terrific news, for everyone. Unfortunately,
19 the competition side of the Hatch-Waxman balance is in
20 jeopardy. This is due to a combination of factors,
21 including a failure of policy to keep pace with
22 changing pharmaceutical market dynamics and the abuse

1 of FDA laws, regulations and policies. While the
2 innovation side of the Hatch-Waxman equilibrium has for
3 decades seen an exponential series of incentives for
4 drug development, things such as additional incentives
5 and exclusivity provisions, additional tools and
6 resources for drug development -- all of which are very
7 important for patient health -- the reality is the
8 access generic side has not received the attention that
9 has been needed. When you combine that with the market
10 realities of today, it reinforces why this hearing and
11 the Commissioner's competition plan are so important.
12 We are submitting more extensive comments to the
13 docket. However, for today I want to focus on the
14 following key points: first, the realities of today's
15 generic drug marketplace; second, the need to prevent
16 gaming and abuse of FDA law, regulation and policies;
17 third, the need to improve the overall efficiency of
18 the generic drug review process; and, lastly, the
19 importance of strong and effective leadership, both
20 here at FDA and from other areas of government and
21 industry, to achieve all of these goals.

22 Starting out, it is very important to

1 understand the current market dynamics that face the
2 generic drug sector. In 2004, FDA published a study
3 showing that a generic drug can cost as little as 20
4 percent of the branded drug, often referred to at that
5 level as commoditized pricing, when eight or more
6 competitors have entered the market. Those days are
7 gone. More recent data suggests that this degree of
8 price erosion, getting to commoditized pricing happens
9 much sooner, often when there are as few as three to
10 four generics in the class. And we heard some of that
11 evidence this morning from several of the researchers.

12 The net effect of this is that it has produced
13 great savings for patients, employers, insurers, the
14 federal government and the states -- \$253 billion in
15 savings in calendar year 2016, alone. Our industry is
16 very proud to be able to deliver these types of savings
17 to the U.S. healthcare system. But -- and as you will
18 hear from several of our members subsequent to me this
19 afternoon -- our side of the pharmaceutical ecosystem
20 faces significant and unique pressures that in many
21 ways distinguish it from the monopolized branded
22 sector. Generic companies face significant

1 consolidation in the wholesale and retail markets,
2 where essentially three wholesalers, three GPOs and
3 three to four retailers each are controlling between 80
4 and 90 percent of their respective markets.

5 We experience wide scale price deflation --
6 not inflation -- frequent supply fluctuations, higher
7 ingredient costs, and increasing regulatory burdens,
8 not to mention some of the barriers to entry that were
9 discussed widely this morning, used to forestall
10 competition. Each of these factors impacts the generic
11 market on a daily basis, including decisions individual
12 manufacturers have to make upon entry and exit
13 decisions. And they are particular acute in low volume
14 markets.

15 When you look at all the challenges I've just
16 outlined you have an even better understanding of why
17 the competition side of the Hatch-Waxman balance is in
18 jeopardy. If you need more proof, then I would suggest
19 to you for the remainder of this afternoon session look
20 at the balance of who is participating in this session
21 in the public hearing. I can assure you, based upon my
22 own professional experience, that if the innovation

1 side of the Hatch-Waxman balance was under any degree
2 of threat to the extent that the generics are, you
3 would see much greater brand company presence here this
4 afternoon.

5 The use of risk evaluation and mitigation
6 systems, or REMS and REMS like programs, and other
7 restricted distribution strategies not required by FDA
8 for patient safety, is not a new phenomenon and has
9 been discussed widely this morning. I would
10 particularly note that Commissioner Gottlieb, in
11 referencing comments today and testifying to Congress
12 recently, has noted the approximately 150 complaints
13 that were submitted to the agency in that regard. It
14 is becoming increasingly clear, if not abundantly
15 clear, that the refusal to provide samples has become
16 primarily about one thing, and one thing only, and that
17 is preventing competition. In 2012, the Senate passed
18 legislation that would have curtailed these practices.
19 But successful lobbying, at the end of the day,
20 ultimately kept it from being enacted.

21 We encourage FDA to take swift action in
22 waiving its requirement to implement a single shared

1 system, when the failure to reach agreement would delay
2 the launch of an otherwise approvable generic
3 competitor. FDA should establish clear, transparent
4 and enforceable timelines for negotiations on a single
5 shared system. Such deadlines, with the understanding
6 that FDA will waive the shared system requirement in
7 the absence of an agreement, will help remove the
8 incentive to prolong the process unnecessarily. But,
9 we also recognize that there is a limit to what FDA can
10 do on its own.

11 As you have heard from other speakers today,
12 we support the fact that Congress needs to take
13 immediate action through the pending bills in the
14 Senate and the House, the CREATES Act and the FAST
15 Generics Act, which are bipartisan legislation -- not
16 often seen today in healthcare -- in the House and the
17 Senate to prevent the misuse of REMS and restricted
18 distributing schemes to delay generic competition.

19 Failure to act in this space will be
20 significant, and it will only encourage further
21 anticompetitive practices to grow, if not addressed. A
22 recent study, and you heard from Alex Brill this

1 morning, estimated that the potential market for
2 products subject to REMS or restricted distribution was
3 worth more than \$20 billion. Abuse of the citizen
4 petition process was also widely discussed this
5 morning. So, in the interest of time I will not go
6 into additional details on that front, other than to
7 say that AAM associates itself with the remarks made by
8 many this morning expressing their concerns on the
9 potential misuse of citizen petitions.

10 In terms of other regulatory priorities,
11 ensuring continuous and consistent transparency and
12 communication between the FDA and the industry is
13 essential to optimize the development, prefilling and
14 review process for generic drugs. It is also important
15 for FDA to address the bioequivalence guidance
16 processes and practices to ensure that applications
17 already under review are not held to shifting standards
18 that may not have clinical relevance to safety and
19 efficacy of a particular medicine.

20 We are very encouraged that the FDA is
21 continuing its focus on improving the processes for
22 approving generic versions of complex drugs in a timely

1 manner, another topic discussed earlier today. Many of
2 today's generic products are scientifically and
3 technically more complex, requiring FDA reviewers to
4 possess more knowledge about new technologies and
5 advances in the drug product manufacturing area. GDUFA
6 II will aid and support this effort as we move forward.

7 And we respectfully encourage the FDA to
8 promptly withdraw its proposed rule supplemental
9 applications proposing labeling changes for approved
10 drugs and biological products which, if enacted, would
11 lead to provider and patient confusion and add costs
12 unnecessarily to the system. FDA is not responsible
13 for all of these issues that I have discussed today.
14 It will require all of us, including payers, the FTC,
15 CMS and other federal agencies, as well as Congress, to
16 play an active role. Even the branded manufacturers in
17 a recent report have publicly talked about in a public
18 relations campaign the importance of incentivizing
19 generic competition. It's time that we all work
20 together to make that happen.

21 Thank you again for holding this hearing.

22 DR. UHL: Thanks, Chip.

1 MR. DAVIS: Sure.

2 DR. UHL: I apologize for arriving late for
3 your presentation. I was dealing with another crisis.
4 Could you elaborate, and maybe not here but in the
5 docket, about AAM's thoughts on BE guidance and BE
6 guidance development and practices? Because I think
7 that would be relatively actionable --

8 MR. DAVIS: Sure.

9 DR. UHL: -- in the short frame -- I mean,
10 the short term.

11 MR. DAVIS: Yes.

12 DR. UHL: Thanks.

13 MR. DAVIS: Dr. Uhl, we will --

14 DR. UHL: If you have ideas right now we're
15 happy to hear, but --

16 MR. DAVIS: Yeah. No, I will -- we will make
17 that as part of our docket submission. I would just
18 say that I think the thing that we've heard, and many
19 of our members will be coming up here, so they may have
20 a perspective on this, is in part because of the
21 regulatory review process and some of the time frames
22 that have shortened under the tail end of GDUFA I and

1 we expect to shorten again under GDUFA II, that
2 sometimes policy would be issued in that area where
3 they were operating under a certain level of
4 understanding and something shifted throughout the
5 process. So, I think the acceleration of timelines
6 will help that, and I think, quite frankly, the level
7 of engagement between the agency and sponsors earlier
8 in the process will also help alleviate that.

9 DR. UHL: And I think what would be helpful
10 is some reflection on the -- there are changes in our
11 understanding of the product, obviously, throughout the
12 product lifecycle that impact our thinking on
13 bioequivalent standards. And so, you know, given
14 industry's experiences how -- you know, how to address
15 that so that we are up to date scientifically and up to
16 date in a regulatory basis on bioequivalence when we're
17 ready to approve a generic.

18 MR. DAVIS: Will do.

19 DR. UHL: Did that make sense?

20 MR. DAVIS: Yes. It did.

21 DR. UHL: Thank you.

22 MS. SIPES: Thanks for your remarks. I had a

1 quick follow-up question for you. One of the topics
2 that you mentioned had to do with factors affecting
3 entry and exit decisions, and you mentioned a number of
4 different factors, including consolidation in the
5 wholesale and retail markets, supply issue, barriers to
6 entry, and others. Could you comment a little bit
7 further on entry and exit decisions with regard to any
8 of those factors? But also, I'm interested in the
9 extent to which you believe companies in the generic
10 market look at the activities of their -- of other
11 generics, and the plans and activities of their other
12 generic competitors.

13 MR. DAVIS: Sure. Just briefly -- and again,
14 this will be, I think, probably a theme that you may
15 hear about from individual manufacturers -- the value
16 proposition in many ways historically, as we all know
17 on the generic side, has been to get to that level of
18 commoditized pricing in the marketplace, whether it was
19 eight to nine, ten competing products a decade ago, or
20 now as soon as three or four -- one of the compounding
21 factors that has impacted that is the consolidation in
22 the buying community, particularly for generic

1 medications. So, if you have three or four major
2 entities that have grown in size and scale through
3 mergers and consolidation within their own sector of
4 the supply chain.

5 It is harder, from simple economics, to see
6 10, 12, 14 different generic manufacturers all
7 competing for the business of three or four large-scale
8 wholesalers or retail pharmacies that are going to
9 control 80 plus percent of their various distribution
10 systems. So, what that ultimately leads to, and one of
11 the concerns that we have, is that if you see
12 additional consolidation -- I'm thinking one of the
13 academic reports this morning they talked about having
14 a small number of companies with very wide-scale
15 portfolios, and then a large number of companies with
16 very small portfolios -- what you've actually seen is
17 an elimination in many ways of some midsized companies,
18 that have either been acquired or ultimately divested
19 into a couple of smaller companies. So, I think it's a
20 marketplace reality that, I -- you know, we are looking
21 at in terms of recognizing the importance of not just
22 competition -- I think that's what you've always heard

1 from the generic sector.

2 We are focused on sustainable competition.
3 How do you get companies that decide early on to file
4 with the FDA, once they file, go to market and then
5 once they're in the market, stay in the market? So,
6 we're going to be -- we're looking at various ideas
7 that -- some of which will have a market impact, some
8 regulatory, some would require legislation that will
9 focus on more creating a sustainable competitive
10 environment moving forward.

11 Thanks.

12 MR. LEICHER: Good afternoon. I'm Bruce
13 Leicher, Senior Vice President, General Counsel,
14 Momenta Pharmaceuticals. Momenta is a biotechnology
15 company engaged in the development of biosimilar and
16 interchangeable biologics, as well as complex generics
17 and novel products. We use innovation to develop new
18 cures and affordable medicine for patients. We want to
19 thank you for scheduling this meeting. We believe
20 there are seven steps the FDA can take today to remove
21 barriers to affordable medicine and promote price
22 competition. Then, the competition will spur

1 innovation and new cures and achieve the balance sought
2 under Hatch-Waxman and the Biosimilar Price Competition
3 and Innovation Act.

4 First, we'd encourage the FDA to promptly hire
5 the staff needed to implement the new user fee
6 agreements with the available carry-over funds. New
7 reforms introduced by GDUFA II and BsUFA II have
8 important innovations. They enhance communication,
9 target review resources, ensure timely meetings that
10 can accelerate development, and use staff more
11 efficiently. But hiring staff is key to their success.

12 Second, the FDA can immediately stop abuses
13 associated with restricted access to reference product
14 and REMS misuse. Today, many reference products are
15 not available to develop affordable medicine. Some
16 brand companies simply refuse to sell their product to
17 generic and biosimilar manufacturers. The timely
18 access to originator product was unrestricted for many
19 years, and understood to be a legal obligation. This
20 time-honored practice is now being thwarted to block
21 development of competitive affordable medicine. And
22 the FDA can fix this problem by issuing a policy

1 confirming that under Hatch-Waxman and the BPCIA it has
2 always been, and is, a condition of originator approval
3 that reference product be sold to generic and
4 biosimilar companies promptly, on commercially
5 reasonable terms, for testing under the regulatory
6 supervision of the FDA.

7 In addition, FDA should work with CMS to
8 implement a policy that makes CMS reimbursement
9 contingent on compliance with that policy. These
10 actions could be taken without legislation.

11 Third, the agency should continue to lead with
12 innovative regulatory science. Advances in science
13 made it possible to develop complex generics without
14 clinical studies, and biosimilars with analytical
15 science and targeted clinical studies. Employing more
16 scientists with analytical expertise and facilitating a
17 science driven flexible approach to review is critical
18 to industry, to attract investment, accelerate
19 development, enhance product quality and make medicine
20 more affordable. Clear guidance that new ideas and
21 innovation are acceptable is key. Rigid 20th century
22 approaches must not slow development of affordable

1 medicine, when innovative 21st century science is
2 available today.

3 Fourth, for interchangeable biologics, issue
4 an explicit policy statement in the Purple Book that an
5 interchangeable biologic may be substituted at the
6 pharmacy without the intervention of a physician.
7 Confirm to CMS that a determination of
8 interchangeability means therapeutic equivalence to the
9 reference product, just as FDA did in the Orange Book.
10 CMS relies on this finding for generic drugs to provide
11 favorable reimbursement and is awaiting guidance from
12 the FDA. The finding is needed to unleash development
13 of more affordable interchangeable biologics.

14 Fifth, adopt a policy that state substitution
15 laws must not conflict with the substitution of
16 interchangeable biologics authorized under the BPCIA.
17 A patchwork of state substitution laws, some of which
18 facilitate substitution and some of which might not,
19 will deter investment in interchangeable biologics. An
20 explicit policy will provide certainty by rendering
21 conflicting laws unenforceable and eliminate the
22 barrier.

1 Sixth, issue a rule completing implementation
2 of the proper name policy for biologics, to make it
3 nondiscriminatory. Today, only biosimilar receive
4 suffixes. Originator products do not. This is very
5 confusing to physicians and patients, and creates a
6 barrier to biosimilar adoption by suggesting
7 biosimilars are different. The naming policy must be
8 fixed to apply equally to all biologics as intended.

9 Finally, allocate application review resources
10 toward truly novel cures, generics and biosimilars.
11 Reduce resources assigned to incremental life extension
12 products. Routine formulation changes or convenience
13 features of existing products lead to product hopping
14 and do not warrant the same priority as new cures or
15 affordable medicine. Patients deserve new cures, and
16 patients deserve affordable medicine.

17 In addition, promptly deny citizen petitions
18 that seek to delay or prevent generic biosimilars, as
19 others spoke about earlier today. Thank you for the
20 opportunity to present our views, and we look forward
21 to supplementing them with our written comments.

22 MS. TOUFANIAN: Thank you, Bruce. Could you

1 expand on your observation that currently it's your
2 perception that there are inappropriate rigid
3 scientific requirements that are outdated?

4 MR. LEICHER: I don't believe there are
5 inappropriately rigid restrictions. I believe that
6 there would be an increase in the flexibility and
7 enhancement by just having a positive statement that
8 facilitated the use of new ideas and new techniques.
9 It's natural for all of us to rely on the way we've
10 historically done things to do something. And a
11 positive statement from leadership that it's okay to
12 think about new ideas I think would make a real
13 difference.

14 MS. TOUFANIAN: Thank you.

15 MS. DICKINSON: Thanks for your presentation.
16 So, I have a question, as a lawyer. Is it your view
17 that FDA already has the authority to effectively
18 preempt state substitution laws?

19 MR. LEICHER: I -- it is -- that is my view.
20 My view is that Hatch-Waxman had nothing in the statute
21 that said you could substitute a generic drug at the
22 pharmacy, if you go -- if you study the statute. The

1 BPCIA specifically includes in the language of the
2 statute that an interchangeable biologic may be
3 substituted at the pharmacy without the intervention of
4 a physician. That's express language. And I would
5 think any law that's passed that conflicts with that
6 language would be superseded under the supremacy
7 clause.

8 MS. DICKINSON: On the biosimilars front --

9 MR. LEICHER: Yeah.

10 MS. DICKINSON: -- there isn't comparable
11 language under the Hatch-Waxman.

12 MR. LEICHER: That's correct. And it's not
13 needed under the Hatch-Waxman. I'm talking about
14 interchangeable biologics.

15 MS. DICKINSON: Be interesting if you --
16 obviously, this is outside the scope of this particular
17 meeting. But, to the extent that you have a full legal
18 analysis, it would be interesting to hear.

19 MR. LEICHER: No. I'd be happy to. I know
20 we've shared some of that with Maryll a couple of years
21 ago, And I can include that with the comments.

22 DR. UHL: Could you elaborate a little bit

1 more on your comment about how resources are utilized
2 under application review, and could you also provide
3 some feedback about how reallocating resources also
4 makes sure that we meet all the deliverables under the
5 different UFAs?

6 MR. LEICHER: No. And I, and -- absolutely,
7 and I think -- a comment was made earlier that I think
8 might provide some -- a good suggestion, that -- as I
9 listened to it, which was if you look at applications
10 that involve convenience or incremental change that
11 occurred during the end of patent life, it would be
12 rational, I would think, for the FDA to conclude that
13 there is a presumption that that's not -- that that's
14 incremental. And then the applicant could perhaps have
15 a burden of showing that there really is a benefit.

16 And if it's not -- if it truly is incremental,
17 then I would think it should not get the same priority
18 as something that's inventing a new cure for patients
19 or that's delivering affordable medicine to patients.
20 And there's got to be a way to get through the question
21 that was asked earlier, on how to tease out what's
22 incremental and what's really delivering value. And I

1 think the time at which it occurs actually is a pretty
2 good place to start. If it's really not that
3 innovative and it only occurs at the end of patent
4 life, one would -- why didn't it happen sooner. And I
5 think that's one way to look at it.

6 And you could pick a time frame in which you might
7 pick that presumption tied to whether it would be
8 handled and approved in sufficient time for a generics
9 company to actually develop a generic to that
10 successive version before patent life -- the original
11 patent life expires.

12 DR. UHL: Can I just follow that up, then?
13 With a -- are you proposing that the agency then modify
14 its regulations for how we regulate prior approval
15 supplements to NDAs? Because at this point in time,
16 those types of assessments -- such as you said benefit
17 is not written into the regulations. So, are you
18 proposing that there's a regulation change?

19 MR. LEICHER: I'm not sure I'm proposing a
20 specific solution. I'm raising an idea that I think
21 would deserve conversation to find the -- a way to
22 think about it. But the -- I think where I think

1 you'll find consensus is that there are a lot of
2 resources that have been devoted, as was discussed
3 earlier, of the agency to products which may or may not
4 be delivering the same value to patients.

5 MR. FLANAGAN: Thanks, Bruce.

6 MR. LEICHER: Thank you.

7 MR. FLANAGAN: We're going to have staff try
8 to turn up the mic a little bit over there. And
9 presenters, remember to speak directly into the mic,
10 please.

11 MR. BOYER: I've never been known not to be
12 able to be heard. But, we'll go for it. Good
13 afternoon, and thank you for having us all here today.
14 My name is Andy Boyer. I am President and CEO of North
15 America Generics, for Teva Pharmaceuticals. Teva
16 Pharmaceuticals is a global company that delivers high
17 quality patient-centric health care solutions used by
18 approximately 200 million patients in 100 markets every
19 day.

20 We are the world's largest generic medicines
21 producer, with a portfolio of more than 1,800 molecules
22 in a wide range of generic products in nearly every

1 therapeutic category. In the U.S. alone, Teva generic
2 medicines are used to fill one out of every six
3 prescriptions. In specialty medicines, Teva has the
4 world leading innovative treatment for multiple
5 sclerosis, as well as late-stage development programs
6 for other disorders of the central nervous system,
7 including movement disorders, migraine, pain, and
8 neurodegenerative conditions, as well as a broad
9 portfolio of respiratory products.

10 There is no doubt, as my colleagues have
11 mentioned, that a balanced implementation of Hatch-
12 Waxman is imperative. As a manufacturer of innovative
13 and generic medicines, we recognize the importance of
14 new treatments and ensuring access to existing
15 therapies. Both are essential. We applaud the
16 agency's focus on improving generic processes,
17 eliminating the backlog of applications, removing
18 unjustified barriers to competition, and speeding
19 generic approvals. These are practical solutions to
20 improve the existing regulatory framework.

21 Working hand in hand with the FDA on novel
22 scientific issues and the logistics of reviewing

1 thousands of applications is no easy task. However, it
2 is certainly one that is vital not only to our industry
3 but to the patients that we serve.

4 In a relatively short period of time, the
5 generic industry has undergone major changes. In 1997,
6 there were 335 ANDAs submitted to the agency. This
7 number has grown significantly over time, peaking at
8 1,473 submitted to the agency in 2014. In 2000,
9 generic medicines represented 47 percent of the
10 approximately 3 billion total prescriptions dispensed
11 in the U.S. Today, they account of 89 percent of the
12 over 3.9 billion prescriptions dispensed.

13 Our engagement with the agency has also
14 changed. As we find ourselves at the conclusion of our
15 first generic drug user fee agreement, we are eagerly
16 awaiting the passage of legislation to solidify our
17 second agreement. The agency and our industry
18 representatives that work diligently to improve
19 communications, address key issue areas and increase
20 funding to fulfill our shared mission of getting safe
21 and effective medicines to patients. We must continue
22 to build upon our successes, improve the quality of our

1 interactions, and make changes that reflect the growth
2 and trends in the marketplace.

3 Communications from the FDA inform the
4 planning and launch preparations inside our companies.
5 In this dynamic marketplace, greater transparency of
6 when an ANDA is granted exclusivity or when exclusivity
7 is forfeited would allow companies to make the
8 necessary decisions to enter the marketplace on the
9 earliest possible date. Currently, it is often unknown
10 for months or even years whether or not a first filer
11 has run afoul of a forfeiture event under the statute.
12 And approval letters can be ambiguous at times. During
13 this time, subsequent filers are unable to prepare for
14 launch, delaying competition.

15 It is also unclear in the context of 505(b)(2)
16 applications what the conditions of approval are for
17 any given therapy. This also can create a great deal
18 of uncertainty, as to whether exclusivity will block a
19 similar 505(b)(2) product within the same therapeutic
20 class. This uncertainty leads to costly litigation,
21 and hinders the introduction of these competitive
22 therapies into the market.

1 We also look to the FDA's Orange Book to
2 inform many of our business decisions. Better Orange
3 Book practices, such as real time listing of NDAs and
4 exclusivity periods for brand medicines, and listing of
5 the therapeutic equivalence ratings for (b)(2)s,
6 concurrent with approval, will improve industry
7 knowledge and market competition. Improving the
8 regulatory process should include eliminating any undue
9 burdens on industry. Regulation that is more
10 disruptive than beneficial will only hinder progress.

11 We look forward to working with the FDA to
12 identify opportunities to fulfill this policy goal, and
13 identify areas where regulatory reduction makes sense.
14 Take, for example, the requirement to provide paper
15 labeling and inserts with our medicines. Modernizing
16 labeling regulations to allow for e-labeling would
17 reduce the cost of medicines and improve the speed and
18 accuracy of information for patients. These paper
19 labels are a waste of time and resources. More often
20 than not, they are discarded by our customers and never
21 viewed in their paper form by the intended audience --
22 physicians.

1 I am joined today by Gregg DeRosa, our Global
2 VP of generic, clinical and product development, and
3 Scott Tomsy, our Vice President of Regulatory for
4 North America. Along with their teams, they work
5 closely with the FDA and on a day-to-day basis will
6 offer more real examples of the improvements that can
7 be made to advance the development, review and approval
8 of generic medicines.

9 Thank you for your time.

10 MR. DeROSA: Good afternoon. My name is
11 Gregg DeRosa, and I'm the Vice President of Global
12 Generic R&D -- Clinical R&D. I represent Teva
13 Pharmaceuticals. And today, there are a couple of
14 items I'd like to discuss. First, I'd like to discuss
15 recent changes to both general and product specific
16 guidances. And two, a little bit about abuse deterrent
17 opioids.

18 As science advances and new medicines and
19 formulations enter the market, FDA must face the
20 challenge of establishing sameness and bioequivalence
21 for complex generic products. These are policy
22 decisions that must be made and clearly communicated to

1 generic applicant sponsors to support our submissions.
2 Changing requirements of both general and product
3 specific guidances after the agency has received an
4 ANDA for review is a significant challenge.

5 This has resulted in significant delays in
6 approvals of generic products, requiring generic
7 manufacturers to repeat formerly accepted tests as well
8 as conduct additional tests. For example, the issuance
9 of the draft guidance on assessing adhesion with
10 transdermal delivery systems and topical patches for
11 ANDAs, which was issued in 2016, has drastically
12 changed the dynamic of measuring transdermal adhesion.
13 All previously submitted ANDAs that utilize the
14 criteria in the previous guidance must now meet very
15 different and more stringent criteria. This clearly
16 has and will continue to delay many products that were
17 tested under the old criteria. Changes to product
18 specific guidances, specifically for certain immediate
19 release locally acting products, have completely
20 redefined the submission requirements, and will
21 inevitably delay generic entry. We can appreciate and
22 support such changes when the changes are made to

1 enhance the safety of a product. However, such changes
2 should be the exception, not the norm, and should not
3 hold up products that have been under agency review.

4 The other topic I'd like to highlight here
5 today is the need for definitive criteria for the
6 approval of generic AD opioids. Teva is committed to
7 ensuring the highest standard of safety and quality to
8 develop generic abuse deterrent pain therapies. We
9 believe the FDA should require all opioids, short
10 acting and extended release, to have abuse deterrent
11 properties and require generic versions to have abuse
12 deterrent properties that are no less abuse deterrent
13 but not necessarily identical to the brand. We believe
14 that for a generic ADF to be considered AB to a branded
15 ADF product, the generic must meet the traditional
16 standard of bioequivalence, qualifying for the same
17 abuse deterrent labeling, possess the same abuse
18 deterrent characteristics, such as physical/chemical
19 barrier, agonist/antagonist combination, and have no
20 less of an abuse deterrent effect than that of the
21 brand, as determined by the FDA.

22 Teva recognizes that there are several

1 variations of ADF products and technologies, and with
2 these variations comes different testing requirements.
3 With that said, we believe the closer the generic
4 formulation is to that of the brand, the nature and
5 grade of excipients, manufacturing process of the
6 generic product to that of the branded product, the
7 more heavily weighted the FDA's recommendations may be
8 toward in vitro testing only. Conversely, the greater
9 the degree or significance of difference between the
10 branded and generic products, with regard to ADF
11 technology, the more likely that additional in vitro,
12 pharmacokinetic and perhaps human abuse liability
13 studies may be warranted. Since the public meetings on
14 this topic in 2014 and 2016, the FDA has approved ten
15 branded ADF opioids. However, to date, there are still
16 no generic ADF approved opioids available to the
17 American public. This poses serious issues, including
18 lack of access to needed affordable medicines for
19 patients with pain. Generic manufacturers can help
20 provide a solution to the opioid problem in the U.S.,
21 but need the FDA to provide the regulatory pathway for
22 approval of a generic ADF.

1 Industry has made several attempts to obtain
2 product specific bioequivalence guidance from the
3 agency, as this guidance is necessary for the generic
4 manufacturer to have a clear understanding of the
5 testing required to make an approvable generic ADF.
6 Teva urges the FDA to provide product specific guidance
7 for the ten currently approved ADF opioids, and follow
8 suit in an expeditious manner as new ADF products come
9 to the market. This will help ensure a level playing
10 field and allow the generic industry to help mitigate
11 the risk of misuse and abuse while providing affordable
12 pain options for our patients.

13 The generic industry can also help provide a
14 solution to the innovator's problems with the FDA
15 requirements of demonstrating post-market effectiveness
16 in terms of ADF effectiveness. To date, the FDA has
17 not awarded any of the ten branded products with post-
18 marketing effectiveness claims, category IV, as drug
19 utilization has been too low to conduct satisfactory
20 epidemiological studies. Further to this, Blue Cross
21 Blue Shield has indicated they will not reimburse for
22 ADFs until the FDA awards innovators with that category

1 IV claim.

2 This clearly poses a serious conundrum. Once
3 generic ADF medicines become available, drug
4 utilization will likely increase, thereby increasing
5 the denominator needed to better assess the post-
6 marketing effect of ADF medicines, medicines for the
7 FDA and for the payer community. Teva welcomes the
8 opportunity to discuss these important issues with the
9 FDA, and help the FDA further the development of
10 generic guidance for generic ADF products.

11 Thank you.

12 DR. UHL: So, I'm curious if you could
13 potentially expand a bit more about the bioequivalence.
14 You know, as a new drug is approved, an NDA is
15 approved, there are frequently some post-marketing
16 requirements for that particular product. So, for
17 example, food effect studies, drug/drug combination,
18 things of that sort that help us better understand the
19 performance of that drug product. So, how would you,
20 Teva, or you, the generic industry, advise us on how we
21 can best deal with evolving information and knowledge
22 about a product so that when we -- when a generic comes

1 in or a generic is being reviewed or the generic is
2 approved that it meets that level of knowledge and
3 understanding of the product?

4 MR. DeROSA: Well, I think to your point -- I
5 mean, perhaps when a product is submitted it should be
6 viewed in the light of the guidance that it was
7 submitted under. Once that guidance changes, I think a
8 post-marketing commitment makes a lot of sense. But,
9 not delaying approval.

10 DR. UHL: So, I actually am referring to
11 post-marketing commitments per the NDA.

12 MR. DeROSA: Okay.

13 DR. UHL: So, while those are being reviewed
14 a lot -- that may happen concurrently with ANDAs in
15 house. So, how are we supposed to apply the, you know,
16 standards of -- understanding of the knowledge of a
17 valid product.

18 MR. DeROSA: Specifically, what are you
19 referring to? Are you referring to my comments about
20 overall bioequivalence, or more about the generic ADFs?

21 DR. UHL: Not about generic ADFs. I'm
22 talking more generally about -- you talked about BE

1 requirements and BE guidance. And so, I'm just trying
2 to elicit more feedback about how do we handle the
3 evolution of product knowledge while we're making
4 regulatory decisions.

5 MR. DeROSA: Well, I think specifically when
6 I think about -- let's use the transdermal products,
7 for an example. I realize that you -- there's been
8 some knowledge gained over the years on how to assess
9 certain aspects of a formulation. But, when we are
10 actually submitting those products, we're utilizing the
11 guidance that you've given us as the time. Right. And
12 so, we are designing our entire bioequivalence program
13 based on that guidance.

14 So, we've submitted it. It sits with the
15 agency for a year or two. And then all of a sudden
16 there's a new guidance, and that guidance changes the
17 paradigm completely. That puts us at a significant
18 disadvantage, and I think perhaps there is some post-
19 marketing commitment that the generics could make to
20 meet these guidances as our scientific knowledge
21 evolves. But it's very difficult for us to have
22 designed an entire program based on a guidance that now

1 no longer really is enforced. And we have no control.

2 MR. FLANAGAN: Thank you.

3 MR. DeROSA: Thank you.

4 MR. TOMSKY: Good afternoon. My name is
5 Scott Tomsy, and I am Vice President for Regulatory
6 Affairs for Teva Pharmaceuticals North America
7 Generics. My colleagues have raised several important
8 topics today. I would like to talk in more detail
9 about some of the process and approval challenges we
10 face. I thank FDA for this opportunity to have these
11 important discussions, and look forward to continuing
12 to work with them to speed safe and effective generic
13 medicines to patients. Commissioner Gottlieb's
14 commitment to the approval of complex generic drugs
15 builds upon the agreement with FDA during user fee
16 negotiations, to work closely with ANDA sponsors and
17 address outstanding policy and scientific issues that
18 have caused delays. Further transparency and
19 communication between industry and FDA will foster
20 higher quality, right first time submissions that can
21 be approved in fewer review cycles, increasing access
22 to more affordable generic medicines. And we are

1 encouraged by the comments by Commissioner Gottlieb
2 earlier today, about the impending MAPP as well as
3 draft guidance to be issued by the end of this year.

4 One of the most important elements of the
5 GDUFA II agreement is the bridging of GDUFA I and pre-
6 GDUFA I files, and their inclusion in the GDUFA II
7 metrics, guaranteeing goal dates for every file after
8 October 1st of this year. Many existing applications
9 have been under review for years, and I urge the agency
10 to increase communication and transparency for these
11 applications so FDA can take action in the form of an
12 approval, rather than a CRL on these files in the
13 coming months. It is these files which present one of
14 the greatest challenges for our industry. Over the
15 years, FDA continues to change the goalposts, and what
16 may have been acceptable in the past to approve ANDAs
17 is no longer the standard for many applications that
18 were submitted years ago, Approved products are often
19 not required to meet these revised requirements, while
20 unapproved applications which met the requirements at
21 the time of submission and matched those applications
22 that have been approved are now penalized and held to

1 these new standards. These pending ANDAs, as a result,
2 go through multiple review cycles, often requiring new
3 batches to be manufactured, new studies to be
4 conducted. These applications are taking away from
5 resources from both FDA as well as industry, leading to
6 less access and competition in the market, and
7 therefore should only be held to new standards when it
8 is absolutely necessary for safety reasons.

9 When guidance has changed for safety and
10 efficacy reasons and a product approved as an ANDA is
11 no longer considered equivalent to its reference
12 product, and loses its AB rating, FDA must take swift
13 action to have these products withdrawn. Allowing
14 these products to remain on the market and substituted
15 undermine the confidence of generic medicines.

16 Another key process and approval challenge we
17 face is gaining approval of more complex medicines.
18 There is currently a lack of cooperation and
19 communication between the centers at the FDA. We are
20 experiencing delays, for example, with combination
21 products. Many of these products were submitted prior
22 to enactment of GDUFA, and therefore currently do not

1 have goal dates. Rather, they have target action
2 dates. And while some of these products may be a
3 priority for CDER, they are not necessarily a priority
4 for CDRH. We've experienced significant delays for
5 such combinations products which require a consult from
6 CDRH.

7 My colleague Gregg touched upon abuse
8 deterrent opioid products, and for these medicines and
9 others that have potentially serious associated risks,
10 REMS are needed. To reduce the overall burden on the
11 healthcare system, industry working groups are formed
12 for multiple manufacturers to agree on a shared REMS
13 strategy. In instances where this -- there is
14 difficulty in coming to an agreement with the working
15 group, FDA has to intervene more quickly. Lack of
16 agreement to shared REMS should not result in the delay
17 of generics to the market. I also echo the concerns
18 raised here today by others that REMS restricted access
19 programs should not be used to prevent generic
20 manufacturers from obtaining samples for bioequivalence
21 testing. This is clearly not the intention of these
22 programs.

1 Finally, for some products that aren't
2 suitable for submission under the ANDA pathway,
3 organizations can achieve the approval of a
4 therapeutically equivalent medicine through the
5 505(b)(2) process. In these instances, it's imperative
6 that the equivalence rating be assigned at the time of
7 approval of these applications, rather than the current
8 process in delaying the listing in the Orange Book of
9 the designation until a committee can meet to assess
10 the therapeutic equivalence rating appropriateness.
11 This prevents substitution, limits competition and
12 increases the cost to the healthcare system. Take, for
13 example, the injectable product azacitidine. Teva
14 submitted a 505(b)(2) application that was approved in
15 April of 2016. However, the therapeutic equivalence
16 rating was not published in the Orange Book until April
17 of 2017, one year later.

18 Thank you for your time today. Teva will be
19 submitting written comments to discuss all these points
20 in more detail, as well as points on the proposals to
21 improve FDA's decision-making and communication
22 practices, consistency of approval standards over time,

1 ending the maintenance of withdrawn applications,
2 faster approval of complex products, reducing
3 regulation and proposed regulations that present undue
4 burden on manufacturers. Thank you.

5 MS. TOUFANIAN: Thank you, Scott. One of the
6 things that -- I won't ask you to do a regulatory
7 analysis on the spot, but I would request of you and
8 your colleague who spoke previously with regards to
9 your request about the appropriate standard to apply to
10 an ANDA on submission when the bioequivalence or other
11 recommendations for approval change -- I would request
12 part of that analysis be in the context of the
13 regulatory and statutory requirements. For example,
14 our bioequivalence regulations require we use the most
15 accurate, sensitive and reproducible method in
16 evaluating bioequivalence. So, as part of your
17 analysis I invite you to address the regs themselves,
18 in that regard.

19 MR. TOMSKY: Thank you.

20 MR. FLANAGAN: Scott, Gregg, Andrew, thank
21 you for this specificity.

22 MR. TOMSKY: Thank you.

1 MR. DUCKER: Good afternoon. My name is John
2 Ducker. I'm the President and Chief Executive Officer
3 of Fresenius Kabi USA. Thank you for the opportunity
4 to provide comments on the important subject of
5 ensuring that Hatch-Waxman continues to provide
6 sustainable competition for generic medicines in the
7 United States. My point of view is informed by
8 Fresenius Kabi being a global healthcare company with
9 more than 30,000 employees around the world,
10 specializing in lifesaving medicines and technologies
11 for infusion, transfusion and clinical nutrition. In
12 the U.S., we are a leading provider of generic sterile
13 injectable medicines. Our portfolio consists of more
14 than 400 injectable drugs administered predominantly in
15 hospitals and other clinical settings. These include
16 chemotherapeutics, analgesics, and anesthetics used in
17 surgery and a wide range of anti-infective and critical
18 care drugs. We manufacturer these products in three
19 states -- Illinois, New York, and North Carolina -- as
20 well as several plants outside the U.S., and we employ
21 more than 2,750 people in the U.S. in manufacturing,
22 R&D and distribution.

1 When the FDA announced this meeting, it asked
2 for input from the public concerning how best to
3 preserve the balance Congress intended with Hatch-
4 Waxman. We agree with Commissioner Gottlieb that the
5 balance between encouraging innovation in drug
6 development and accelerating the availability of lower
7 cost alternatives to innovator drugs needs to be
8 preserved for the benefit of public health.
9 Availability of lower cost medicines is important.
10 Sustained availability of lower cost medicines is
11 critically important.

12 We all know that the use of generic medicines
13 reduces healthcare costs. We also know that many do
14 not fully understand or appreciate how the generic
15 marketplace works. Our hope is that today's meeting
16 and the steps announced by the Commissioner will help
17 policymakers gain a better understanding of how the
18 generic marketplace works, to the benefit of patients.
19 I would now like to address comments to some of the
20 specific questions FDA posed prior to this meeting.
21 Firstly, exclusivity periods. Generally, the 180-day
22 exclusivity afforded to first Paragraph IV ANDA holder

1 has stimulated the process of bringing generics to
2 market earlier than otherwise would be likely. There
3 are, however, disincentives in the forfeiture
4 provisions for late ANDA filers, following a first
5 filers patent settlement, that allows the parking of
6 exclusivity, which prevents second filers from
7 attaining approval 180 days later, and this should be
8 addressed to promote further competition in the
9 marketplace.

10 Turning to innovator drug product labeling, as
11 you know the Office of Generic Drugs practice requires
12 ANDA labeling to be exactly the same as the reference
13 listed drug at the time of approval. When changes are
14 made to the reference listed drug's labeling during the
15 final stages of ANDA approval, that approval can be
16 delayed by several months while the ANDA labeling is
17 updated. FDA should allow for post-approval
18 commitments for the labeling changes rather than
19 requiring the label to be updated prior to approval,
20 unless there is a significant and immediate safety risk
21 associated with the labeling revision. In our view,
22 the FDA could -- should consider that a post-approval

1 commitment from the ANDA holder generally provides no
2 more risk than the RLD itself, because inventory of the
3 reference drug, carrying the old label, will persist in
4 the marketplace for several months.

5 Additionally, there are still numerous citizen
6 petitions filed by brand companies regarding protected
7 indications. This is generally done when the generic
8 approvals are imminent, and the request is made to FDA
9 for so-called safety reasons to block the approval of
10 ANDAs that don't include the innovator's protected
11 language in the labeling. In most cases, this is
12 clearly a delay tactic, and there are numerous examples
13 of FDA's denial of these petitions. We believe FDA
14 should address this abuse of the citizen petition
15 process, either in guidance or regulation.

16 I would also like to comment on post approval
17 changes to innovator drug products, such as
18 reformulations. The practice of making minor
19 formulation changes and then obtaining a patent is a
20 common practice by the reference list drug holder to
21 continue market exclusivity. At the time the FDA
22 approves these formulation changes, FDA should also

1 make a public determination about the reason for the
2 withdrawal of the previous formulation -- safety or
3 efficacy. Requiring ANDA applicants to file citizen
4 petitions for such a determination is not an effective
5 of FDA or industry resources, and only serves to delay
6 competition. These determinations are best made during
7 the review of the formulation, and not several months
8 or years later.

9 Dr. Woodcock talked about wanting to
10 understand the reasons for lack of competition in some
11 cases. So, let me turn to marketplace dynamics and
12 incentives. The competition created by multiple
13 generics entering a market has been demonstrated to
14 cause prices to fall dramatically. However, less
15 efficient manufacturers or those receiving an ANDA
16 approval several months after generic market formation
17 may decide not to launch or to withdraw their product
18 from the marketplace because margins have turned
19 negative. So, competition initially has a beneficial
20 impact on prices, but when prices are driven too low in
21 a commodity market, like generic medicines, competition
22 falls away.

1 Remember that many generic drugs sell for a
2 few cents per dose, and unlike branded medicines have
3 very slim margins. As a point of reference, in 2016
4 Fresenius Kabi's average selling price across our
5 entire portfolio was \$5.09 per unit, about what some of
6 us here paid for our Starbucks latte on the way in.
7 Remember that we only market sterile injectable drugs
8 for use in acute care settings -- not oral solids. A
9 healthy sustainable generic marketplace requires
10 pricing power to be in balance between buyers and
11 sellers or manufacturers. This balance has been
12 disturbed by the tremendous consolidation that has
13 occurred amongst buyers, namely group purchasing
14 organizations on the acute side of the healthcare
15 system and retail pharmacy wholesaler alliances on the
16 retail side. There are, in effect, three major buyers
17 in both the retail and acute hospital markets, and each
18 prefers to list only a single generic version of a
19 particular drug. This increasingly means there is only
20 room for three manufacturers in the market. This
21 increases the risk of drug shortages, because the
22 number of manufacturers of any one product may be

1 limited.

2 You may also be aware that generic drug
3 manufacturers take a very modest share of the profit in
4 the generic pharmaceutical supply chain. A recent
5 study by the independent USC Schaeffer Center for
6 Health Policy and Economics showed that for every \$100
7 paid for a generic drug, manufacturing costs represent
8 \$18 and the generic manufacturer typically makes
9 another \$18 to offset their development and
10 distribution costs. The remaining \$64 goes to others
11 in the supply chain, specifically pharmacies,
12 wholesalers, insurers and pharmacy benefit managers. I
13 would ask you to reflect on whether these downstream
14 profits are appropriate in the context of the current
15 concerns about drug pricing.

16 Good competition must also be fair
17 competition, and that means FDA must take steps to
18 ensure consistent compliance inspection standards are
19 adopted across all facilities supplying the United
20 States, whether here or overseas. I do not believe
21 this is the case today.

22 And finally, FDA asked are there market niches

1 where the Hatch-Waxman Amendments' incentives to
2 develop an ANDA are insufficient. For marketed
3 unapproved products, there is no exclusivity awarded
4 for bringing the product through the approval process.
5 The only exclusivity is that which results by default
6 for the time it takes a competitor to get an ANDA
7 approved. These products being on the market for so
8 many years rarely offer any new patent opportunities,
9 so there is little reward for all of the financial and
10 R&D resources expended in filing an ANDA and bringing
11 it to approval. FDA should consider an exclusivity
12 period equivalent to a new chemical entity.

13 So, thank you for the opportunity to speak on
14 behalf of my company, on behalf of patients who benefit
15 from access to affordable medicines. I believe that
16 the generic pharmaceutical industry shares many of the
17 same objectives with Commissioner Gottlieb and the
18 agency, and as a board member of AAM I would welcome a
19 more transparent and regular dialogue with FDA so we
20 can get things done together. Thank you.

21 MS. DICKINSON: Hi. You made one assertion,
22 and I wonder if it's backed up with any studies. And

1 that is the extent to which 180-day exclusivity is a
2 motivator for companies to enter into the marketplace -
3 - to provide an adequate incentive. Has AAM or are you
4 aware of other studies that have been done to support
5 that, that survey, the extent to which otherwise risky
6 product development might be undertaken with the
7 promise of exclusivity?

8 MR. DUCKER: Are you talking about the first
9 filing Paragraph IV ANDAs?

10 MS. DICKINSON: Yes. 180 day -- the promise
11 of 180 day.

12 MR. DUCKER: Yeah. Okay. It's how the
13 industry works. It's the only way we make money. We
14 don't make money unless we're first to market, and we
15 take advantage of that initial steep price curve. When
16 the market is commoditized, none of us are making much
17 money. We wouldn't exist as companies if it were not
18 for the 180-day exclusivity. We don't need to do a
19 survey. I mean, we could have a show of hands here
20 from every manufacturer --

21 MS. DICKINSON: I can imagine. I can
22 imagine.

1 MR. DUCKER: -- in the room, I promise you
2 you'll get the same answer.

3 MS. DICKINSON: And is there a -- have there
4 been studies of the extent to which the first -- that
5 exclusivity period is actually enjoyed, in the sense
6 that the first -- a first ANDA holder actually launches
7 its product and is able to be the sole or one of a
8 limited number of marketers during that time period, as
9 opposed to the exclusivity being forfeited or otherwise
10 lost?

11 MR. DUCKER: I'm not aware of any studies in
12 that particular situation. No.

13 MS. DICKINSON: Okay. Thank you.

14 DR. UHL: John, maybe I misheard you. You
15 said something about there being three major buyers,
16 and that they each only want one -- that's one generic
17 of any particular. Can you explain --

18 MR. DUCKER: That's correct.

19 DR. UHL: -- the dynamics around that, and
20 the -- or, maybe that's not you to explain and it's
21 more --

22 MR. DUCKER: Oh, sure. Look, on the hospital

1 side where we operate most the -- most of the contracts
2 -- most of the RFPs that GPO puts out are for sole
3 awards. They're going to award their entire volume --
4 and remember the purchase power they wield, it -- you
5 know, in the case of Visian it's nearly 50 percent of
6 the entire hospital volume in the U.S., and they're
7 going to award one supplier a sole award. So, you
8 know, somebody wins. And there are two other GPOs that
9 carry any significance in the United States. They're
10 each making sole awards -- predominantly sole awards.
11 Not exclusively, but predominantly sole awards.

12 If there are five generics and there are only
13 three places at the table, two of you don't have
14 anywhere to market your product at all. That's the
15 dynamics. It's happening exactly the same way in the
16 retail wholesale side. The retailers only want to
17 stock one generic, and the brand. They don't want to
18 have their shelf space, you know, taken up with five
19 different generic versions of vancomycin. So, the same
20 dynamic is happening.

21 You've had such enormous consolidation on the
22 buy side, that's why you're getting consolidation on

1 the sell side. That's why manufacturers are having to
2 consolidate, because there's no room at the table for
3 so many manufacturers. It's just simple economics.

4 Thank you.

5 MS. McCLINTIC COATES: Good afternoon. My
6 name is Marcie McClintic Coates, and I'm the Head of
7 Global Policy at Mylan. With a 55-year history in
8 working closely with FDA, Mylan appreciates the
9 opportunity to provide comments to the agency's
10 consideration today on this very important topic.
11 Mylan has the -- one of the generic industry's broadest
12 and most diverse portfolios, selling more than 635
13 products in the United States at an average sales price
14 of 25 cents a dose across all major disease areas.
15 Mylan provides more than 10 percent of all generics in
16 the United States, and has more than 200 ANDAs pending
17 with FDA, 45 of which are first generics.

18 Ensuring that the Hatch-Waxman system works to
19 its full capacity to expedite access to low cost
20 generics could not come at a more important time. Our
21 nation's healthcare system is at an important
22 inflection point, as we all know, given significant

1 recent changes for how medicines are paid. For
2 example, patients have historically had two deductibles
3 associated with their insurance coverage, one for
4 medical services, such as hospital visits, and another
5 for pharmaceuticals. Today, patients usually have only
6 one consolidated deductible, and an increasing number
7 of consumers are moving to higher deductible health
8 plans. In fact, Kaiser Foundation estimates that at
9 least 51 percent of covered workers must personally
10 cover their out of pocket expenses on medicines until
11 they reach their deductible of \$1,000.

12 With even more patients expected to move to
13 high deductible health plans in the near future, the
14 availability of more affordable generic alternatives
15 has never been more important. Based on the recent IMS
16 report released in June, a generic prescription on
17 average, on a price per prescription basis, is \$30,
18 compared to a brand product which is \$667. About 90
19 percent of generic copays are under \$20 for patients.
20 So, those are tremendous savings. Every day earlier
21 that a generic can come to market makes a clear
22 difference to U.S. patients.

1 It is with this in mind that we share some
2 general considerations to shape the thinking on this
3 important topic, and look forward to supplementing the
4 docket with additional examples. As the Supreme Court,
5 has noted, it is the meaningfully different and special
6 regulation of generics, under Hatch-Waxman, that has
7 allowed the "generic drug market to expand, bringing
8 more drugs more quickly and cheaply to the public." We
9 believe two longstanding bedrock principles have
10 historically contributed to the success of the generic
11 program at FDA, and the agency's implementation of this
12 critical law.

13 The first is FDA's commitment to carrying out
14 the unique Hatch-Waxman Act of getting generic drugs
15 into the hands of patients by approving generics on the
16 earliest day that a legal barrier to approval no longer
17 exists, and two, FDA's strong reliance on science to
18 continuously improve and evolve the agency's thinking.
19 This effort has resulted in generics representing
20 almost 90 percent of prescriptions dispensed, but only
21 26 percent of the overall cost of prescribed medicine.
22 In the last decade, generics have saved the U.S.

1 healthcare system more than \$1.6 trillion. Mylan is
2 proud to have provided more than \$180 billion of
3 savings in our generic portfolio over the last decade.

4 This success, though, of the generic program
5 has led to shared challenges, as we know, for both FDA
6 and industry, due to the number of generic drug
7 applications submitted. To meet these challenges, FDA
8 embarked on a significant effort to build a sustainable
9 generic program under GDUFA, and it has been a
10 significant effort, we might add. And just like any
11 startup program, while there have been growing pains on
12 both sides of the equation, I think the foundational
13 work built is worth noting by the FDA staff.

14 With GDUFA I soon reaching its end, the agency
15 now shifts its working with industry to reduce the
16 number of redo cycles necessary to approval, and expand
17 its focus on complex generics under GDUFA II. We
18 applaud Dr. Gottlieb's interest in accelerating the
19 availability and approval of complex generic products.
20 As the recent IMS report found, complex and specialty
21 products make up 32 percent of prescription drug spend
22 today, but only represent 1 percent of the total

1 prescriptions written. That means the 10 percent of
2 generic utilization that is not happening today is of
3 extreme value to the U.S. marketplace and to patients
4 who today do not have affordable generic alternatives.
5 Continuing to find ways to provide more interactive
6 iterative science-based exchange, both before and after
7 submission of a complex generic, will help to encourage
8 companies like Mylan who engages in the billions of
9 dollars of research and development necessary to bring
10 these products to market, providing greater
11 predictability and earlier access to medicine.

12 Additionally, continuing to prioritize more
13 timely generic approvals, including first generics, is
14 equally critical, as the agency identifies ways to
15 improve access. Recognizing the importance of the
16 first generic approval, and the significant investment
17 that is needed to develop a generic product, and engage
18 in costly litigation needed to challenge questionable
19 brand patents, Congress provided incentive in the form
20 of 180-day exclusivity. FDA's continued prioritization
21 of first generics, even as it works to further increase
22 competition through additional approvals, is vital to

1 maintaining the Hatch-Waxman balance and incentivizing
2 generic drug development in areas where consumers lack
3 generic alternatives. And I would add that I concur
4 with the statements made by John Ducker regarding the
5 criticality of 180-day exclusivity. As 1984 has
6 continued to evolve, that's incentive -- the one
7 incentive that we do have. It's vital, especially as
8 the expectations for continuous improvement in
9 manufacturing and quality and supply chain, the ability
10 during that 180 period is more important than ever.

11 The approval of just one generic can
12 significantly drive down the prices of medicine at
13 generic market formulation, and most often triggers, as
14 we all have seen, the immediate entry of an authorized
15 generic as well, upon that first generic approval. A
16 robust Hatch-Waxman framework also requires that brand
17 companies be prevented from manipulating the system to
18 unduly extend their patent or exclusivity protections
19 and otherwise delay the onset of generic competition.
20 For example, as we've heard many times, the well-
21 intentioned REMS requirements are constantly delaying
22 the onset of generic competition. This is an abuse,

1 unfortunately, we've had more than a decade of
2 experience in fighting against, and it's still not
3 solved for. While we've all taken several steps to
4 mitigate some of this, abuses continue to exist. These
5 and other maneuvers by brand companies significantly
6 delay and in some cases, foreclose consumer access to
7 competition, through late-stage label changes, guidance
8 comments that seek to impose unnecessary new
9 requirements on generics are just a few examples we
10 face. We look forward to working with FDA and AAM and
11 others in industry to combat these efforts.

12 Lastly, as the agency considers ways to
13 improve access to generics, additional opportunities
14 exist for more efficient practices. Moving forward
15 from -- to e-labeling from paper-based labeling is a
16 great example of an effort that would reduce
17 unnecessary regulatory and operational burden. With
18 the increasing use of electronic health information
19 systems, the availability of prescribing information in
20 an electronic format can add further efficiencies to
21 the healthcare system, in addition to reducing
22 environmental costs and increasing patient safety

1 through the availability of real time updates to drug
2 labeling.

3 In closing, these are just a few
4 considerations and we look forward to supplementing the
5 docket with additional detail regarding the questions
6 raise in the federal register notice, as well as
7 working with AAM on areas of common industry interest,
8 including many of the topics raised in just this
9 afternoon's discussion on guidance and label changes.
10 We agree it would be helpful to determine whether such
11 changes truly represent an imminent risk to public
12 health, when evaluating whether a post-approval
13 commitment can be made as changes are made later on,
14 either to labels or guidances.

15 Thank you again for the opportunity to speak
16 today, as well as comments to the docket. We are very
17 encouraged by the opening by Dr. Gottlieb. Right out
18 of the gate, some of the comments on the new MAPP as
19 well -- both for industry and for FDA. I think that
20 was a goal we asked for at the beginning of GDUFA I
21 negotiations. I think the agency said that was a
22 little premature. Looking back, I think it was. Now

1 is the right time. It's great to set that standard.
2 That's a nice surprise, to hear that coming out. I
3 think it's going to go a long way in getting us to the
4 first cycle rate that we're wanting to get at, and it's
5 overdue for generics.

6 Look forward to any questions you may have.

7 MS. SIPES: Thank you for your presentation.
8 I had a quick question for you on your point about
9 post-marketing commitments related to labeling changes.

10 MS. McCLINTIC COATES: Sure.

11 MS. SIPES: Could you say a little bit more
12 about the range of labeling changes that you think
13 could be addressed in that fashion?

14 MS. McCLINTIC COATES: Sure. I think that
15 the -- you know, obviously, the statute came out and
16 provided some relief for late stage label changes.
17 But, as that is written it's pretty narrow in the very
18 circumstance in which that can apply. And a lot of
19 those abuses, I will say, have been curbed and we've
20 been able to point to that statute for help. But
21 whether it's label changes or guidance changes or the
22 like, you know, it's part of that iterative sort of

1 science evaluation of whether something is a must have
2 or a nice to have, in terms of right now versus post-
3 approval. Are those changes that the brand is
4 withdrawing product from the market to get into their
5 marketplace, or allowing to have that current version
6 on the marketplace and then supplementing with it, and
7 so forth.

8 A lot of times especially toward the end this
9 can add a lot of time, and days really matter in terms
10 of access. Days can matter in the form of if it's a
11 new formulation that the brand has switched to from the
12 original formulation, and you're trying to get out
13 there. Or it may be a difference of completely
14 reprinting entire batches, which is at additional cost.
15 The agency has in limited circumstances applied some
16 discretion. We think there's just opportunity to
17 revisit that, and possibly looking at that language as
18 well to see if that could be expanded also.
19 Fortunately, it's an area where I do think a lot of
20 improvement has happened, and we should acknowledge
21 that. But abuses do still exist.

22 Thank you.

1 MR. KRISHNAN: Hi. Good afternoon. My name
2 is Kiran Krishnan. I'm the Senior Vice President for
3 Global Regulatory Affairs at Apotex. I'm here to
4 present Apotex's perspective on steps that can be taken
5 to administer the Hatch-Waxman Act in a manner that
6 better achieves Congress's goal of striking an
7 appropriate balance between spurring innovation in the
8 pharmaceutical marketplace and increasing patient
9 access to quality, affordable generic medicines.

10 As successful as the Act has been, since its
11 enactment, it has and continues to be routinely gamed
12 in numerous ways to delay generic competition at great
13 cost to the public. I would like to thank Commissioner
14 Gottlieb, Dr. Woodcock, and Dr. Uhl and the OGD team
15 for holding this hearing. Apotex acknowledges that the
16 agency has taken significant steps to streamline the
17 generic drug review process, and to the best of its
18 ability to remove the roadblocks impeding generic drug
19 approvals.

20 Apotex would like to highlight some additional
21 steps the agency and Congress should take to further
22 increase public access to generic drugs. Apotex will

1 provide very detailed comments to the dockets, but
2 here, I am highlighting some of the essential elements.

3 First one is around the exclusivity structure.
4 Apotex believes that the current 180-day exclusivity
5 structure undermines more timely generic competition,
6 by granting the award solely to the first applicant to
7 file an NDA with the Paragraph IV certification. Under
8 this system, subsequent filers have no incentive to
9 continue patent fights that could lead to earlier
10 competition if the subsequent filer were to knock out a
11 patent that the first filer has left in place in a
12 settlement. If the subsequent filer were to win, its
13 competitor would be the beneficiary of that victory.
14 The first filer would be permitted to launch upon the
15 subsequent filer's victory. Despite being the party
16 responsible for opening the market to generic
17 competition, that subsequent filer would only be
18 permitted to enter the market after the first filer ran
19 its exclusivity. To promote earlier generic
20 competition, the Hatch-Waxman exclusivity structure
21 should be changed to grant exclusivity right to
22 companies who win the patent challenges in addition to

1 ones who are first to submit the ANDA with the PIV
2 certification.

3 To be sure, Apotex fully supports the right of
4 generic companies to settle Hatch-Waxman patent
5 challenges, because we don't believe the settlement in
6 itself is a problem. We believe the fact that because
7 somebody can settle in part the exclusivity, that's the
8 problem. And that can be resolved if there can be
9 amendments made to the Hatch-Waxman Act to allow a
10 subsequent filer to fight out and win the patent
11 litigation, and then enable that person to come to
12 market.

13 The other aspect that I wanted to focus today
14 is on product labeling and other product changes. The
15 RLD holders slow down the process of ANDA approvals by
16 introducing last-minute labeling changes and other
17 formulation changes prior to ANDA approval that do not
18 make the original or the most recent R&D less safe or
19 effective. Example, addition of a sprinkle labeling to
20 the product. The product itself has been approved for
21 over six years. When the 30 month stay for the generic
22 comes -- is -- it's coming along, the RLD holder tries

1 to get an approval for a sprinkle indication for that
2 product. And then it actually creates a problem for
3 the generic holder, because now they have to repeat a
4 sprinkle study. This is just one of the examples, but
5 there are many more examples where the RLD holders make
6 labeling updates. The recent approvals of the generics
7 for Abilify, generics for Gleevec, have -- are classic
8 examples which are well-known to the agency where the
9 brand holders game the system.

10 Apotex would also like to focus agency's
11 attention on the patent listing process. RLD holders
12 continue to manipulate the use codes, because they have
13 not been standardized, even for products with similar
14 uses. The FDA should review and enforce more
15 standardized use codes that conform to the identified
16 text in the product labeling and patent claims, and
17 publish carve-out language where applicable.

18 In addition, Apotex would also like to request
19 the agency or provide agency few comments to consider
20 as it relates to streamlining the ANDA review process.
21 A lot has been spoken about the bioequivalence guidance
22 as a moving target. This in itself is a challenge when

1 -- for global companies like Apotex and many others
2 that submit these applications to a lot of
3 jurisdictions, including the FDA, doing the same study
4 that was done for purpose of submission to the FDA.
5 What we find is while the other regulators approve this
6 application in the -- because when we kind of develop a
7 dossier, it's a global dossier. It doesn't -- we don't
8 develop a dossier that is specific for U.S. Now with
9 the new stability requirement, we develop a global
10 dossier. And the studies that are conducted are in
11 many instances the same kind of studies that apply for
12 multiple jurisdictions. But what happens is when the
13 FDA changes its requirements, it is -- we have incur
14 more time and, in some cases, like -- which was, again,
15 highlighted earlier, the original NDA would have been
16 submitted with one metabolite, or the parent compound.
17 And then the agency comes back and asks us to monitor
18 another metabolite. In those instances, we do not even
19 have access to those plasma samples, so we have to --
20 or, we don't have -- we have to -- or, they probably
21 wouldn't enough shelf life. So, you have to end up
22 running another biostudy. It all adds up to the cost.

1 And also, I would like to highlight here on
2 the drug shortage items, Apotex would like to appeal
3 the agency on the drug shortage items to work with the
4 sponsors to ensure that there is a process to rapidly
5 review where there could be a phone technical
6 discussion and not -- we have seen instances where drug
7 shortage items are put into the same bucket as a
8 standard ANDA in terms of its review requirements, and
9 in terms of the screening requirements. So, Apotex
10 would urge agency to consider a different set of
11 screening requirements and review requirements for drug
12 shortage items to ensure that there is rapid approval.

13 And lastly, Apotex will also request the
14 agency to -- in the ANDA review process for the older
15 applications, there -- that go through an endorsement
16 phase, we've seen applications that sit in an
17 endorsement phase for a long period of time. So, there
18 has to be -- FDA should streamline this process by
19 providing a maximum response time for endorsement
20 phase, either it's for an approval or a CR letter, and
21 should set time frames of not more than 30 days.

22 Lastly, I do concur with all the comments made

1 today on the REMS. So -- because a lot of comments
2 have been made today, Apotex will submit its comment to
3 the docket. Apotex does support the CREATES Act and
4 the FAST Generics Act, as we believe that these offer
5 bipartisan solution for addressing the problem.

6 Thanks.

7 MR. FLANAGAN: Kiran, I'm sorry, my pen
8 couldn't keep up with your presentation. Thank you for
9 the specificity, and concision. You said -- on the
10 first item, you said the settlement is not the problem.

11 MR. KRISHNAN: Yes.

12 MR. FLANAGAN: And then my notes say blank
13 equals the problem. Can you expand on what the problem
14 is?

15 MR. KRISHNAN: So, what I mean by that is the
16 settlement in itself is not a problem. The fact that
17 there is no incentive -- if I'm a subsequent filer, I
18 have no incentive to go and fight a patent challenge.
19 Because if I'm able to do it, if then it's -- then what
20 happens is you as the agency can approve it. Right
21 now, you cannot approve an ANDA application, because
22 there is obviously -- or, even if you approve an ANDA

1 application that -- they can park their exclusivity.

2 But you cannot approve a subsequent ANDA application
3 because the exclusivity is parked.

4 So, all that Apotex is trying to request is to
5 -- a process to amend possibly the Hatch-Waxman Act
6 wherein the subsequent filer that is there will have
7 the ability to fight the patent challenge and will be
8 able to have a position possibly that is different than
9 the first filer, and be able to get a favorable verdict
10 from the court. As a result of which, it would force
11 the -- right now there are provisions where it forces
12 the first filer to launch within 70 days.

13 But the part of the problem is it -- you have
14 to get a ruling from a federal circuit that cannot be
15 appealed. So, we -- all we're saying is we don't have
16 to go through that kind of process, but we want to go
17 through a process where you -- being a subsequent
18 filer, if you're able to get a favorable decision, if
19 the agency can approve the subsequent filer then that
20 creates competition. That actually -- in that case,
21 settlement is not the problem.

22 MR. FLANAGAN: Got it.

1 DR. UHL: Kiran, I have a hand cramp because
2 of how quickly you were talking. But --

3 MR. KRISHNAN: Yeah. I just --

4 DR. UHL: -- you did mention --

5 MR. KRISHNAN: -- had five minutes, so --

6 DR. UHL: -- towards the end drug shortage.

7 MR. KRISHNAN: Yes.

8 DR. UHL: And you said that we should
9 consider different review or screening requirements.
10 Can you expand upon that? What your thinking is?

11 MR. KRISHNAN: Yes.

12 DR. UHL: How many -- and if you have even
13 deeper thoughts about that, to submit to the docket.

14 MR. KRISHNAN: Sure.

15 DR. UHL: I would love to hear what your
16 thinking is.

17 MR. KRISHNAN: Sure. So, right now there is
18 a standardized requirement for ANDA screening process.
19 An applicant should come in with six months of
20 stability at accelerated room temperature conditions.
21 The DMF has had to have undergone a complete
22 assessment, and there are all these standard

1 requirements. We appreciate that, and we follow that
2 for every other ANDA.

3 But drug shortage is a different scenario.
4 So, what we're saying is the agency should consider a
5 mechanism by which you don't have to do a six-month
6 stability at the time that we submit the application.
7 Where -- because there were times when applicants who
8 were submitting with three months of data. We
9 understand, we've now moved on, we are in the six-month
10 era.

11 But, then for drug shortage items all we're
12 requesting is that the agency can consider accepting
13 applications with three months of data, and as it
14 relates to the DMF reviews or the screening of the
15 DMFs, a commitment from the ANDA holder that -- and the
16 DMF holder that we will resolve all inquiries during
17 the review process. Because some of these
18 applications, Dr. Uhl, you have to appreciate, are for
19 items for which you can't find people who submit DMFs.
20 So, some of these are newer players who are trying to
21 submit DMFs. So, it's going to take them some time to
22 get to the standards of documentation that is the

1 expectation of the agency.

2 So, all that we're trying to say is if there's
3 a mechanism for these drug shortage items, where we
4 have a more condensed screening process, and as far as
5 the review process is concerned if there is an
6 opportunity for more -- what -- discussions or post-
7 approval commitments on some of the aspects, so you can
8 enhance and move quickly to get the product to the
9 market. But, again, as -- to your point, we do want
10 to make sure that the products that are coming out are
11 safe and effective and they are high quality products.

12 DR. UHL: So, by screening do you mean filing
13 review --

14 MR. KRISHNAN: Yes.

15 DR. UHL: -- or are you meaning something
16 different?

17 MR. KRISHNAN: Filing review.

18 DR. UHL: Okay. Thank you.

19 MR. FLANAGAN: Any other questions? Thanks,
20 Kiran.

21 MR. KRISHNAN: Thank you.

22 MS. EDWARDS: Good afternoon. My name is

1 Candis Edwards, and I'm Senior VP of Regulatory Affairs
2 at Amneal Pharmaceuticals. First of all, I want to
3 thank Dr. Gottlieb and the FDA for convening the
4 public hearing, so that we can examine the delicate
5 balance between brand drug development and timely
6 access to the -- by the public to more affordable
7 generic medicines, which is embodied in the Hatch-
8 Waxman Amendment.

9 As a bit of a background, Amneal
10 Pharmaceuticals is a privately-owned U.S. company
11 started about 15 years ago, by two brothers, Chintu and
12 Chirag Patel, and today is one of the fastest growing
13 global generic developers. We rank seventh -- I
14 believe the seventh largest generic manufacturer in the
15 U.S., and we have a diversified portfolio of over 100
16 products. We employ approximately 5,000 employees
17 globally, and we're in the process of bringing about
18 approximately 200 more products to the market within
19 the next couple of years, where we'll be touching on
20 all dosage forms in the generic arena.

21 So, what I'd like to do is present just a
22 couple of concerns, possibly using some examples,

1 around the issues that we're here to discuss today.
2 The first topic I'd like to talk about is the impact of
3 changes to -- post-approval changes to formulations and
4 how that could impact approvability of ANDAs, and I'll
5 give an example here. So, we have -- and what we
6 believe is that this is an area where they might be
7 able to look at some administrative relief. So, most
8 of my talk is going to be focused around where can we
9 get some administrative relief, as opposed to statutory
10 relief, which is probably easier to implement.

11 So, this example I have -- we have an
12 injectable product. There's no generic equivalent.
13 The original formulation was discontinued after FDA
14 approved the newer formulation. And it was only minor
15 changes to the formulation. We believed that the
16 changes were some minor quantitative changes. There
17 was no impact to safety or efficacy, and that was
18 evidenced by the fact that the product still -- the
19 original product continued to remain on the market. It
20 was discontinued, but there's no recall or anything of
21 that nature. So, that led us to believe it was just an
22 issue where the brand, again, was making a decision to

1 move the product because there wasn't a generic
2 approved.

3 In this instance, Amneal was very close to
4 approval. And then there was also a citizen petition
5 which was issued on the product, and it requested that
6 the agency make a determination as to whether the
7 product was withdrawn for reasons of safety or
8 efficacy. So, to date the petition hasn't been
9 resolved and what's happened is the combination of the
10 petition and the formulation changes now creating some
11 policy issues for the agency, and there's been no
12 decision or delayed decision on the approvability of
13 the product.

14 So, in order to rectify some of these
15 unintentional product approval delays, we believe that
16 the agency should have some procedures in place where
17 we assure that you comply with the statutory
18 requirements to address these blocking petitions in a
19 more timely fashion. We also believe that it will be
20 beneficial to the patients if there's some expedited
21 review process in place to resolve those petitions that
22 block generic competition when a product is single

1 source, and results in some unintended monopoly by the
2 brand product.

3 Also, FDA may want to consider clear and
4 transparent review process for the petitions, similar
5 to that associated with some other user fee programs
6 and include timelines for review and some mechanism for
7 the petitioner to be updated to understand the impact
8 of when that petition will be addressed.

9 Another area of concern for Amneal is a policy
10 of revising bioequivalence requirements. There have
11 been several speakers that have addressed that issue.
12 And the concern is that these changes are made and the
13 ANDA holders, we don't have any idea or any
14 instructions because we've already fought -- we've
15 conducted studies in the preexisting conditions. The
16 changes occurred during midcycle review, and they can
17 definitely impact the approvability of the ANDA if the
18 FDA comes to a decision that because of the change in
19 the guidance the study has to be repeated.

20 We understand that if the change impacts
21 safety and efficacy, yes, this study needs to be
22 repeated. That's a different issue. But there's some

1 changes -- simply a study design, we've had a recent
2 one changed from normal healthy volunteers to patients,
3 and probably that change might have been made for
4 safety reasons, in conducting future studies. So, the
5 study has already been conducted. It's safe, and it
6 meets the requirements. So, you know, what -- there's
7 a big question mark for us, are we going to end up with
8 a complete response that says, well, the guidance
9 changed so your study is no longer acceptable. So,
10 that comes to the idea of transparency and
11 understanding when these changes are going to impact
12 our approvability, and not necessarily waiting until
13 that ten-month goal date to say -- to get that letter,
14 when in the meantime, if indeed it was determined it
15 did affect approvability, we would have used that ten
16 month period during the agency's review or whatever
17 time that's left to repeat the study, and be prepared
18 when that action was taken on the application.

19 So, what we're asking here is the agency
20 implement an administrative policy that will allow
21 review and approval of BE studies conducted under
22 preexisting requirements when changes to the

1 requirements are made midcycle and the changes do not
2 impact safety or efficacy of the product. Also, that
3 you consider the impact of the products that are
4 already on the market, not only how those changes
5 impact the pending ANDAs but possibly there might need
6 to be a need for those products that are already on the
7 market to repeat some studies in some reasonable amount
8 of time as well. So, that would be, then, something
9 that we address there.

10 Another concern, first of all, regarding the
11 REMS program has affected us significantly. We applaud
12 Commissioner Gottlieb's recent emphasis related to
13 REMS, and we understand the need for the REMS program
14 for distribution of dangerous drugs. We believe the
15 REMS serves a compelling public value. However, the
16 companies frequently relying on REMS as lifecycle
17 management strategy to block or delay generic market
18 entry.

19 There are two concerns, one related to FDA's
20 review of protocols in issuance of a letter of
21 authorization to the brand to sell the samples to the
22 generic company, and one related to the issuance of

1 waivers. So, with regard to -- we understand that
2 there is no sample, there's not going to be a generic.
3 So, the first area of brand abuse is in the delay or
4 request for unreasonable requirement for the sale of
5 samples to the generic -- in our experience, when a
6 drug is covered by REMS, the brand often refuses to
7 sell samples, either directly, or they request
8 unreasonable contract terms when they're dictated
9 through this letter to do so.

10 So, just as an example, starting in 2015 we
11 submitted approximately seven requests for REMS
12 protocol reviews, and the timelines were pretty long.
13 First cycle review was 9 to 23 months. Second cycle
14 review, because we had to make changes and resubmit,
15 took about two to seven months. So, we're looking at -
16 - we looked at an average of about 18 months for the
17 agency just to review the protocols. And then to date,
18 out of all of these products we've had two letters sent
19 to brand companies and one which has resulted in actual
20 product acquisition.

21 So, you can see that we think that the process
22 needs to be addressed. We would ask that the agency

1 implement an administrative guideline on FDA response
2 timelines for review of the protocols, under the
3 current guidance, in perhaps three to six months,
4 something that would be more timely. And then we also
5 say that once the generic is developed, we are -- we
6 have a problem with the impact of stalled negotiations
7 with certain brand companies when we're working
8 together toward a single REMS program.

9 So, another ask we have is that is it possible
10 maybe to put some timelines, just as regards to the
11 waiver. So, if we were to put a timeline to it, in
12 effect say, okay, if you negotiated, let's say, for six
13 months with the brand, you were not successful, then
14 there would automatically be a waiver granted without
15 further delay. And then we could move on in the
16 process, have us some prescribed timeline there.

17 Another area that we ask the agency to
18 consider an administrative policy is possibly adding a
19 category or product classification in the Orange Book
20 that might allow for the use of a similar RLD that is
21 approved, let's say, under an EU jurisdiction, in a
22 conduct of a BE study. So, more so the reference

1 standard, especially when there might be barrier to
2 obtaining that product in the U.S. market. And we can
3 provide evidence and confirmation that the two products
4 are actually the same products, just marketed in
5 different -- or, approved in different jurisdictions
6 but manufactured as one product. So, for example, if
7 the product is manufactured by a company and approved
8 in the EU and the U.S. and the generic company is able
9 to prove that, then the foreign product might be able
10 to be eligible for use as a reference standard, just
11 possibly for conducting the BE studies whereby we still
12 would have our basis for approval, which is the
13 statutory requirement for approval. So, we're talking
14 about a common reference standard, possibly, by
15 possibly recognizing EU approved products as a common
16 recognition of EU and U.S. products.

17 So, I thank you for the opportunity to present
18 our views. We do intend to provide further comments to
19 the docket. And any questions, I'm available. Thank
20 you.

21 MR. CALTRIDER: I had some slides. Are there
22 slides -- there we go. I'm Steve Caltrider. I'm

1 Deputy General Patent Counsel at Eli Lilly and Company.
2 Lilly is a 141-year-old innovator. Our company has
3 been in the business of discovering, developing and
4 manufacturing new medicines, particularly in diabetes
5 and oncology. We've had recent success in diabetes and
6 oncology. We've also done a tremendous amount of
7 research in Alzheimer's, where we've been researching
8 for 25 years and without yet developing a new medicine.
9 But we continue our efforts.

10 None of what we and other innovators of new
11 medicines accomplish would be possible without strong
12 intellectual property protections. I will focus my
13 remarks today on the first question raised in the FDA
14 federal register notice. This involves the question,
15 and the quote from Senator Hatch underscores its
16 importance of how well the balance struck in 1984 is
17 working for patients and for innovators and generic
18 firms. In this law review article, Senator Hatch goes
19 on to say that if the law and its administration can be
20 improved, it should, and that is why we're here today.

21 Much has been written about Hatch-Waxman, and
22 it's fair to say Justice Scalia noted that the statute

1 is not exactly easy to read. Federal District Judge
2 Roger Titus made a more pointed comment than Justice
3 Scalia.

4 Despite its complexities, the statute, most
5 would agree, however, that Hatch-Waxman has been one of
6 the most successful healthcare related laws ever
7 enacted. The substantial savings generated by Hatch-
8 Waxman, as identified by Dr. Woodcock, 1.46 trillion
9 from 2005 to 2015, sometimes gets underappreciated in
10 the debate over reforming the healthcare system.

11 I want to focus particularly on the segment of
12 the market that makes generic copies possible in the
13 first place -- pioneering drugs. Pioneering drugs are
14 the innovation that treats the unmet medical needs --
15 the innovation that sustains the branded pharmaceutical
16 industry and the innovation that the generic industry
17 relies upon to sustain its business model when the
18 patents expire. Simply stated, without an NDA there's
19 not an ANDA. A healthcare system without innovation
20 fails all stakeholders, most importantly patients
21 waiting for cures. The next few slides are from a
22 peer-reviewed paper coauthored by a subgroup of experts

1 convened by the Institute of Medicine. The purpose of
2 the group was to identify the scientific and other
3 barriers to making advances to address the many complex
4 and debilitating nervous system related diseases, such
5 as Alzheimer's.

6 The first observation that I would like to
7 point out, that was made by the coauthors, is that the
8 law is patent-centric. That is, useable patent life is
9 the core incentive to justify the cost and the risk of
10 the investment in CNS drug research. It is also
11 noteworthy that since Hatch-Waxman was enacted in 1984,
12 the U.S. as part of the obligations under the GATT
13 Treaty has moved from a patent term of 17 years from
14 issuance to 20 years from filing. This change in law
15 is significant, as the patent clock starts running
16 earlier. In disease states, such as neuroscience
17 diseases, in this study, that have longer preclinical
18 and clinical development cycles, the incentive
19 contemplated by the 1984 act is significantly shorter
20 than the 14 years originally conceived. It's critical
21 to recognize that there is no causal link between
22 patent ability and FDA approvability. Most patented

1 molecules fall by the wayside during the development
2 process. To state the obvious, the patentability of a
3 new drug doesn't contribute to whether the drug is
4 sufficiently safe and effective to become a drug. It
5 is an irrelevant consideration to the underlying
6 science. But yet, it is too often the controlling
7 consideration. An unpatented molecule could, as a
8 matter of science, be both safe and effective in
9 treating a disease, but it will never been developed as
10 a drug. There are inadequate incentives to do so with
11 the patent-centric focus of Hatch-Waxman.

12 One of the effects of the limitations or caps
13 on Hatch-Waxman patent term restoration is that
14 products which may require longer clinical trials, such
15 as neuroscience trials, are not encouraged. Several
16 questions can be raised about the caps. If 14 years is
17 the period necessary to support innovation, the cost
18 which has increased substantially since 1984, why cap
19 restoration at five years? What is the benefit and
20 justification for a five-year cap? Why should a day in
21 clinical trials deserve only half the patent term
22 restoration of a day in NDA review? Why doesn't the

1 time spent in animal and other preclinical studies
2 deserve any patent term restoration?

3 In order to amplify the points, I've just
4 made, I will refer to a 2013 study by three academic
5 researchers from highly respected institutions -- Eric
6 Budish from the University of Chicago, Ben Roin from
7 the Harvard Law School, who is now joined by a third
8 coauthor, Heidi Williams at MIT. The study is titled
9 and raises important questions -- "Do fixed patent
10 terms distort innovation?"

11 I encourage FDA and other stakeholders to
12 review this study that analyzed over 46,000 cancer
13 clinical trials that took place between 1973 and 2010.
14 The authors examined empirical evidence and drew a
15 number of conclusions on how the IP system affected the
16 cancer clinical development pipeline. A central
17 finding of the study is the observation that cancer R&D
18 has been decidedly skewed toward end-stage cancers.
19 The authors suggest this distortion is due in part to
20 the rules of the patent system. In the opinion of the
21 authors of this study, this is due to the fact that all
22 things equal it takes less time to conduct chemical

1 research on these types of conditions than earlier
2 stage cancers. In general, the longer the trials the
3 shorter the effective post-patent life.

4 One of the points that the authors make is
5 that the current system gives little incentive for
6 development of preventative agents, such as potential
7 prostate cancer vaccines, because the clinical trials
8 would need to last longer than the life of the patent.
9 The data on this graph raises questions about whether
10 the current system is providing the right development
11 pipeline in terms of public health.

12 One conclusion of this study is Hatch-Waxman
13 is directionally correct in restoring patent term, but
14 the suggestion to policymakers is that Hatch-Waxman
15 does not go far enough. As you can see, the
16 recommendation is that there ought to be
17 reconsideration to more directly align the patent term
18 with the date of FDA approval. Hatch-Waxman goes part
19 of the way, but because of the five-year cap and other
20 provisions it is patent-centric and skews R&D
21 investment. I highly recommend all stakeholders to
22 review the two publications that I just outlined. It

1 may be time to think outside the box and reexamine some
2 of the very basic IP rules of Hatch-Waxman. This was
3 certainly done in the case of biologics, where the 12-
4 year data protection period was created in acts to make
5 the law less patent-centric. There have been other
6 proposals advanced by patient organizations on the
7 Hill, and by such leaders as Senator Hatch, to create
8 greater IP incentives that will drive more research
9 investment toward unmet medical needs.

10 I've already discussed how the exclusivity
11 periods set out in the Act have resulted in skewing
12 research and development to be patent-centric. I'd
13 like to briefly comment on the data period for new
14 clinical indications. Due to developments in the law,
15 induced infringement, the FDA practice of skinny
16 labeling, and generic substitution, the exclusivity
17 period, data package or patent exclusivity falls well
18 short. In my opinion, the incentive contemplated by
19 the Act for new clinical indications has really never
20 been realized.

21 You really aren't able to discuss the delicate
22 balance set out in the Act without considering broader

1 considerations. I want to turn briefly to this
2 additional context. Under the current law, the
3 litigation framework set out in Hatch-Waxman is not the
4 end of the story. The America Invents Act introduced a
5 new way to challenge patents at the Patent and
6 Trademark Office. A patent can be fully litigated and
7 upheld by the federal district court, and by the
8 federal circuit court of appeals, through the Hatch-
9 Waxman mechanism, and then the patent can be subject to
10 further litigation before the patent trials and appeals
11 board -- the PTAB, in a proceeding called inter partes
12 review.

13 In 2016, nearly 70 percent invalidity rate was
14 reported for patents reaching final decision before the
15 PTAB, and only 15 percent of the patents have all
16 claims that survived the proceeding. Imagine any
17 endeavor with a 70 percent defect rate. This has been
18 a major disruption to the balance in Hatch-Waxman.
19 This is a complicated system, and people debate whether
20 the invalidity rate should be measured by patent or by
21 claim. There are also complex explanations for this
22 dynamic. But I think it's fair to say the disruption

1 to innovators that rely on their investment of hundreds
2 of millions of dollars, only to find these same patents
3 are ruled invalid later by the same agency that issued
4 the patents in the first place, such a defect weight
5 will continue to only skew the system to be further
6 patent-centric.

7 Thank you for the opportunity to discuss these
8 issues with you today. I recognize that virtually all
9 of what I've said is beyond the purview of the FDA to
10 address through its existing regulatory authority.
11 Your federal register notice announcement calls for
12 discussion about the overall balance of Hatch-Waxman in
13 today's environment. You cannot address the issue of
14 balance through regulations without understanding the
15 broader environment and the context. I hope these
16 comments have provided some useful insight on how the
17 IP environment colors the aspects of our R&D pipeline
18 decisions. We have provided some suggestions about
19 ways to improve the current incentives so that more of
20 the thousands of currently unmet medical needs can be
21 addressed. Thank you.

22 MR. KLEINHENZ: I also have slides -- thank

1 you. Good afternoon. Kenneth Kleinhenz, from Cytori
2 Therapeutics. We are a very small pharma company in
3 San Diego, and we do manufacture in the United States.
4 I'd like to share with you my thoughts on a couple of
5 very interesting comments that were made this morning.
6 And one of those comments was that -- the question was
7 why are there shortages in some of these drugs, and the
8 second comment was that there are companies that are
9 gaming the system to decrease competition. I'd like to
10 give you a case study in that -- those exact concepts,
11 with the liposomal doxorubicin product that we're
12 trying to develop.

13 This all started in 2012, when there was a
14 shortage of the doxorubicin liposomal form, and that
15 the -- then the new facility was closed down and it
16 resulted in a complete drug shortage. In this process,
17 there was a citizen petition that had affirmed that the
18 new reference standard was going to be the Sun Pharma
19 product that's called lipodox. And in 2017 -- in April
20 of 2017, the Orange Book changed and the change now
21 listed the original NDA drug, Doxil, as the RLD, where
22 it wasn't listed before. And keeping in mind that as a

1 small biopharma company, we need to know who the
2 reference standard is so that we can do our
3 bioequivalent studies. And that's very important to
4 us.

5 When we look at the guidance document for
6 ANDAs, we note that it's very clear that the
7 bioequivalent studies are to be performed against the
8 reference standard, and that the reference standard is
9 now a Sun Pharma product -- we understand that and can
10 follow that. And the guidance document even goes
11 further to say that if the RLD is brought back to the
12 market that the reference standard typically will
13 remain as the BE -- bioequivalence comparator -- all
14 makes sense to us. However, there is a product
15 specific guidance document for liposomal doxorubicin,
16 and this guidance document states that you can use the
17 reference standard or the reference listed drug. And
18 we find that very curious, although we do appreciate
19 that flexibility. But, again, it does now seem to
20 conflict with the ANDA guidance document that we cited
21 previously.

22 The problem for us is that the Orange Book

1 reference was made in April 2017 to relist the RLD back
2 to the original NDA product. However, there was no
3 guidance put out regarding that. There was no
4 indication for that coming through. So, it caught us
5 all by surprise.

6 Also, it does create a conflict between the
7 guidance document and the product specific guidance
8 document. Now, this becomes a problem for us because
9 what we would be looking for would be some specific
10 guidance that comes out in the product specific
11 guidance document that was reissued in April of 2017
12 also. And again, the guidance document was reissued
13 but it always says the reference standard or the
14 reference listed drug. And we would propose that there
15 would be some specific documentation that would talk to
16 the specific products in the product specific guidance
17 document. It would really help to clarify the
18 situation here, because it is highly unusual. And
19 given the tumultuous product that was taken off the
20 market, and now put back on the market -- again, there
21 creates a significant amount of confusion in the
22 industry for this specific product. Moreover, there is

1 another confusion where there are two products --
2 there's a Doxil product and a Caelyx product -- that
3 are both manufactured by the same manufacturer,
4 chemically equivalent in every way, and simply labeled
5 differently for the European versus the U.S. markets.

6 And again, the question becomes why are there
7 so few products on the market. When we are looking to
8 make our decision on the bioequivalence, not only are
9 we looking to do the reference standard or the
10 reference listed drug now, we're also looking to
11 determine whether or not there is a Doxil or is there a
12 Caelyx. And again, the point here is that if the
13 agency is flexible in accepting two completely
14 different manufactured products, they should also be
15 flexible in accepting the same product labeled
16 differently for different markets. And this has been
17 brought up multiple times today.

18 So, that is our request. We're just asking
19 for clarity. We applaud the agency's efforts and
20 simply ask for greater clarity on this very specific
21 drug, especially given the fact that there is a product
22 specific guidance document that really could use some

1 additional clarification.

2 Thank you so much.

3 MR. FLANAGAN: Thank you. Thanks.

4 MR. KLEINHENZ: Thank you.

5 MR. KORN: Thank you for holding this
6 meeting, and inviting the views of the public. I'm
7 David Korn, Vice President for IP and Law at the
8 Pharmaceutical Research and Manufacturers of America
9 (PhRMA). PhRMA represents leading innovative
10 biopharmaceutical companies whose mission is to
11 research and develop new and improved medicines for
12 patients. PhRMA is here today to discuss the successes
13 of Hatch-Waxman over the last three decades, and also
14 to address some discrete issues that have arisen in
15 implementing Hatch-Waxman.

16 Intellectual property, or IP, including both
17 statutory exclusivity and patent protection, is the
18 lifeblood of innovation, given the unique attributes of
19 the biopharmaceutical R&D process, which is lengthy,
20 costly and uncertain. It takes on average 10 to 15
21 years and costs \$2.6 billion to develop a new medicine.
22 PhRMA members alone invested in 2015 roughly \$60

1 billion in researching and developing medicines. IP
2 protection supports such continued future innovation in
3 the long-term. PhRMA supports the important role of
4 generic products for patients. The natural evolution
5 of medicines is that after an innovator undertakes the
6 time-consuming and expensive development process and
7 obtains approval, it enjoys an appropriate period of IP
8 protections following which a generic version becomes
9 available for patients. Indeed, this is the very cycle
10 that the Drug Price Competition and Patent Term
11 Restoration Act, or Hatch-Waxman, attempted to
12 encourage. Hatch-Waxman has fostered this competition
13 through the timely entry of generics.

14 A few key facts. As FDA officials, have
15 recognized, nearly 90 percent of all prescriptions are
16 filled with generic products. And for brand medicines
17 facing generic entry in 2013 and 2014, generics
18 captured an average of 93 percent of the market by
19 volume within a year of entry. Competitive pressure is
20 expected to continue to fuel this dynamic in the years
21 ahead.

22 The patent challenge procedure under Hatch-

1 Waxman is also robust, as multiple applicants typically
2 challenge listed patents as soon as they are able. So,
3 over 30 years after its enactment, Hatch-Waxman
4 continues to strive for a balance between innovation
5 and competition. However, PhRMA recognizes that there
6 are certain areas where competition or incentives for
7 innovation may be insufficient. The existing five-year
8 data protection period does not alone sufficiently
9 reward investment in small molecule drugs, particularly
10 for the novel and complex drugs currently under
11 development. Instead, the statute to provide more
12 substantial incentives for development of new biologics
13 with a longer data protection period that provides more
14 certainty for innovators and more appropriately rewards
15 innovation. When patents are also considered, patent
16 challenges from generic manufacturers in the form of
17 Paragraph IV filings have been filed more frequently
18 and earlier in the brand-name drug lifecycle, with many
19 as early as four years after launch. And the market
20 exclusivity period before first generic entry for small
21 molecules has declined over time, such that the brand
22 medicines have faced generic competition at about 12

1 1/2 years after brand launch, even though the basic
2 patent term is 20 years.

3 Combined with the uncertainties of the patent
4 system, including the recent increasing usage of the
5 IPR process at the Patent and Trademark Office, with
6 some petitions filed even before the four-year mark,
7 this could create challenges for innovative companies
8 looking to develop new products. And efforts to
9 further limit patent settlements would create
10 additional challenges for companies.

11 On the other hand, review times for generic
12 drug applications also have been an issue. PhRMA
13 supports FDA's work to streamline and expedite the
14 generic drug approval process, especially where there
15 is no IP. In particular, we support FDA's steps to
16 foster preparation of more high-quality generic
17 applications to reduce the number of review cycles for
18 these applications. Further, as FDA recognizes in its
19 meeting notice, there are certain circumstances where
20 existing incentives may be insufficient to spur generic
21 development. PhRMA applauds FDA's recent actions to
22 help address this issue, including by publishing a list

1 of off-patent, off-exclusivity drugs without approved
2 generics and updating its internal procedures to
3 provide for expedited review of certain generic
4 applications. PhRMA believes there are additional
5 steps FDA and Congress can take to address this issue,
6 such as development of regulatory incentives for
7 bringing such generic drugs to market.

8 PhRMA looks forward to working with FDA and,
9 where appropriate, Congress to help address these
10 issues, including swift passage of the user fee
11 legislative package to foster increased competition.

12 I'll now address some specific questions
13 raised in FDA's meeting notice. FDA's notice suggests
14 that REMS with elements to assure safe use, or ETASU,
15 "can prevent generic companies from obtaining drug
16 products for bioequivalence testing" and may upset the
17 intended balance of Hatch-Waxman. PhRMA believes that
18 REMS are not upsetting the balance, that FDA has
19 authority in this area and that legislation is not
20 warranted.

21 First, FDA has used its REMS authority to
22 approve a number of important innovative drugs with

1 serious safety risks, from cancer drugs to drugs for
2 ultra-orphan populations that otherwise could not have
3 been approved. Second, many drugs subject to REMS with
4 ETASU have generic competitors or tentative approvals.
5 Of the 42 REMS with ETASU programs, 10 are shared
6 systems, meaning that generic versions have been
7 approved. Thus, REMS with ETASU do not preclude
8 generic competition. FDA has asked what additional
9 actions it might take to promote generic company access
10 to drug samples. PhRMA recognizes FDA's 2014 draft
11 guidance, that sets forth a process for generic
12 manufacturers to obtain letters from the agency stating
13 that bioequivalence study protocols contain safety
14 protections comparable to a REMS. However, this
15 guidance has not been finalized, as noted earlier, and
16 it leaves open important scientific regulatory and
17 legal questions, which we identified in our February
18 2015 comments.

19 We urge FDA to address these key questions in
20 a final guidance. This would give our members more
21 confidence that when they provide samples to generic
22 developers the samples will be handled and used safely,

1 and our members will not be subject to liability.

2 FDA's notice also asks how FDA should apply
3 its statutory authority to waive the single shared
4 systems REMS requirement to facilitate generic entry.
5 PhRMA believes that FDA may more broadly exercise its
6 waiver authority, based on the determination that the
7 burdens outweigh its benefits.

8 FDA also asks how the citizen petition process
9 has affected the balance struck in Hatch-Waxman. The
10 citizen petition process serves as an important venue
11 for raising critical scientific, policy and legal
12 issues for FDA's consideration through a transparent
13 constitutionally protected public process. Indeed, the
14 statute requires that requests concerning abbreviated
15 applications be submitted in citizen petitions under
16 Section 505(q). Innovators have important
17 contributions to make regarding these issues, due to
18 their extensive knowledge and experience with the drugs
19 in question.

20 Typically, 505(q) petitions are reviewed while
21 FDA is also reviewing the related abbreviated
22 application. Moreover, upon the deadline for

1 responding to the petition, FDA commonly issues an
2 interim response indicating it has not yet ruled on the
3 petition because of its complexity, or denying the
4 petition without comment because the agency has not
5 decided whether to approve the abbreviated application.
6 And the statute already prohibits FDA from delaying
7 approval of an abbreviated application due to a
8 petition unless FDA determines "that a delay is
9 necessary to protect the public health." FDA's own
10 reports to Congress put 505(q) petitions in context,
11 with only ten resulting in a delay of approval of an
12 ANDA or 505(b)(2) application in eight years.

13 We also wanted to address FDA's question about
14 how post-approval changes to innovator drug products
15 affect the Hatch-Waxman balance. Post-approval
16 changes, such as new dosage forms and routes of
17 administration, are a critical part of pharmaceutical
18 innovation, producing important treatment benefits for
19 patients. R&D does not stop with initial FDA approval
20 of a drug. A drug's safety and effectiveness are not
21 determined solely by its active ingredient, and its
22 therapeutic usefulness is not limited to the disease

1 for which it is studied initially. Post-approval
2 changes can improve a drug's tolerability,
3 effectiveness, adherence or convenience, and supports
4 its approval for new diseases with unmet medical needs.
5 Such continuous medical advances benefit patients and
6 the public health, and should be incentivized by Hatch-
7 Waxman.

8 Providing IP protection for such innovation
9 does not negatively affect access to generic versions
10 of the original product. Once the period of protection
11 on the original product has ended, and provided there
12 are no safety concerns, generic copies of that product
13 may be approved. Healthcare providers and payers can
14 then decide whether clinical benefits offered by
15 improved branded products are more important than the
16 cost savings available through use of less expensive
17 generic versions of original products.

18 In conclusion, PhRMA looks forward to working
19 with FDA on improvements to the biopharmaceutical
20 ecosystem, including modernizing the drug discovery and
21 development process and increasing competition for
22 older medicines. We need a policy and regulatory

1 framework that fosters the continued innovation needed
2 to address our most challenging diseases. Thank you.

3 MS. TOUFANIAN: Thank you for your comments.
4 Could you describe in greater detail the concerns you
5 have about the newly established IRP process, and how
6 that undermines the balance that was originally created
7 with the Hatch-Waxman Amendments?

8 MR. KORN: The -- you're referring to the
9 process of the Patent Office?

10 MS. TOUFANIAN: Yes.

11 MR. KORN: Okay. It -- as was noted by the
12 prior speaker, it creates another avenue for challenges
13 that has people -- has companies defending challenges
14 in multiple venues on different standards, and impacts
15 just certainty as companies are looking -- trying to do
16 planning. It adds an additional level of uncertainty.

17 DR. UHL: My pen moved a little too slowly.

18 MR. KORN: Sorry.

19 DR. UHL: When you were talking about post-
20 approval changes, you said about the ability to improve
21 tolerability, adherence -- I believe you had four
22 specific examples that you used. So, my question is

1 should there be a requirement to demonstrate any or all
2 four of those when the agency approves any
3 postmarketing type changes to the innovator?

4 MR. KORN: I think that there is -- post-
5 approval changes are just a natural evolution. And I
6 don't think there is a reason -- although we would need
7 to see any proposal -- I don't think there is a reason
8 to have different standards for different approval
9 changes, if they're otherwise warranted as being a safe
10 and effective product going forward.

11 DR. UHL: Okay.

12 MS. SIPES: Thanks for your comments.
13 Earlier in the day, there were some proposals made that
14 the letters issued under the guidance you referred to
15 be made public. What do you think of that proposal?

16 MR. KORN: That's something that we would
17 need to consider. As I mentioned, we had a number of
18 comments on the guidance as a whole. But we'll
19 consider that proposal.

20 DR. STEIN: You mentioned that even though
21 there is challenges in approvals with the REMS process
22 that ultimately that hasn't led to substantial delays,

1 from the report you mentioned. Yet it clearly, from
2 what we've heard earlier, has been a substantial
3 burden. Can you just comment on how you would balance
4 that? Clearly, there is the -- the efforts are
5 substantial to try to overcome and to get to an
6 approved REMS. How would you balance that?

7 MR. KORN: Well, I think we were looking at
8 two ways of looking at it. And one is through the
9 process with the letter. And then we can look at the
10 factors, but I think the statute talks about in the --
11 for the single shared system has a number of factors
12 that FDA could weigh in looking forward and trying to
13 figure out what the right balance is. We don't have a
14 proposal on that. We could think through that as well.
15 But, I think it does give FDA a menu of factors to
16 review.

17 MR. MURPHY: Thank you for the opportunity
18 for BIO to present some comments here today. My name
19 is John Murphy. I'm Deputy General Counsel for
20 Healthcare at BIO. And I will do my best not to just
21 repeat things some of my colleagues said, and try and
22 give you some perspectives that some of BIO's more

1 diverse membership has. At the outset, we appreciate
2 FDA's willingness to hear these diverse viewpoints on
3 the important topic. And the biopharmaceutical
4 industry supports the goals of the Hatch-Waxman
5 Amendments, and strives to ensure a robust, innovative
6 and competitive biopharmaceutical marketplace in the
7 United States. In fact, last year BIO's board adopted
8 a policy directing the organization to ensure we
9 promote policies across the organization that ensure
10 both a competitive innovative market but also a
11 competitive generics biopharmaceutical marketplace.
12 So, it is something that we hold very important within
13 the organization.

14 And to that end, we believe FDA has done an
15 admirable job in advancing the goals of Hatch-Waxman to
16 date. The evolution of PDUFA and the newer addition of
17 GDUFA and now biosimilar user fee acts have created
18 what we believe is a marketplace for innovative generic
19 biopharmaceutical products that has expanded greatly,
20 and I don't think I need to restate the statistics that
21 have been shown around here, other than to say that it
22 is continuing to get even larger with the approval

1 recently of the fifth biosimilar to come to the
2 marketplace, and then the discussion earlier today of
3 almost 50 products, or at least programs, under review.
4 We also believe that FDA's recent efforts to publish
5 the list of products with a noncompetitive market
6 dynamic, and coupled with a commitment to expedite ANDA
7 submissions of generic versions of these products,
8 should go a long way to help relieve some of the
9 concerns addressed in the federal register notice. And
10 I would probably amend that to say that some of the
11 initiatives announced by Commissioner Gottlieb this
12 morning wrapped around those other two previously
13 announced proposals ought to probably go a long way in
14 facilitating some of that.

15 What we -- probably makes sense to do is turn
16 to some of the more specific questions that I think
17 will help inform our comments. Much has been said by
18 others about the sort of REMS products and the ability
19 to access samples. And, you know, there is sort of
20 another side of the point that we would like to raise
21 on that issue. We hear from many of our more small
22 biotech members on this topic, sort of on the regular,

1 and it is not so much a proactive policy suggestion but
2 rather some words of, I suppose, caution from some of
3 these members that simply obtaining a letter from FDA
4 assuring that a product's sale won't violate a REMS,
5 while crucially important in the discussion, is not the
6 only component that our members have to consider when
7 looking at these sample requests.

8 There are questions of indemnity and liability
9 that often arise in the discussions between
10 manufacturers and sample-seeking entities, and also
11 there are true concerns about supply in some instances,
12 for biotech drugs that are in some instances not
13 produced in a capacity that allows for a lot of overage
14 outside of what is made to meet the needs for patients.
15 And it doesn't necessarily mean that there would be no
16 access, but it means that sometimes the timelines
17 prescribed or demanded for access to those samples are
18 difficult for companies to meet.

19 And there's also concerns that have been
20 raised by some of our companies about the sort of
21 almost in, what seems like, recent mostly legislative
22 discussions unlimited supply of sample products that

1 might be required, because biotech -- sometimes biotech
2 testing, even in the biosimilar space, can go on for a
3 longer period of time. And we have heard concerns from
4 members that, you know, there ought to be some
5 discussion about how to appropriately couch or have
6 some guidance on to how to negotiate those discussions.

7 We also want to raise the issue about
8 incremental innovation. A lot has been said today
9 about some of the other names that that product
10 lifecycle takes on. But, oftentimes some of the most
11 profound innovations take place in the studying of what
12 would otherwise be an incremental innovation. You
13 know, the organization -- and we have discussed ways to
14 propose to the agency new policies around that issue,
15 and if we are able to come to agreement we would be
16 happy to submit that for the written record, for your
17 consideration. But at a minimum, we wanted to raise,
18 you know, the concept that not -- you know, thinking
19 about incremental innovation in a one aspect scenario
20 wherein it might only be a product change that -- you
21 know, to the type of pill, but also there's a lot of
22 incremental innovation that leads to profound changes

1 for a patient's experience, or for the patient's
2 ability to access medicines.

3 And then finally, I think David said it
4 earlier but we would also submit to the point that, you
5 know, manufacturer oftentimes have some of the best and
6 most up to date safety information about their own
7 products. And their ability to openly convey that
8 information to FDA via a citizen petition process is
9 crucial. And many of them don't take that process
10 lightly, and have serious discussions and
11 considerations at issue when they -- prior to filing
12 those things. And it's an important component in the
13 product lifecycle for their products.

14 BIO will be submitting comments for the record
15 that we will happily supplement with any questions any
16 of you have, and hopefully come to some agreements on
17 some proactive steps you can take. Thanks.

18 MR. FLANAGAN: 2:50. 2:50 -- 3:30. Okay.
19 Ten-minute break. We'll be back at 3:30.

20 (Off the record at 3:17 p.m.)

21 (On the record at 3:34 p.m.)

22 MR. FLANAGAN: So, as with the previous

1 presentations, I'll announce the first speaker but not
2 each of the subsequent presenters. So, please approach
3 the podium when the slide that lists your name and
4 affiliation appears on the screen. And after the last
5 presenter, I'll make very brief closing remarks and
6 then adjourn. Mr. Love.

7 MR. LOVE: Thank you very much. Let me
8 figure out how this works. The first topic I wanted to
9 talk about was transparency. Evidence is important --
10 important evidence, rather, is lacking in many areas,
11 including evidence used to measure and evaluate the
12 performance of current policies that influence
13 investments in research and development and decisions
14 on drug pricing.

15 The studies by Joe DiMasi and other industry
16 consultants lack transparency about basic parameters,
17 and are often used to confuse rather than inform policy
18 debates. There is a need for more independent and
19 granular data on R&D expenditures. There are proposals
20 to require greater -- outlays on R&D outlays, prices,
21 revenues and other aspects of pharmaceutical markets.
22 The most important initiatives as regards R&D are those

1 that require companies to report the enrollment and
2 costs of each clinical trial relating to the marketing
3 approval of a drug, and the third-party funding, tax
4 credits and other subsidies relevant to financing the
5 development of the drug.

6 Investments in research and development
7 involve risks and capital that are correlated to the
8 timing and phase and stage of the development. The
9 more granular the reporting is of the trial costs,
10 including as it relates to specific trials, the year in
11 the expenditure which incurred, and the amount and
12 nature of the third-party subsidies, the more useful
13 the information will be to policy makers and the
14 public.

15 Investors are entitled to transparency of
16 certain basic economic facts that are material to the
17 price of a security. The public, on the other hand, is
18 typically barred from the most basic information
19 relevant to drug development costs, pricing, et cetera.
20 There are currently many transparency initiatives,
21 including, for example, the U.N. High-Level Panel on
22 Access to Medicines recommendations, provisions in

1 Senate Bill 771 and HR 1776, and state legislative
2 efforts, of which there are many.

3 The FDA should insist on standardized
4 disclosures of trial costs, R&D subsidies, and revenues
5 from products, broken down at least by country, in
6 terms of the international revenues. Federal agencies
7 that fund research, such as the Army, BARDA, CDC and
8 the NIH, should report on the enrollment and cost of
9 each trial they fund, subsidize or co-sponsor. This is
10 a practice that the National Cancer Institute used to -
11 - they used to publicize their per-patient cost per
12 trials, and the amount that they spent on trials in the
13 past. They don't do it now.

14 The licensing of federally-funded research
15 should be more transparent, as regards the entities
16 requesting exclusive licenses, all of the terms of the
17 licenses, the R&D costs, the revenues and prices of
18 products sold and the distributions of royalties.

19 There should be more robust authority in the
20 United States for the non-voluntary licensing of
21 patents, and better discretion on how to determine
22 remuneration in those cases. Bayh-Dole rights in --

1 both the march-in rights and the royalty free rights
2 could be used in some cases, but only apply to a small
3 number of products. 28 U.S.C. 1498, the government
4 use provisions and statutes, when the patent is used by
5 or for the government, are broader, but there are risks
6 that it involves, in terms of setting the remuneration
7 and the compensation, which could be addressed.

8 The general rule should be that when there is
9 an excessive price, a shortage or a blocking patent,
10 the monopoly rather than the patent -- or, I'm sorry,
11 the general rule should be that when there is an
12 excessive price, a shortage or a blocking patent, the
13 monopoly rather than the patient should be at risk.

14 I want to illustrate a couple of recent cases.
15 Last week, the Armed Services Committee in the United
16 States Senate published a report which had a mandate
17 for the Department of Defense to exercise march-in
18 rights and the royalty free rights in cases when the
19 price of a drug in the United States, a vaccine or
20 other medical technology is higher in the United States
21 than the median price charged in the seven largest
22 economies that have a per capita income of at least

1 half the per capita income in the United States.

2 In Germany, on July 11th, 2017, the German
3 Federal Supreme Court announced that it affirmed the
4 decision of the Federal Patent Court to issue a
5 compulsory license allowing Merck to continue selling
6 raltegravir in Germany. And I provided here a brief
7 quotation. So, you have these two examples, very
8 recently -- this month actually -- one in the U.S.
9 Senate and one in Germany, on this issue.

10 We think that exceptions are needed for all
11 regulatory exclusivities. The test data in NDAs, BLAs,
12 orphan drug, pediatric and regulatory delay
13 exclusivities should be subject to limitations and
14 exceptions. Policies that require duplicative trials,
15 which are necessary during the period of test data
16 exclusivity, violate Paragraph 16 of the 2013
17 Declaration of Helsinki on Ethical Principles for
18 Medical Research Involving Human Subjects.

19 In Europe, regimes of risk adjusted cost
20 sharing exist to avoid unethical duplicative
21 experiments involving animals, you know, except for
22 humans. Like, if it's a rabbit or if it's a rat they

1 invoke these ethical principles. But, they don't do
2 the same thing for humans. But, I think they should do
3 it for humans.

4 Federally funded drugs like Spinraza, which
5 are ridiculously expensive and also protected by
6 regulatory barriers to entry, such as the orphan drug
7 exclusivity, undermine the benefits of Bayh-Dole march-
8 in rights as a remedy. In Europe, after an initial
9 period of market exclusivity, you can waive the market
10 exclusivity on the orphan drug provisions in Europe, if
11 you can demonstrate it wasn't necessary or appropriate.
12 When the United States faces shortages of drugs, such
13 as in the case of Doxil and Fabrazyme, test data
14 monopolies should not be a barrier to registering drugs
15 that are needed, as was the case in the Fabrazyme case,
16 and it was used in excuses not to use the march-in
17 rights.

18 The FDA pediatric testing exception can and
19 should be reformed. We've recently been estimating the
20 cost of doing these trials. These are things that the
21 FDA requests from a company. There's a large number of
22 drugs where the cost of doing a trial per child exceeds

1 \$1 million, in terms of the cost that's imposed on the
2 public. And in those cases, I think you need to secure
3 alternative financing. That's an FDA imposed
4 exclusivity which is exercised only at the discretion
5 of the FDA.

6 This is a slide on asthma inhalers. My son is
7 an asthmatic. He complained to me about this problem
8 last week. As you know, the FDA used to have an
9 exception that allowed the older CFC inhalers to be
10 used for asthmatics. There is an environmental issue
11 with that technology.

12 But, most people that have looked at it have
13 said that the actual impact on the environment -- I'm
14 not even going through with my -- somebody else is
15 doing the slides for me, because -- yeah, thank you.
16 Because I obviously -- yeah, thank you, I mean, because
17 I forgot to do any of the slides. I'm just looking at
18 my own slides, and not for the whole group here. So,
19 if you got me -- that's right. Just -- if you could
20 just keep going, I -- help me out, because I'm doing
21 badly on this. All right.

22 So, basically, very little impact on the

1 environment of prohibiting the older inhalers. So, if
2 you have a product like Ventolin, which was put on the
3 market a long, long time ago -- it now has 15 patents
4 on the Orange Book, and it costs between \$50 and \$80.
5 I think the FDA could revise -- revisit this policy to
6 allow the less expensive ones to do.

7 I've only got about two and a half minutes
8 left. I think you're going to enforce the time limit
9 this time around. So, I'm going to just skip this,
10 except to say that in the areas of personal importation
11 and parallel trade there's a lot going on in
12 Switzerland and Italy in this area right now, in terms
13 of as a way of addressing what they think are excessive
14 prices on Hep C drugs. And these are, I think, really
15 interesting cases. We generally think in most cases
16 you should think about parallel trade as a remedy where
17 you regulate the parallel traders for safety, as they
18 do in Europe extensively, and have for years. But you
19 limit the parallel trade to the United States normally
20 with countries that have at least 50 percent of the
21 U.S. GDP.

22 This is my last slide. I think it's the most

1 important thing. I think governments have failed to
2 regulate monopolies in the public interest, and this
3 hearing is an example of that. The delinkage paradigm
4 is rooted in the idea that the incentive that companies
5 need to invest in research and development does not
6 have to be packaged in the way of a market exclusivity
7 or a monopoly. They need money, and they should be
8 rewarded robustly for successful innovation efforts.

9 But if you move from the granted monopoly to
10 money, you get to rationalize your incentive system in
11 a hundred different ways, including describing -- the
12 examples given by PhRMA in the paper they cited
13 earlier, from Professor Williams and others. All these
14 discussions about -- in the executive order, and the
15 discussions about performance based pricing or
16 indication based pricing or performance based prices
17 are all much easier to implement if you delink the
18 incentive to the inventor from the price of drug. As
19 long as you have the drug price be the incentive, you
20 set up a conflict between innovation and access,
21 innovation and affordability. Everything you do that
22 reduces the price of the drug will be seen as a threat

1 against innovation. If you haven't heard it before --
2 and I'm sure you have -- you're going to hear it every
3 time anything comes up that's designed to protect
4 consumers or roll back excessive prices.

5 The way forward on this is not to just give up
6 on controlling high prices. It's to recognize that
7 this thing is a fundamental policy incoherence, as this
8 U.N. panel has stated. The progressive way forward, in
9 terms of avoiding, like, radical shocks in the short-
10 term is to strengthen the methods that provide
11 incentives that are not tied to the price of the drug
12 at the same time that you invoke measures that reduce
13 the price of drugs.

14 I think I've run out of time. Thank you very
15 much.

16 DR. UHL: Okay. Thank you. You mentioned
17 during the transparency part here that the NCI used to
18 publish the cost per patient. Do you happen to know
19 when they stopped doing that, and why?

20 MR. LOVE: I'm not sure when they stopped
21 doing it. I was involved in a series of hearings in
22 the early nineties, where some of these issues about

1 drug development costs and government funded drugs were
2 -- and I know at that time we -- in the early 2000, we
3 used to look at those things. I know that the cost was
4 below \$10,000 a patient on oncology trials, for
5 example, at that -- about 15 years ago, when they used
6 to publish those statistics.

7 DR. UHL: Okay. And then you also mentioned,
8 all the way at the end, about incentives not linked to
9 the price of the drug. Do you have any suggestions
10 about what those incentives might be?

11 MR. LOVE: Well, I think the incentives
12 should be in the form of money. For example, right now
13 you grant a monopoly for the pediatric studies. That's
14 a way of financing the -- you can -- you have studies
15 that cost, maybe, \$30,000 a patient to do, for the
16 studies, and you're effectively giving the person an
17 incentive that's, in some cases, \$2 or \$3 million a
18 patient. That's not very effective. But, if you -- in
19 the antibiotics space, Senator Franken has proposed,
20 along with 15 cosponsors on his legislation, that there
21 be a \$3 billion fund set up to reward successful
22 innovators in the area of antibiotic drugs, because

1 they don't want to tie the reward for developing
2 antibiotic drugs to the volume of the use of the drugs,
3 because that breeds more resistance. So, there's, you
4 know, a special issue in antibiotics.

5 In HIV, Senator Sanders proposed that the
6 government put up a \$3 billion per year reward system
7 to the development of new drugs in the HIV space, of
8 which in the last 30 years you have approximately one
9 novel chemical per year being put on the market, decade
10 in and decade out. And that was only from the United
11 States of America, and it wouldn't include the rewards
12 that would be forthcoming from putting the drug on the
13 market in Japan, Europe, developing countries outside
14 the United States.

15 I think this kind of -- Senator Franken and
16 others have proposed that the National Academies do a
17 study of the feasibility of delinkage in the area of
18 cancer, in the area of HIV, in the area of antibiotics
19 or all drugs. The National Academies is quite keen to
20 do this study. And it would be great if the FDA
21 personnel would engage in the terms of reference of
22 such a study.

1 MS. SIPES: I had a quick question for you.
2 Your fourth slide, on non-voluntary licensing. You
3 state that the rules on compulsory licensing should be
4 amended to provide more robust authority. Can you say
5 a little bit more about the kinds of amendments you
6 think would make sense?

7 MR. LOVE: Yes. I think there is -- you
8 could write an entirely new statute. There's two
9 simple ways you could do it. If you were to take the
10 Bayh-Dole march-in rights, for example, which is now
11 limited to subject conventions, which are those
12 conventions that involve funding by the NIH, the Army
13 or some other federal agency, you could say for medical
14 inventions that that march-in rights could be extended
15 to any drug, vaccine or medical device that's regulated
16 by the FDA. And then you would have a better standard
17 which exists in the march-in ring for compensation than
18 you do in the government use -- the government use
19 statute is more like a taking approach, and the
20 jurisprudence all over the map in terms of how these
21 things turn out, in terms of the compensation.

22 It's not well-suited for pharmaceutical drugs.

1 And it was originally fashioned over disputes on
2 patents on building roads and airplanes and things that
3 are defense related. But, I think that the discussion
4 about, in a non-voluntary setting as to what the
5 compensation should be should be clarified and there
6 should be sufficient discretion that the agency is
7 willing to move forward.

8 In the Hepatitis C case, where the consequence
9 of the high price was a small fraction of the patients
10 receiving treatment when you could have treated a wider
11 group of people, and when the VA ran out of the ability
12 to provide the drug to their own -- to veterans, the
13 Veterans Administration turned down a request to use
14 this authority, because they were uncertain as to how
15 much you'd have to compensate. And it -- in the VA's
16 thinking, if the drug was selling at that time for a
17 very high price and they had a lot of patients, they
18 felt if they went ahead and used the government march-
19 in rights -- I mean, the government use rights under 28
20 U.S.C. 1498, they wouldn't find out for years how much
21 money they would owe for having made that decision.
22 And that stopped them. And what they did is they

1 robbed another program for veterans. They took another
2 appropriation for veterans that should have benefited
3 veterans in a complete different way, and took the
4 money out to make sure they could pay for a drug that
5 was generating about \$2.5 billion a month at the time,
6 for the company.

7 MS. SIPES: Thank you. If you - I don't know
8 if you're submitting any comments to the docket, but if
9 you do and if you have any further thoughts on these
10 issues, particularly, you know, authority for expanding
11 the march-in rights, that would be of interest.

12 MR. LOVE: Thank you very much. I certainly
13 will. That's it. Okay. Thank you.

14 MR. BYDLAK: Thank you very much for the
15 opportunity to speak with you today about the
16 taxpayer's case for encouraging competition in the drug
17 market. As Founder of the Coalition to Reduce
18 Spending, I represent the interests of Americans
19 nationwide who are concerned about the rising national
20 debt and fiscal irresponsibility in Washington. In a
21 time of ever-growing partisanship and political
22 dysfunction, practical and bipartisan solutions can

1 very much be in short supply. And that's why we're
2 very encouraged at any efforts to reform one aspect of
3 the fastest growing part of the federal budget.

4 As I'm sure you're aware, in 1960 healthcare
5 costs were just 5 percent of the gross domestic
6 product. By 2015, they were nearly 18 percent, and on
7 track to keep growing. Prescription drug costs were 10
8 percent of total healthcare spending, and in recent
9 years their growth rate has outpaced that of all other
10 healthcare services. When costs rise, it's the federal
11 government that bears the largest burden, at nearly 30
12 percent. Federal involvement in healthcare is likewise
13 projected to outpace other sectors in the near future,
14 as more and more Americans join the Medicare rolls and
15 otherwise age into federal programs. While the current
16 political climate has shown how difficult it can be to
17 make large-scale changes to U.S. healthcare policy, the
18 Food and Drug Administration has a unique opportunity
19 to encourage development of and access to cheaper
20 generic prescriptions. By doing so, you can preserve
21 patient safety, spur increased innovation and by
22 extension reduce healthcare costs. Straightforward

1 steps like clearing out FDA's generic backlog would go
2 a long way toward helping to realize drug savings.
3 But, I'd also like to address one other means by which
4 FDA can support affordable prescriptions, and that's by
5 taking steps to discourage abuses of risk evaluation
6 and mitigation strategies.

7 As you know, REMS were created to encourage --
8 ensure consistency in drug manufacturing, and thereby
9 minimize potential risks to patient safety. However,
10 in recent years, REMS increasingly have been used to
11 make it more difficult for generic and biologic
12 manufacturers to enter the marketplace, and have served
13 to reduce competition and innovation rather than
14 encourage it. We believe that in addition to being a
15 clear violation of FDA's intent, REMS abuses have the
16 side effect of increasing drug costs to consumers.

17 These abuses occur when brand name producers
18 refuse to let generic competitors participate in shared
19 safety protocols. In other words, pharmaceutical
20 companies use their REMS as an obstacle to innovation
21 under the implicit assumptions that only they can
22 provide -- can safely produce the medications Americans

1 desire. In these instances, rather than fostering a
2 diverse marketplace for consumers, REMS can serve as a
3 tool for creating drug-specific monopolies. This
4 monopoly power is reinforced by other means, such as
5 refusing to let generic competitors have access to the
6 biological materials necessary to test and prove that
7 their generic versions are safe.

8 And the harm to consumers and taxpayers from
9 these abuses is hard to overstate. A 2014 analysis
10 showed that industry abuse cost the healthcare system
11 over \$5 billion per year. And again, \$1.8 billion of
12 these costs are borne by the federal government. Other
13 analyses have found numbers as high as \$14 billion in
14 annual lost savings when generic drug production is
15 stifled. And while allowing for healthy competition in
16 the pharmaceutical marketplace has obvious benefits for
17 American patients, improvements can come to our
18 nation's public finances as well.

19 As one example, a 2013 analysis found that the
20 ten-year savings from allowing just 11 biosimilars to
21 enter the market would exceed \$250 billion. And while
22 there are costs like these that are seen, there are

1 many others that go unseen. For example, in an
2 environment where brand name prescription drug
3 manufacturers face less pressure from competitors, how
4 many potentially lifesaving drugs do they not invest in
5 because it's more profitable to litigate claims against
6 generic competitors or otherwise work to maximize the
7 profits from drugs they've already developed.

8 It's for these reasons that the Coalition to
9 Reduce Spending is enthusiastically supporting current
10 legislative efforts like the CREATES and FAST Acts,
11 which offer paths to relief from bad faith REMS action
12 on the part of brand competitors. It's critical, in
13 our opinion, to remember that competition in the
14 marketplace should mean pressure based on who develops
15 the best prescription remedies, not from litigation and
16 exploitation of the spirit of FDA's rules. While some
17 may argue that these legislative solutions would
18 encourage frivolous litigation against brand name
19 manufacturers, the reality is that disputes of all
20 kinds are already being litigated through the court
21 system, and adding clarity to FDA's rules would reduce
22 misunderstandings, not increase them.

1 These narrowly tailored proposals would give
2 an affirmative defense for brand manufacturers against
3 frivolous claims, while ensuring that REMS functions as
4 intended -- to protect patients, not to defend anyone's
5 bottom line. And, of course, less litigation would
6 ultimately mean lower drug costs for consumers and the
7 U.S. Government. We also believe it would be
8 beneficial to taxpayers for FDA to provide further
9 clarity on when the agency will waive single shared
10 REMS requirements.

11 You know, we believe that you have a critical
12 role to play in ensuring consumer safety, by taking
13 proactive steps to ensure that your systems are not
14 used to crush competition. You can also ensure the
15 needs of consumers and taxpayers are considered as
16 well. Americans rightfully want the government to
17 spend less and provide for the best possible quality of
18 life for its citizens. The FDA has an opportunity, in
19 our opinion, to achieve both goals.

20 Thank you very much for the opportunity to
21 address you.

22 MS. TOUFANIAN: Thank you for your

1 presentation. You referenced a number, I think, two or
2 three different studies, one in 2014, a different one
3 in 2015. I'd encourage you to submit that information
4 to the docket for our consideration.

5 MR. BYDLAK: We will. Yes.

6 MS. TOUFANIAN: Great.

7 MR. BYDLAK: Thank you very much.

8 MR. MITCHELL: Good afternoon. I apologize
9 in advance for not supplying my prepared remarks in
10 advance for the panel. I'm Jack Mitchell. I'm the
11 Director of Government Relations at the National Center
12 for Health Research (NCHR). NCHR performs original
13 health research to inform public policy and
14 legislation. We also advocate for patients and
15 consumers. We also have a -- we manage an informal
16 coalition of two dozen nonprofit organizations which
17 focus on public health issues. NCHR accepts no funding
18 from pharmaceutical or medical device companies, so I
19 have no conflicts of interest to report.

20 We agree with Commissioner Gottlieb's recent
21 blog posting and subsequent comments that brand name
22 companies are sometimes gaming FDA's regulatory rules

1 in ways that unduly delay generic drug approvals beyond
2 the time frame that the law intended. Generic drug
3 companies usually need 1,500 to 3,000 dosages of the
4 originator drug to use for testing. Some companies are
5 using regulatory strategies to deliberately block
6 access to these needed testing samples. For example,
7 branded companies might use restrictions they place in
8 the commercial contracts or their agreements with
9 distributors to make it more difficult for
10 intermediaries in the drug supply chain to sell the
11 drugs to generic drug developers. Or, brand products
12 are sometimes subject to limited distribution, either
13 through REMS or through the company's voluntarily
14 adopted limitations. We believe that these
15 longstanding hurdles need to be corrected or amended.

16 We also believe that it should be possible for
17 generic sponsors to buy the branded products for
18 testing at affordable prices. This is especially
19 important since the most expensive branded drugs are
20 making healthcare increasingly unaffordable for many
21 patients and consumers. And of course, one of Dr.
22 Gottlieb's stated goals here is to reduce high drug

1 prices.

2 The Commissioner also pointed out that besides
3 limiting access to testing samples, some branded
4 companies may be using the statutory default
5 requirement to have a single shared REMS across both
6 the branded and generic versions of a drug as a way to
7 block generic entry. These single shared systems can
8 be used to delay the entry of safe and effective
9 generic drugs under the marketplace. This must also be
10 corrected or amended.

11 Finally, we want to express our concerns about
12 various mechanisms that have been used to extend patent
13 protection on drugs, including the so-called pay for
14 delay tactics. It is well-known that many of these
15 mechanisms have ended up increasing, not reducing, the
16 cost of treatments and provided relatively little
17 benefit regarding access to safe, effective and
18 affordable treatments available for patients, including
19 children and patients with rare diseases.

20 So, in summary, the legislation popularly
21 known as Hatch-Waxman, named after its two primary
22 Congressional sponsors, over time has had a significant

1 impact on increasing both drug innovation and access to
2 cheaper but effective generic drugs. For its
3 continuing success, there needs to be a bit of a course
4 correction. We have no specific suggestions, but just
5 in summary I would like to point to some of the
6 excellent suggestions made by Professor Carrier this
7 morning, in his presentation. We would certainly
8 concur with the idea of, if it's feasible, for FDA to
9 consider requiring sample deposits to ensure they're
10 testing for future availability for generic drug
11 manufacturers.

12 We would also like, as Professor Carrier
13 stated, to have REMS related and citizen petition
14 abuses addressed. They are longstanding, and they
15 violate both the spirit and intent of Hatch-Waxman. We
16 urge, as you've already committed, to work with
17 Congress and FTC and your other federal partners to
18 curb these abuses, which, as I said, have been
19 longstanding. Just finally, we hope FDA will follow
20 and implement the Commissioner's recommended course of
21 action to further improve this system for the future
22 benefit of patients and industry alike. Thank you very

1 much for hearing my comments.

2 MS. COX: Good afternoon. My name is Ayeisha
3 Cox, and I serve as a Policy Advisor to the not-for-
4 profit Center for Lawful Access and Abuse Deterrence,
5 also known as CLAAD. Our organizations works to reduce
6 prescription drug fraud, diversion, misuse, and abuse
7 while advancing consumer access to high-quality
8 healthcare. CLAAD's funders include treatment
9 centers, laboratories and pharmaceutical companies and
10 are disclosed on our website at claad.org. Thank you
11 for the opportunity to provide CLAAD's input on
12 preserving the balance between encouraging innovation
13 in drug development and accelerating the availability
14 to the public of lower cost alternatives to innovator
15 drugs.

16 The FDA can accelerate the development of
17 generics using its current authority under the FDCA.
18 For example, CLAAD recently filed a citizen petition
19 detailing how the FDA should act once it has approved
20 three oral immediate release or extended release long-
21 acting opioid analgesics with abuse deterrent labeling
22 with the same active moiety. In such event, the FDA

1 should mandate that all oral opioids without abuse
2 deterrent properties with that active moiety and
3 release profile be converted to an ADO within three
4 years of the approval date of the third ADO.

5 Otherwise, it should be removed from the market after a
6 three-year period, if they have not been converted to
7 an ADO.

8 Given that to date no generic opioid has
9 received FDA approved abuse deterrent labeling, such
10 action by the FDA would incentivize generic
11 manufacturers to bring generic ADOs to market faster.

12 Additionally, protecting patient safety and
13 encouraging the development of generics are not
14 mutually exclusive, specifically for products with
15 REMS. As you know, part of the REMS statute,
16 medications carrying serious risks would not be allowed
17 on the market but for REMS safety protocols.
18 Therefore, REMS safeguards must be preserved.

19 Important safety risks that brand
20 manufacturers mitigate through REMS should be equally
21 addressed by generic manufacturers. If brand and
22 generic manufacturers cannot agree on a shared REMS,

1 the FDA should identify the elements in the brand
2 manufacturer's REMS program that generic manufacturers
3 must meet. A REMS proposal that lacks these elements
4 should be denied.

5 Under the statute, the FDA has broad authority
6 to remove a drug with an unsatisfactory REMS from the
7 market if it does not meet the elements required to
8 ensure patient safety. This requirement of equal
9 safety protocols is consistent with the policy the FDA
10 established in its draft guidance on principles to
11 evaluate the abuse deterrence of generic opioid
12 analgesics. The guidance emphasizes that moving
13 forward, generic drug manufacturers seeking approval of
14 their product must ensure that the generic is no less
15 abuse deterrent than its brand counterpart on the
16 market.

17 Lastly, we also encourage the FDA to use its
18 authority to require product specific REMS when
19 appropriate, instead of removing a drug from the market
20 that meets an otherwise unmet need. For example, the
21 FDA could have required a product specific REMS for the
22 soon to be removed extended release oxymorphone product

1 to better manage the risk associated with a product
2 while also ensuring its availability to patients who
3 need it.

4 Thank you again for this opportunity, and
5 please contact CLAAD if we can be of any service to
6 you. Thank you.

7 DR. UHL: I did not attend the most recent
8 public meeting related to opioids. And I'm curious or
9 not if CLAAD was there, and if you submitted comments
10 to the docket related to the whole abuse deterrent
11 opioids and REMS and all that kind of stuff.

12 MS. COX: We were not in attendance at that
13 public meeting.

14 DR. UHL: Okay. Thank you.

15 MS. COX: Thank you.

16 MR. KNIEVEL: Hello. Thank you to the panel
17 for the opportunity to present on the vitally important
18 issue of lowering drug prices. Public Citizen is a
19 national consumer advocacy organization with more than
20 400,000 members and supporters. We advocate in an
21 array of issue areas to advance the public interest,
22 including insuring prescription drugs meet high safety

1 and efficacy standards and are made more affordable,
2 both in the U.S. and abroad.

3 In our view, the root problem of high U.S.
4 drug prices is the monopoly power of the pharmaceutical
5 industry. Government granted monopolies provide
6 incentive for prescription drug corporations to engage
7 in a range of abusive behaviors, from fraudulent
8 reimbursement schemes to price gouging to efforts to
9 inappropriately extend monopolies through evergreening,
10 REMS abuse and pay for delay deals. I will use the
11 remainder of my time to identify a menu of existing
12 policy options, as well as suggested policy reforms for
13 your consideration.

14 Because our nation's medicine affordability
15 crisis derives from the pharmaceutical industry's
16 monopoly power, the first step is for policy makers to
17 stop expanding monopoly powers. For instance,
18 proposals for a new six months' exclusivity period for
19 all indications on an existing medicine, when that
20 medicine gains approval for a new orphan indication,
21 should be rejected. We do not have a scarcity of
22 orphan drug development in this country, and the new

1 monopoly period would increase prices and provide
2 incentive for abuse. We are encouraged by the planned
3 GAO study into the Orphan Drug Act.

4 When drug corporations abuse their government
5 granted monopolies by price gouging consumers and
6 taxpayer funded government health programs, the U.S.
7 Government should exercise its existing authority to
8 remedy the abuse. This is especially the case when it
9 comes to U.S. Government funded biomedical inventions.
10 35 U.S.C. 203 provides federal agencies with the
11 authority to march-in on U.S. Government funded
12 inventions, to allow for generic competition when a
13 patent holder fails to make a product available on
14 reasonable terms. When U.S. taxpayers are paying more
15 than other wealthy countries for an invention developed
16 through taxpayer dollars, it is inherently
17 unreasonable. When that is the case, NIH, DOD and
18 other agencies should exercise march-in.

19 In cases of drug industry price gouging of
20 government health programs, 28 U.S.C. 1498, also known
21 as government use, is another tool currently available
22 to remedy drug industry monopoly abuses. For example,

1 Louisiana Secretary of Health and Human Services
2 Rebecca Gee recently wrote experts to explore the
3 viability of utilizing 1498 to expand access to
4 treatment for people with Hepatitis C. Public Citizen
5 submitted joint comments in support. Patients in
6 Louisiana and other states are facing treatment
7 rationing, such as requirements to get sicker before
8 they'll be granted access to treatment. From a public
9 health perspective, this is irrational. And from a
10 moral perspective, this is unconscionable. When drug
11 industry profiteering prevents access to lifesaving
12 medicines, the government should use 1498 to allow
13 generic competition.

14 Generic industry consolidation impedes
15 competition, increasing potential for off-patent no
16 exclusivity products that face no competition to allow
17 for sharp price spikes. FTC should work to prevent
18 mergers and acquisitions in the generic drug industry
19 to ensure that we have the robust competition necessary
20 for a well-functioning generic drug marketplace.

21 Rather than expanding the monopoly power of
22 the pharmaceutical industry, legislators should also

1 seek to curb monopolistic abuses to lower medicine
2 prices for consumers, taxpayers and government health
3 programs. FTC estimates that backroom pay for delay
4 deals cost consumers and taxpayers \$3.5 billion
5 annually. The FTC should continue to aggressively
6 prosecute such deals, and legislators should pass the
7 Preserve Access to Affordable Drugs Act, introduced by
8 Senators Klobuchar and Grassley, to help curb this
9 abuse.

10 Pharmaceutical abuses of REMS inappropriately
11 extend monopolies and delay competition, costing
12 consumers and taxpayers \$5.4 billion annually.
13 Legislators should stop these abuses through bipartisan
14 reforms, like the CREATES Act and FAST Generics Act.

15 IMSHealth's recent study of biosimilars in
16 Europe found that biosimilar competition lowers prices
17 and increases patient access to the whole product
18 class, even beyond the biosimilar and its reference
19 products. The legislators should reduce the period of
20 biologic's exclusivity from 12 to 7 years, as has been
21 proposed in legislation. Such legislation has been
22 scored to save the federal government around \$7 billion

1 over a ten-year period, and it's reasonable to
2 anticipate that the rate of accrual of such savings
3 would increase in later years.

4 Public Citizen's analysis found that from 1991
5 to 2015 the pharmaceutical industry paid more than \$35
6 billion in civil and criminal penalties to states and
7 the federal government. Fraudulently overcharging
8 Medicaid and other government health programs was the
9 most common violation resulting in such payments. But
10 these fines and payments are not enough to curtail the
11 abuse. When drug corporations abuse consumers and
12 taxpayers through fraudulent and other criminal
13 behavior with relation to a drug, the government should
14 stop providing market protections to the corporation
15 with relation to that drug. The Public Citizen
16 supports language in the Improving Access to Affordable
17 Prescription Drugs Act, which would do just that. The
18 prescription drug industry spends several billion
19 dollars annually on direct to consumer advertising,
20 often in efforts to steer consumers to more expensive
21 treatment options when lower cost effective
22 alternatives are available. We support language in the

1 Improving Access to Affordable Prescription Drugs Act
2 that would remove special tax incentives for DTC
3 advertisements, helping to make treatment decisions
4 more rational and provide savings to consumers and
5 taxpayers.

6 Finally, as policymakers seek solutions, they
7 should watch out for reforms that would have no or
8 negligible impacts, especially when they may have
9 negative unintended consequences. Generic drug
10 priority review voucher proposals represent a
11 fundamental misunderstanding between the different ways
12 the brand name drug market and the generic drug market
13 operate. A generic PRV program would provide little to
14 no incentive to induce competition for sole source off-
15 patent small market drugs, and would not prevent
16 Shkreli style price gouging or lower prices.

17 The House passed user fee reauthorization bill
18 includes in Section 808 a new 180-day exclusivity
19 period for so-called first generics. Such a mechanism
20 would not achieve the stated goal of increasing
21 competition for otherwise uncompetitive markets, and
22 even further that 180-day exclusivity period would

1 delay more robust competition for other products and as
2 a consequence keep prices higher for longer, increasing
3 drug prices. FDA research has shown the dramatic price
4 reductions only occur when there are two or more
5 generic competitors on the market. We were pleased to
6 learn that on Thursday the White House shares Public
7 Citizen's concern with this provision.

8 Once again, I want to thank you for the
9 opportunity to provide these remarks. We look forward
10 to providing written comments on these and other issues
11 relating to lowering drug prices, as well as working
12 with you and other policy makers towards our shared
13 goal of ensuring Americans have access to affordable
14 medicines that they need to lead healthy and productive
15 lives.

16 MR. FLANAGAN: Thanks for your very specific
17 comments. When you do submit comments to the docket,
18 the comments focusing on how, at least, FDA can
19 leverage its existing authorities to -- and develop
20 administrative and regulatory reforms are probably the
21 ones that are most immediately useful to us.

22 MR. KNIEVEL: Yes, sir. As was previously

1 commented, the call for testimony at this spoke to the
2 generic marketplace generally. So, we wanted to
3 provide comments broader than that specifically.

4 MR. FLANAGAN: Thank you.

5 MS. DICKINSON: Do you have a working
6 definition of price gouging?

7 MR. KNIEVEL: I think that is generally
8 understood to be profiteering behavior, where companies
9 abuse their either government granted monopoly or de
10 factor monopoly to charge unduly high prices. I could
11 -- we could speak to that further in our written
12 comments, though.

13 MS. SIPES: Thanks for your comments. You
14 mentioned the Bayh-Dole march-in rights and also the
15 government use law, as did a previous speaker who, if I
16 understood correctly, suggested that march-in rights
17 could be extended to any product regulated by FDA. Do
18 you have a reaction to that?

19 MR. KNIEVEL: I believe that those rights are
20 limited to government funded inventions, in a
21 particular stage of funding in the drug's development.
22 We would be very interested in that law being expanded

1 to include funding for more stages of development.

2 But, that is my understanding of the statute.

3 MR. FLANAGAN: Thank you.

4 MR. KNIEVEL: Thank you.

5 MS. WILD: Hi. Good afternoon. My name is
6 Nellie Wild, and I would like to thank you for the
7 opportunity to be here to provide comment. I do want
8 to note that I am delivering comments prepared by
9 Phyllis Greenberger, who is the Senior Vice President
10 for Science and Health Policy for HealthyWomen, the
11 nation's leading independent, nonprofit health
12 information source for women.

13 A priority for HealthyWomen and the women's
14 health community in general is to increase the
15 development and availability of life-enhancing
16 medicines where the safe use of these innovative drugs
17 and biologics is paramount. However, we also support
18 expanded patient access to lower-cost generic drugs and
19 appreciate the Food and Drug Administration's effort to
20 implement policies that will advance both goals.

21 Before joining HealthyWomen, I served as
22 President and CEO of the Society for Women's Health

1 Research, SWHR, where I spearheaded an initiative in
2 2009 with the Institute for Alternative Futures.
3 Together we hosted a stakeholder workshop to chart the
4 optimal development and application of FDA's Risk
5 Evaluation and Mitigation Strategies, or REMS, program.
6 The effort resulted in the publication of a detailed
7 report, Optimal Futures for Risk Evaluation and
8 Mitigation Strategies, in 2010.

9 My background enables me to reflect upon the
10 needs of women when designing and implementing REMS
11 policy, including recognition that women face unique
12 drug safety challenges that REMS can address, such as
13 preventing fetal exposure to teratogenic medicines, and
14 women are also disproportionately affected by diseases
15 and conditions like multiple sclerosis which are
16 effectively treated with medicines approved with REMS
17 requirements.

18 Going back to 2009 when the REMS program was
19 still in its infancy, there was already an interest in
20 supporting the development of generic drugs subject to
21 REMS, due to the recognition that the number and
22 variety of these lower-cost medications would increase

1 significantly in coming years. Accordingly, the
2 stakeholder meeting focused on the implications of REMS
3 requirements for generic drug developers, leading to
4 the call for policies that would assure branded and
5 generic drug manufacturers are held to the same
6 standards when implementing tightly controlled
7 restricted distribution programs.

8 This assessment was based on examining the
9 initial design of the iPLEDGE risk management system
10 for the acne treatment, isotretinoin, a potent
11 teratogenic drug, where insufficient safety controls in
12 the first year of operation of this risk management
13 system resulted in 122 unplanned pregnancies. Towards
14 this end, the workshop attendees and the resulting
15 report called on FDA to develop quantitative methods to
16 evaluate or validate a generic's risk management
17 program and to develop a contemporaneous monitoring and
18 enforcement policy.

19 Seven years have passed since the publication
20 of the Optimal Futures for Risk Evaluation and
21 Mitigation Strategies report and during this time the
22 REMS program has matured. Part of the evolution has

1 been the approval of a number of generic drugs subject
2 to REMS safeguards. Based on the latest information
3 from FDA's website, there are now 42 REMS with elements
4 to assure safe use, ETASU, the most restrictive types
5 of REMS. Of these REMS with ETASU, 11 are shared
6 systems where both branded and generic versions use the
7 same REMS procedures to manage the risks of potentially
8 dangerous drugs.

9 For the nation's over 160 million women, this
10 development represents an important step forward.
11 According to FDA's estimates, Americans save \$8 billion
12 to \$10 billion a year by purchasing generic drugs
13 rather than brand-name medications. Yet, REMS exist
14 because some medicines can cause life-threatening
15 complications and terrible birth defects, which is why
16 it is critical for FDA to preserve the integrity of
17 REMS and its Elements to Assure Safe Use requirements,
18 including restricted distribution systems, even as the
19 agency works to approve more lower-cost generic options
20 of branded REMS drugs.

21 In examining the 42 drugs or drug classes
22 requiring REMS with ETASU, there are some common safety

1 concerns. The largest number of REMS medicines marked
2 with ETASU requirements cause birth defects -- nine
3 drugs or drug classes -- a key concern for the women's
4 health and reproductive health communities.
5 Additionally, seven drugs or drug classes prevent
6 diversion, overdose and misuse, four address
7 hepatotoxicity and hepatic injury, and four prevent
8 life-threatening infections. Therefore, one possible
9 solution to accelerate the availability of drug samples
10 is for FDA to develop and publish customized guidance
11 for medications based on the specific safety risk, for
12 example birth defects, the REMS with ETASU designed to
13 mitigate.

14 This concept does not work for all medications
15 requiring ETASU but for those where there is a common
16 safety challenge. Providing an apples to apples
17 roadmap for branded and generic drug manufacturers to
18 follow could streamline the process, saving time for
19 the companies and costs for the agency.

20 HealthyWomen commends FDA on its leadership in
21 implementing the REMS program and for continually
22 working to improve this drug safety system based on

1 patients' needs. Thank you for the consideration of
2 these comments.

3 MR. REYNOLDS: Good afternoon. I'm Ian
4 Reynolds, representing the Pew Charitable Trusts. Pew
5 is a nonprofit nonpartisan research and policy
6 organization. One of our focus areas is the challenge
7 of rising drug spending.

8 Hatch-Waxman has largely been a success,
9 giving manufacturers incentives to develop new drugs
10 while facilitating competition and access to
11 medications. The law has driven innovation and created
12 a robust generics market. The savings from this
13 competition is estimated in the hundreds of billions of
14 dollars per year. However, there are areas where the
15 law may not be working as intended, and some practices
16 can inhibit the availability of lower cost generics and
17 undermine competition. Additional efforts to remedy
18 these challenges may be warranted.

19 It's important to recognize that some barriers
20 to competition lay outside the scope of FDA's current
21 authority, and changes may require Congressional
22 action. As a baseline for understanding the

1 pharmaceutical market, FDA must have reliable data on
2 the status of approved products. The version of the
3 FDA reauthorization act that passed the House would
4 require that sponsors inform FDA whether approved drugs
5 are currently marketed. If enacted, we encourage FDA
6 to require this information be provided to the agency
7 in a standard format, so it is easily usable and can be
8 made public.

9 There are three key issues related to Hatch-
10 Waxman we would like to comment on today. First is the
11 use of risk evaluation and mitigation strategies, or
12 REMS, to delay generic entry. Generic and biosimilar
13 developers can encounter challenges in accessing sample
14 brand drugs, subject to REMS, that include elements to
15 ensure safe use. This can inhibit generic developers'
16 ability to conduct bioequivalence testing. In
17 addition, brand and generic makers of drugs with these
18 kinds of REMS are required by law to participate in a
19 single shared REMS protocol, unless FDA waives the
20 requirement, which would allow for separate REMS.
21 However, some innovator manufacturers may make it
22 difficult for generics to participate in a joint REMS

1 protocol. Each of these can delay access to lower cost
2 products.

3 We appreciate FDA's acknowledgement of these
4 challenges, and signaling that it may use its authority
5 to waive the shared REMS requirement more often.
6 However, waiving this requirement also has the
7 potential to create inefficiencies. For example,
8 participating pharmacies and prescribers may need to
9 spend additional time enrolling in or training on
10 multiple REMS systems. We urge FDA to exercise this
11 authority judiciously when waiving the shared REMS
12 requirement. We suggest the agency do so in a way that
13 creates parallel systems and minimizes any potential
14 for discrimination between the uptake of the brand and
15 generic products.

16 While FDA's authority is limited, and
17 proposals in Congress would take further steps to stem
18 abuse of REMS, we note that current law prohibits drug
19 makers from using the REMS to block or delay the
20 approval of a generic application, or to prevent a
21 generic developer from participating in a shared REMS
22 program. While we're not aware of FDA ever using its

1 authority in this area, we recommend the agency take
2 enforcement action when it's appropriate.

3 The second issue of concern is the abuse of
4 the citizen petition process. Citizen petitions can be
5 useful when they contain legitimate recommendations or
6 raise valid scientific concerns for FDA consideration.
7 The citizen petition process has often been used to
8 request the FDA take action relating to pending
9 applications for generic drug approval. However,
10 citizen petitions have the potential to delay generic
11 approval and reduce competition. The majority of
12 citizen petitions related to generic applications are
13 ultimately denied. This suggests that many are
14 meritless.

15 Although FDA has met statutory deadlines for
16 reviewing petitions related to generic applications,
17 its 2015 report notes that the agency has had to
18 redirect resources from other work in order to do so.
19 That same year, FDA reported that two generic
20 applications were delayed due to citizen petitions, and
21 in one case brought by the FDC earlier this year the
22 commission alleged that abuse of the citizen petition

1 process to delay access to generics of just one drug
2 resulted in hundreds of millions of dollars in
3 additional cost.

4 We recognize FDA's recently implemented
5 changes to help ensure that citizen petitions are not
6 improperly used to delay approval of generics. We
7 recommend that FDA continue to monitor potential abuses
8 of the program, including establishing procedures to
9 identify when manufacturers or their proxies frequently
10 submit petitions that lack valid concerns and are
11 routinely denied, and to make this information public.

12 Our last point focuses on the FDA's unapproved
13 drugs initiative. This initiative has an important
14 goal, but it has the potential to drive up prices by
15 creating exclusivity to already widely prescribed
16 medications. The grant of exclusivity should be
17 commensurate with the costs to the sponsor conducting
18 new research and submitting an application. We
19 encourage FDA to conduct and publish an analysis on the
20 scope of new clinical research on drugs for which
21 exclusivity has been granted under this initiative, as
22 well as evaluate how the prices for these drugs have

1 changed after receiving exclusivity.

2 Finally, we recommend FDA not focus on
3 importation or changing its quality or safety standards
4 in order to speed access to generics. These approaches
5 may pose risks to the patients, and have other intended
6 consequences. Thank you.

7 DR. UHL: Thanks. Under your first item,
8 related to REMS, you mentioned that the FDA should
9 consider taking enforcement action. Could you expand
10 upon that, and under what circumstances you would
11 suggest to us that we do that? And then what kind of
12 enforcement action?

13 MR. REYNOLDS: FDA -- if FDA believes that
14 REMS are being used to delay generic access or
15 approval, you know, that's a decision that FDA can make
16 internally. But, if there are situations perhaps where
17 the law is not clear, that's something that could be
18 discussed further with Congress as well.

19 MS. RINKER: Good afternoon. I am Martha
20 Rinker. I'm the Vice President for Public Policy for
21 the National Organization for Rare Disorders (NORD).
22 And we're a unique federation of voluntary health

1 organizations dedicated to helping people with rare
2 orphan diseases, and assisting the organizations that
3 serve them. NORD is committed to the treatment and
4 cure of rare disorders through programs of education,
5 advocacy, research and patient services. And I want to
6 give you a few basic facts before I present NORD's
7 three points on Hatch-Waxman.

8 There are more than 8,000 known rare diseases.
9 There are 30 million Americans that are affected by
10 these rare disorders. 50 percent of them are children.
11 And as of December 31st, 2016, there have been 549
12 orphan indication approvals for 449 drugs since the
13 Orphan Drug Act was enacted in 1983. And another very
14 important piece of this is many patients with rare
15 disorders have no approved therapeutic treatments for
16 their disorders, and receive off-label therapies.

17 Now, with that landscape in mind here are the
18 three points that NORD would like to present today.
19 NORD supports the robust development and availability
20 of generic products, once an innovator's Orphan Drug
21 Act incentives have run their course. We appreciate
22 the need to balance product development, innovation and

1 public access to lower cost alternatives. NORD
2 supports efforts by the FDA to develop processes for
3 expediting the generic drug approvals, such as
4 proposals to provide early guidance for applicants.

5 And finally, NORD asks the FDA to be sensitive
6 to the patients' needs. Drugs should be available and
7 affordable to patients when they require them. And
8 with that, I end my brief statement and thank you for
9 the opportunity to present those points.

10 MS. TOUFANIAN: With respect to your last
11 point regarding -- Keith agrees with my question. He
12 doesn't know what I'm going to say. Could you
13 elaborate a little bit more on your last point,
14 regarding consideration of the patient? And if there
15 are specific policies or steps that the agency can take
16 to address or incorporate that specific concern into
17 our regulatory practice.

18 MS. RINKER: Well, I think it's knowing the
19 patient journey and taking in the patient's viewpoint
20 on access to care, I think. We can address that more
21 in our -- on our written statement, though.

22 MS. TOUFANIAN: Please do. Thank you.

1 MR. FLANAGAN: I was going to ask the same
2 question.

3 MS. RINKER: Okay.

4 MR. FLANAGAN: Thank you.

5 MS. RINKER: Anything else?

6 MR. FLANAGAN: Thanks.

7 MS. RINKER: Okay. Great. Thanks.

8 MR. MITCHELL: Thank you. Good afternoon and
9 thank you for this opportunity to present today. I am
10 David Mitchell. I am President and Founder of Patients
11 for Affordable Drugs, a national patient organization
12 focused exclusively on policies to lower prescription
13 drug prices. To maintain our independence, we do not
14 accept funding from any organizations that profit from
15 the development or distribution of prescription drugs.

16 Since we launched our effort five months ago,
17 we have heard from more than 7,000 patients from all
18 over America. They've shared their stories of skipping
19 doses, cutting pills in half, choosing between food and
20 the drugs they need.

21 More specifically to the discussion today, I
22 am a relapsed cancer patient with multiple myeloma, an

1 incurable blood disease. Drugs are keeping me alive,
2 literally. So, the importance of innovative,
3 affordable drugs is not theoretical to me at all. It
4 truly is a matter of life and death. I am very grateful
5 for the work of the FDA and for the drugs produced by
6 the science and research sector in our country. But
7 lifesaving drugs don't work if people can't afford
8 them.

9 A week ago, I sat in an infusion room for five
10 hours receiving a two-drug combination -- thank you for
11 those drugs, by the way -- priced at more than \$20,000
12 per treatment. I will have this treatment 22 times this
13 year. \$450,000 or so of drugs is what's keeping me
14 standing here right now.

15 Prior to this drug regime, however, I took
16 Revlimid for five and a half years, and I participated
17 in Revlimid's Risk Evaluation and Mitigation Strategy
18 program, of course made by Celgene. I obtained my
19 drugs only from specific specialty pharmacies. Each
20 month, I received counseling on the risks of the drug,
21 and I participated in a survey designed to remind me of
22 those risks and make sure I understood them. The most

1 dangerous risk with Revlimid -- the generic is
2 lenalidomide, it's a derivative of thalidomide -- so
3 the most dangerous risk is birth defects. The
4 counseling consisted of a nurse reading a list of
5 cautions to me. The survey was an automated phone call,
6 -- press one for yes and two for no. The whole process
7 took five to ten minutes. It could easily have been
8 duplicated by any generic manufacturers. It truly
9 wasn't rocket science.

10 Of course, during the same period, Celgene was
11 hiding behind its REMS program to delay versions of the
12 drug, refusing to give samples to generic drug makers
13 so that a cheaper generic could come to market. Here's
14 what that meant for me. My out of pocket cost for
15 Revlimid went up by 500 percent, from \$42 a month to
16 \$250 a month by the time I had to stop taking it
17 because of side effects. Another side effect of
18 Revlimid is blood clot. I had one. The docs changed
19 me up.

20 The retail price for a four-week cycle of
21 Revlimid during that period jumped to more than \$500
22 per capsule. Now, I'm lucky. At the time, I had good

1 employer-provided insurance. But others aren't so
2 fortunate. The median out of pocket cost for Medicare
3 beneficiaries taking Revlimid is \$11,500 per year,
4 almost half their annual income. Now, that's the impact
5 of REMS and restricted distribution system abuse.
6 Patients are forgoing their medication. They're
7 spending their retirement funds and their kids' college
8 savings to afford drugs when a generic competitor sits
9 around the corner.

10 I have three points I'd like to make today to the
11 FDA. First, thank you to you and to Scott Gottlieb. I
12 applaud you for clearly articulating that the agency
13 will not consider it a violation of REMS or any other
14 rules for a brand pharmaceutical corporation to allow
15 another manufacturer to perform necessary testing to
16 create an equivalent generic drug. Contrary to what
17 one of the gentlemen said from PhRMA or BIO, you sent a
18 letter to Celgene, told them to release the samples.
19 They refused to do so. It is very difficult for me to
20 imagine that any brand name company the size of, for
21 example, Celgene, putting out a dangerous drug -- it is
22 a dangerous drug, it requires a REMS -- would not have

1 adequate indemnity insurance to protect them from
2 lawsuits from patients, or anyone else who might touch
3 the drug or somehow be hurt by the drug. So, the idea
4 that not having -- being concerned about lawsuits seems
5 to me to be beyond the pale.

6 Secondly, as a patient, I understand that
7 safety is absolutely paramount. A single shared REMS is
8 efficient for patients, doctors, and regulators. But
9 bad actors are currently abusing the current system.
10 The FDA should forbid companies from declaring
11 information about REMS to be proprietary. After all,
12 REMS are a public good. They are not intended to
13 protect corporate monopolies. FDA should collect and
14 issue best practices for REMS so all manufacturers --
15 now and in the future, brand and generic alike -- can
16 draw upon previous learnings and easily set up systems.
17 If a drug corporation like Celgene refuses to share
18 REMS information with a generic manufacturer, the FDA
19 should use its authority to waive the requirement for a
20 single shared system.

21 Finally, the FDA should take additional action
22 to ensure generic companies can obtain samples for

1 testing. If the FDA does not have the proper resources
2 or authority to require the provision of samples,
3 perhaps joint action with the FTC could be undertaken
4 to stop this anticompetitive behavior. Most
5 importantly, where the FDA doesn't believe it has
6 sufficient authority to stop these abuses, I urge the
7 agency, on behalf of patients like myself and others,
8 to request immediate Congressional action. I believe
9 the FDA should be explicit in support of solutions such
10 as the bipartisan CREATES Act and FAST Generics Act,
11 which aim to correct these distortions of the law.

12 And I thank you very, very much for the
13 opportunity to come and talk to you about my personal
14 experience, and how it reflects on the policies of this
15 country. Thank you.

16 DR. BAKER: I'm Jim Baker, and I'm CEO of
17 FARE, which is Food Allergy Research and Education.
18 It's the organization that represents the 15 million
19 Americans with food allergy. I've also been an
20 allergist for over 35 years, developed drugs in the
21 military, academia, large pharma and biotech. So, I
22 have a broad perspective on generic markets.

1 I'd like to focus today on the epinephrine
2 auto-injector market, which is a remarkable microcosm
3 of all the issues related to generic substitution in
4 the U.S. This market is very important to our members,
5 because it involves a lifesaving medicine that they all
6 need. Unfortunately, it's been manipulated and
7 competition has been limited by several moves, and this
8 has resulted in literally billions of dollars of excess
9 cost for Americans.

10 One of the things we'd like to do is see more
11 competition in this area, and we applaud the FDA's
12 recent quick approval of the Adamis auto-injector,
13 which along with the reintroduction of the AUVI-Q and
14 the Impax Lab's generic device give consumers more
15 choice. However, the cost of these devices still
16 remains very high, and because of insurance changes
17 more and more families find this untenable. And so,
18 FARE would like to have even more competition in this
19 space, and I'd like to focus on three options to
20 encourage this goal.

21 Because epinephrine administration requires a
22 device drug combination, there are unique regulatory

1 issues. One of the marketing companies has been able
2 to argue that the auto-injector devices are not
3 equivalent with very small differences, even their
4 color simply being the difference, despite the devices
5 all working. As a physician who has cared for allergic
6 patients, I believe that almost anyone can be taught to
7 use almost any device. And remarkably, patient choice
8 in this is very divergent. So, no one device is really
9 better than another.

10 If another safeguard is needed to assure that
11 the substitution is safe, it could be done as it's done
12 in Canada, where the pharmacist is required to explain
13 the device. And in Canada, a prescription is not even
14 required for this device, and the cost is one-sixth of
15 what it is in the United States.

16 We also believe that references like FARE's
17 website, that provide instructions for all of the
18 approved devices, could help in this. We strongly
19 encourage rapid approval of any device that's currently
20 awaiting FDA review. Several devices in this area were
21 rejected for what appeared to be relatively minor
22 issues, and we would hope that you could also

1 facilitate that.

2 Finally, there are four auto-injectors in the
3 European market that are not available in the United
4 States, and help result in a much lower out of pocket
5 cost in the EU. These are high quality devices, but
6 they've not been brought into the U.S. because of
7 regulatory hurdles. And even though they compare
8 favorably in size and ease of use and accuracy, they
9 would require substantial regulatory findings to get
10 into the U.S. We suggest that the FDA allow the
11 facilitated importation of these devices into the U.S.,
12 in a manner similar to shortages of cancer drugs or
13 vaccines, especially until the market stabilizes.

14 We also urge the FDA to harmonize regulatory
15 approvals with the EMA to facilitate the entry of these
16 products. We want to really emphasize that the excess
17 cost of generic products prevents true innovation in
18 the pharmaceutical space. Every dollar spent on
19 epinephrine that's not necessary is a dollar that
20 cannot be used to develop new therapies that could
21 prevent life-threatening allergic reactions. While in
22 the short term we want better access to auto-injectors

1 for allergic sufferers, our real hope is a future where
2 they won't require epinephrine at all.

3 Thank you.

4 DR. UHL: Thank you very much. I wonder if
5 you might elaborate a little bit, and especially in
6 your written testimony, about the differences in the
7 auto-injectors, or other types of drug device
8 combinations. So, even in your patient population,
9 where you have, one, life-threatening patients with
10 anaphylaxis who would require an auto-injector, and,
11 two, what you kind of concluded with -- individuals who
12 are allergy sufferers, which is obviously not
13 necessarily life-threatening situations, but where
14 there still might be the need for medications that are
15 drug device combinations. So, do you have any thoughts
16 about permissible differences, differences in different
17 scenarios? Along those lines.

18 DR. BAKER: The most important aspect of this
19 is the patient actually uses the device. And there
20 have been recent studies that have shown that 50
21 percent of patients who don't give epinephrine to
22 themselves never get it on the way to the hospital, or

1 even at times in the emergency room. So, getting
2 compliance with the patient is most important.

3 All these devices are a little bit different,
4 and that's usually in the way the injection occurs.
5 Some give a spring that gives a hard bash. Others give
6 sort of electronic injection that delivers the drug.
7 And different patients like different routes. So, in
8 fact, patient choice is most important here. So, we
9 would like patients to have more choices. And since
10 all these devices have been shown to deliver the drug
11 effectively, they can't be approved without that, we
12 feel that all of the options are viable. And I'll put
13 more of that in our written commentary. Thank you.

14 MR. SPERLING: Good afternoon. My name is
15 Andrew Sperling. I'm the Director of Legislative
16 Advocacy for the National Alliance on Mental Illness
17 (NAMI). I want to thank you all for giving me this
18 opportunity, and thank you for the long day you've had
19 sitting up there listening to all these inputs. So,
20 NAMI is the nation's largest organization representing
21 people living with serious mental illness in their
22 families. We place a high value on accessing

1 treatment, to innovative therapy to treat disorders,
2 such as schizophrenia, bipolar disorder, major
3 depression, severe anxiety disorders.

4 The key thing for all of you to understand,
5 and hopefully many of you know this, the therapies we
6 have available to treat these disorders are not
7 disease-modified. They're largely palliative, helping
8 individual patients control their symptoms so they can
9 reach some modicum of recovery and higher functioning.

10 We do not have disease-modifying therapies to
11 actually change and allow people to get by without any
12 treatment at all. And that's what we're yearning for.
13 But, that breakthrough therapy that would really be a
14 game changing therapy, will allow someone to never
15 experience an episode of acute psychosis or acute mania
16 or severe depression. Enormous public health burden --
17 close to 40,000 suicides every year related -- 90
18 percent related to untreated mental illness. So, we
19 have a long way to go.

20 But, we also believe -- place a high value in
21 incremental improvements. So, for example, a new
22 antipsychotic medication that has no weight gain

1 associated with it is something that's of high value to
2 patients. The side effect profiles of some of these
3 medications are very challenging, particularly when you
4 have to take them, in many cases, for the rest of your
5 adult life. So, we value both that breakthrough
6 therapy that we're lacking but also support incremental
7 improvements. We have a long way to go.

8 But there's a good story to tell here, in
9 terms of the value that Hatch-Waxman has meant for
10 helping people access treatment to treat disorders such
11 as schizophrenia, bipolar disorder and major
12 depression. As you've heard earlier, the value of
13 generics to the overall system -- \$253 billion in
14 savings in 2016 alone, according to QuintilesIMS data.
15 We actually have fairly good data on what those savings
16 has been across the therapeutic categories, to treat
17 serious mental illness.

18 For example, of the top ten therapeutic areas
19 in which there is data on the savings to the overall
20 system for serious mental illness, four of them are
21 therapeutic categories related to serious mental
22 illness -- the top being depression, with savings of

1 close to \$37 billion. Number four, anxiety disorders
2 at \$22 billion. Number five, bipolar disorder, at \$18
3 billion in savings. And number eight, schizophrenia at
4 \$16 billion in savings. So, this is where -- if
5 there's any case where Hatch-Waxman has been a value in
6 bringing savings to the system, it's in medications to
7 treat serious mental illness.

8 So, we have just a few brief recommendations
9 for the FDA, of what you can do to improve on this
10 record of success with Hatch-Waxman. Number one,
11 eliminate the backlog and support development of
12 quality applications. And I think Commissioner
13 Gottlieb laid out what the agency is going to be doing
14 on that this morning. We believe that's very much a
15 positive step that the agency could really move out
16 front on this.

17 The other critical piece -- beyond your
18 control, but many of us as advocates in the room -- to
19 push Congress to timely reauthorize all of the user fee
20 agreements that provide the important resources that
21 you need to get that job done. And many of the patient
22 advocacy groups -- hopefully many of them that are here

1 talking to you today -- are supporting that effort.
2 That got through the House earlier this week -- last
3 week -- and we hope will have success in the Senate
4 very, very soon.

5 Number two, prioritize review of ANDA
6 applications for medications to treat mental illness.
7 You did -- I think the agency did a pretty good job
8 with the large number of antipsychotics and
9 antidepressants that have gone off patent over the last
10 decade. And we want to see that continue, as products
11 lose their patent protection and generics become
12 available to lower those prices.

13 Number three, FDA can further explore
14 potential barriers to development of medicines to treat
15 serious mental illness. This is an enormous challenge.
16 Drug discovery in the realm of psychiatry is really
17 probably the most challenging area. We don't have a
18 biomarker for schizophrenia. It's very, very difficult
19 to do animal testing. You can't actually ask a lab rat
20 if they're feeling psychotic, if they're feeling
21 depressed, if they're feeling anxious. So, big
22 challenges in this arena. The actual clinical trials

1 themselves cost significantly more than in other
2 therapeutic areas. So, we need the FDA's help to
3 validate biomarkers. Work with your colleagues at the
4 NIH to develop innovative trial designs. Use of
5 patient-reported outcomes to spur innovation and foster
6 competition. There's a lot we need to do to spur the
7 innovation and that's really, quite frankly, what our
8 members who live with these disorders, and their family
9 members, every day are desperate for -- is that
10 breakthrough therapy. No one is content with the
11 treatments we have available to treat these disorders,
12 and we need both the incremental improvement and the
13 breakthrough therapy.

14 So, thank you for this opportunity to talk to
15 you today. And if there's any questions, I'll be happy
16 to answer them.

17 MR. FLANAGAN: Thanks, Andrew.

18 MR. SPERLING: Thank you.

19 DR. WHITLOCK: Thank you. Pleasure to be here
20 this afternoon. Thank you all for hosting the meeting.
21 I'm Rodney Whitlock. I am a Policy Advisor to the
22 Campaign for Sustainable Drug Pricing. Let's see if

1 this works. Okay. The campaign is a project of the
2 National Coalition on Health Care Action Fund,
3 nonprofit and nonpartisan organization dedicated to
4 improving the healthcare system and keeping it
5 affordable. The campaign's mission is to foster and
6 inform the debate on sustainable drug pricing, and we
7 are working to raise the profile of this issue and
8 develop market-based policy solutions developed around
9 transparency, competition and value.

10 This is our set of logos. Rather than go
11 through all of those, just to say we're a broad
12 stakeholder group including insurers, providers,
13 inclusive of health systems and hospitals and
14 physicians, inclusive of patient advocates, large
15 employers and employee groups. And they're all subject
16 generally to the consequence of rising drug prices,
17 which draw them together to talk about the subject.

18 This is an example of data that speaks to the
19 concern that our members face when drug prices outpace
20 other cost growth in healthcare. The problem that
21 we'll be talking about today, and particularly pulling
22 off of the drug competition action plan that FDA

1 described in the blog by Dr. Gottlieb, goes to the
2 competition issue, and particularly towards REMS. And
3 again, that we have seen competition work to the
4 advantage of the system, now saving, in this case,
5 \$1.67 trillion.

6 Generic competition, our concern is, is too
7 often blocked by de facto extensions and de jure
8 monopolies. Specifically, as noted in the blog post,
9 that occasionally the rules are gamed or misused. And
10 in Dr. Woodcock's testimony, that some branded
11 manufacturers feel that it is their duty to their
12 stockholders to delay competition as long as possible.
13 As a coalition, our concern remains with what we see as
14 affirmative barriers to competition, created under the
15 existing regulatory regime. The problem that we are
16 focusing on, and particularly want to raise for the
17 purpose of this conversation, is with the REMS process.

18 And pulling from the blog post, you know, that
19 the use of REMS and non-REMS to restrict distribution,
20 and access to samples required for comparative testing
21 is problematic, along with the intentionally prolonged
22 negotiation over single shared REMS, that the blog post

1 itself pulled out as an issue. A study by the
2 Association for Accessible Medicines found that
3 restricting distribution network abuse costs the health
4 system as much as \$5.4 billion annually.

5 Competition is a good thing. Competition
6 drives down costs. One of PhRMA's own studies found
7 that the price of generic medication falls 66 percent
8 during the first year of competition coming onto the
9 market. And that increased generic competition creates
10 significant savings, and reduces barriers to taking
11 medicine at the appropriate intervals. We know there's
12 no silver bullet in the area of drug pricing. There's
13 no magic wand to wave here. It is not -- in any way do
14 we say here's the fix, take it from here. It's a set
15 of steps that you would take to try to improve upon the
16 existing system. And the opportunities are out there
17 currently.

18 The action plan suggested by Dr. Gottlieb is a
19 step in the right direction. We also see that the FDA
20 does have constraints on what is their legal authority
21 -- what they're able to do. We know that there are
22 pieces of legislation currently before Congress, the

1 bipartisan, bicameral FAST Generics and CREATES Act
2 that would help deliver on the course charted by Dr.
3 Gottlieb in the drug action plan.

4 And so, to close, on behalf of us, I'd like to
5 put this in context for you all in what the legislative
6 process needs to produce. With any good fortune, we'll
7 be done with the user fee acts imminently, one would
8 hope. Okay. After that, turning to other subjects,
9 particularly addressing the REMS issues, the
10 opportunity is there. The legislative process works
11 best when the legislative branch works with the
12 agencies to agree upon legislative language that is
13 delivered into law that can then ultimately be turned
14 into something that could be implemented by the
15 regulatory agency. That working together is the
16 opportunity that you have that Dr. Gottlieb has already
17 launched. And we look forward to seeing that done, in
18 the case of the REMS process, to something that will
19 benefit the consumers generally. I'll stop with that.

20 MS. ABRAM: I have one. Hi, Rodney. Thank
21 you for your comments.

22 DR. WHITLOCK: I was hoping your microphone

1 would break.

2 MS. ABRAM: Nope. It's working loud and
3 clear. I just wanted to encourage you, and to carry
4 this back to the extent that the Campaign for
5 Sustainable Drug Pricing has suggestions or areas that
6 you would recommend to the agency to look at, within
7 our administrative authorities. We would appreciate
8 that feedback as well, in addition to what you might
9 suggest with respect to legislative opportunities.

10 DR. WHITLOCK: Certainly. And if I can turn
11 the question, where you see the extent of your
12 authority ending -- where counsels are telling you uh-
13 uh, you know, getting that out for the purposes of both
14 folks like us but certainly folks on the Hill, is
15 valuable.

16 MS. ABRAM: Received. We're in a listening
17 mode today, and want to encourage lots of comments in
18 the docket.

19 DR. WHITLOCK: Yes, ma'am.

20 MS. ABRAM: Thanks, Rodney.

21 MR. BALTO: Good afternoon. I'm David Balto.
22 I used to work with Markus at the Federal Trade

1 Commission, helping to lead efforts in the -- against
2 anticompetitive conduct in pharmaceuticals. I am a
3 public interest antitrust attorney, and I lead the
4 Coalition to Protect Patient Choice, a coalition of
5 consumer groups concerned about healthcare competition
6 issues. Here's the best news of your afternoon. I'm
7 going to do this in 5 minutes, even though you've given
8 me 15. If you can turn to slide number seven. You
9 know, as somebody who works -- maybe it's the slide
10 before that. It's a quote by Robert Bork. The -- it's
11 -- keep going. It's important when we look at -- I
12 wanted to start off with three basic principles that I
13 think should guide the way you look at -- there, that's
14 the slide.

15 This slide in fact -- there should be a big marble
16 block in front of the FDA, and Judge Bork's quote
17 should be on that block. And every FDA regulator
18 should see this quote before they walk in every day of
19 work. Predation by abuse of governmental procedures,
20 including administrative and judicial procedures,
21 presents an increasing danger to competition. He said
22 that 40 years, and never is it more true than at this

1 agency than at this point in time.

2 You know, I work generally in healthcare
3 competition markets. And no market functions quite as
4 effectively as the generic drug market. But, there has
5 to be a generic drug market before that competition
6 will occur. And the process of FDA regulations
7 provides a tremendously fertile medium for the abuse of
8 the regulatory process, to keep that competition from
9 ever occurring. You know, regardless of where you are
10 in the political spectrum -- abuse of the regulatory
11 process, acquiring monopoly power through that abuse --
12 is the most pernicious form of monopoly power.

13 Why? Because if Google or Microsoft acquire
14 monopoly power by inventing some better product, we
15 don't worry quite as much. Because someone else is
16 going to arise and develop a better product, and
17 develop a better product and displace them as the
18 monopolist.

19 But when someone secures monopoly power from
20 the abuse of the regulatory process, no market force
21 can displace that. When the FDA decides that somebody
22 drawing a line across a tablet is something that's

1 worth putting in the Orange Book, there's nothing that
2 a soul in this universe can do to go and permit the
3 generic firm to enter the market. That's why, as a
4 first principle, the agency and Congress needs a heavy
5 dose of regulatory humility. Because wherever you put
6 that regulatory spectrum, the greater powers that are
7 exercised -- the powers that are exercised that aren't
8 supervised, especially the powers that are exercised
9 where no one gets to see what's happening, that's the
10 best medium for monopoly power. John D. Rockefeller
11 couldn't even dream of that.

12 Second, let's talk about innovation. Alex
13 Brill had a great comment. Innovation is not contrary
14 to the growth of the generic market. In fact, they are
15 complements to each other. And when the regulatory
16 process is abused, it's not only stopping these generic
17 firms from entering the markets. It delays competition
18 from other branded pharmaceutical companies. It goes
19 and it starts the incentives to innovate, because firms
20 know that other firms can use the abuse of the
21 regulatory process to delay entry.

22 Finally, transparency is the enemy of all this

1 abuse. The greater disclosure -- going and holding a
2 hearing like this, going and disclosing what individual
3 firms are doing, making information available -- is
4 critical. It's not only so erstwhile academics like
5 Mike Carrier and other people who testified this
6 morning have that information to better inform you. It
7 also is because besides the Federal Trade Commission we
8 have private Attorneys General. We have state
9 Attorneys General, and we have private litigants who
10 can bring cases. And the more information that is
11 publicly available about the abuse of the regulatory
12 system -- things like abuse of citizen petitions, sham
13 product hopping -- the more likely it is that other
14 entities that have rights will be able to go after
15 those problems.

16 And I wanted to give an example of how to
17 solve these problems by looking at the pay for delay
18 issue. First, there shouldn't be a -- anybody who
19 wants to spend endless hours talking to me, I'll
20 explain that the problem with pay for delay is not an
21 antitrust problem. It's a regulatory problem. As that
22 guy who talks a million times faster than me, from

1 Apotex, tried to explain, the incentives are all
2 screwed up. The firm that's willing to litigate and
3 then wins -- wins, that's an interesting concept --
4 wins is the firm that should get the patent
5 exclusivity.

6 But, how was the problem solved? It was a
7 combination of an FTC study, their power under Section
8 6 of the FTC Act, where they have subpoena power to ask
9 the companies the questions you can't ask. To go and
10 see their actual internal documents that tell you why
11 they hop and switch, that tell you why they go and
12 adopt a new REMS strategy, that tell you why they, you
13 know, engage in this variety of conduct. They then
14 informed Congress, and then Congress provided
15 transparency in reporting. So, that every patent
16 settlement has to be filed with the FTC.

17 And when you know that your potentially bad
18 acts have to be filed with the FTC, that does affect
19 your conduct, as the FTC studies have shown that the
20 problematic patent settlements have decreased once
21 people knew that they had to walk before Markus Meier
22 and say here's the settlement, is this settlement

1 kosher.

2 Now, let me turn to -- so, let me turn to the
3 three problems. First of all, I have some degree of
4 common sense, even though my wife will disagree. And
5 after hearing David Mitchell's presentation on REMS, I
6 don't think there's another word that you need to hear.
7 David Mitchell's presentation, combined with Mike
8 Carrier's presentation, give you a clear roadmap of
9 what an egregious public problem that is being abused
10 by the branded pharmaceutical industry that has a
11 relatively clear solution, combinations of both
12 regulatory and legislative actions.

13 Now, in citizen petition, you'd have to live
14 under a stone to think that there was something
15 worthwhile about a process in which people filing these
16 petitions -- oftentimes at the last moment -- only get
17 it right like 8 percent of the time. You can't play
18 baseball if your batting average is 8 percent. And I
19 think the ideas that Mike Carrier has come up with are
20 sound. Let's have greater disclosure of those citizen
21 petitions -- I mean, as much public disclosure as
22 possible. That's what affects the branded companies'

1 incentives, knowing people will look at it.

2 Then finally, as to product hopping, I can see
3 why this is a really significant concern. And look,
4 the -- there is a small set of situations where firms
5 really push the envelope. And as long as you can do
6 this in secret, why not? What's the worst thing that's
7 going to happen -- you're going to get involved in ten
8 years of antitrust litigation. But some of these
9 switches are just beyond the pale -- turning a capsule
10 into a tablet, drawing a line across a tablet. I mean,
11 they are just not serious innovations.

12 Perhaps the FDA should have an obligation --
13 you know, when you do regulations you have a paperwork
14 reduction act statement in which you have to say that
15 you're not creating unnecessary paperwork. Maybe when
16 you list drugs in the Orange Book, you should have a
17 competition statement, that says that competition will
18 not be harmed by listing these patents in the Orange
19 Book. Maybe you should have to do some kind of broader
20 assessment of the overall impact of extending
21 exclusivity. As the speaker for Public Citizen so
22 aptly put it, the use of exclusivity here is really

1 egregious and can cause tremendous competitive
2 problems.

3 Those -- in our written comments, the consumer
4 groups will give you more detailed, more thoughtful
5 comments on specific reform measures. But, I
6 appreciate your questions. Okay. Thanks.

7 MR. FLANAGAN: Wait, no. I'm sorry. I'm
8 sorry. Questions?

9 MS. SIPES: Yeah. I'm sorry. One quick
10 question. When you talked about this idea of maybe
11 listing in the Orange Book being conditioned on the
12 listing not having a negative impact on competition, I
13 was wondering if you could say a little bit more about
14 how you felt that determination might be made. You
15 know, obviously, there's the question of trying to make
16 a determination about whether the change itself or the
17 -- you know, if it's a formulation change or something
18 like that, is significant or not. But, I'm wondering
19 if you have any other thoughts to offer right now on
20 how an agency might make that determination.

21 MR. BALTO: I think it would be great for
22 everybody at the FDA to receive competition training.

1 I think some kind of analysis of what the impact would
2 be on the market, and how valuable it would be. Look,
3 I don't think you necessarily have to get the answer
4 right. I think you have to ask the question. And once
5 branded pharmaceutical companies know that the question
6 is being asked, just as they know that now when they
7 engage in patent settlements, the FTC may ask the
8 question -- just by knowing that the question gets
9 asked, that will affect their conduct.

10 MR. FLANAGAN: So, I'm sorry. Is it lawful
11 for us to subject, you know, reformulations to a
12 competitiveness filter?

13 MR. BALTO: I don't know why you -- that will
14 be a question we will answer thoughtfully when we
15 submit written comments. Thanks.

16 MS. DICKINSON: Can I ask -- so, full
17 disclosure, the cartoon you have on page 35 --

18 MR. BALTO: Yes.

19 MS. DICKINSON: -- I have it on my wall,
20 having worked in Hatch-Waxman for a long time. It's
21 dated 2002. That's 15 years ago. Have -- is it the
22 case that there are actually more incidents of the kind

1 of product hopping and successive iterations of product
2 development? Or is it that we're feeling we -- the
3 U.S. population feeling the effect of that more,
4 because of the increase in drug prices?

5 MR. BALTO: I don't know that someone studied
6 the number of things. By the way, I do think if
7 anybody -- if -- I think that the problem in REMS is
8 clearly increasing. On hopping, they are some of the
9 larger drugs and some of the conduct is pretty
10 egregious. But, I don't know that that's been studied.
11 Thanks.

12 MS. SIPES: Sorry. I'm sorry.

13 MR. BALTO: Sorry.

14 MS. SIPES: You're walking faster than we're
15 thinking. I was intrigued by your comment when we were
16 -- in response to my previous question about, you know,
17 a statement about impact on competition where you said
18 that just asking the question has an impact on
19 behavior. Do you -- what do you think of -- you know,
20 you had sort of proposed a statement having to be made
21 or determination about impact on competition. Do you
22 think similar purposes would be served by something

1 slightly lesser -- for example, simply just increasing
2 transparency around the exact relisting determination
3 that was being requested, or the product that was going
4 to be listed -- simply making that more public in
5 different ways. Do you think that that would -- just
6 putting that information out there would have an
7 effect?

8 MR. BALTO: I do. I mean, secrecy is the
9 friend of cartelists and monopolists. You know, if
10 they know their conduct isn't going to be looked at and
11 isn't going to be disclosed, they're more willing to
12 engage in that type of conduct.

13 MR. FLANAGAN: Thank you.

14 MR. BALTO: Thanks.

15 MR. FEMIA: Good afternoon. My name is Bob
16 Femia. I'm Senior Vice President of Chemical Medicines
17 at USP. Drs. Gottlieb, Woodcock and esteemed panelists
18 from FDA and FTC, on behalf of USP I'd like to thank
19 the agency for the opportunity to comment on this
20 important topic of facilitating increased competition
21 in the market for prescription drugs through the
22 approval of generic medicines. As we know for more

1 than three decades, generic medicines have
2 significantly increased patient access to quality
3 treatment while lowering healthcare costs in the United
4 States. We've certainly heard this many times today.

5 We believe that generic medicines continue to
6 hold similar promise for the future, and we applaud
7 FDA's efforts to modernize and enhance the abbreviated
8 new drug application process, which was created by
9 Hatch-Waxman Amendments, and help ensure the intended
10 balance between encouraging innovation in drug
11 development and accelerating the availability to the
12 public of lower cost alternatives to originator drugs.

13 USP is an independent scientific nonprofit
14 organization which is dedicated to protecting and
15 improving public health. We collaborate with FDA,
16 clinicians, other practitioners, manufacturers, and
17 many other stakeholders to develop public standards and
18 related programs that help ensure the quality, safety
19 and benefit of medicines, as well as foods. USP shares
20 FDA's goal of advancing and promoting patient safety
21 across medicines, and we support efforts to broaden
22 access to safe and effective generic medicines. Better

1 access to generic medicines will facilitate the
2 availability of lifesaving therapies, while helping to
3 ensure costs to patients and the healthcare system
4 remain affordable and sustainable, thus upholding FDA's
5 standard for evidence based, science based regulation.

6 USP offers the following comments for the
7 agency's consideration, and we welcome opportunities to
8 work with the agency, industry and other stakeholders
9 to enhance patient access to quality medicines.

10 My comments are focused on three main topics.
11 Number one, USP's public standards help facilitate the
12 entry of products from multiple manufacturers to the
13 market. USP's public standards provide common
14 benchmarks which help define the target for quality
15 medicines for industry, also contributing to
16 practitioner and patient confidence in the integrity of
17 these products. In particular, generic drug
18 manufacturers use USP standards to establish the key
19 quality attributes of their products. In this way,
20 USP's public standards facilitate the entry of products
21 from multiple manufacturers because manufacturers can
22 use USP's public standards in their applications to set

1 forth the quality, purity and strength of their
2 products or substances, thereby minimizing the
3 necessity to establish these parameters themselves, and
4 advancing the availability of lower cost beneficial
5 medicines for patients.

6 Public standards help both industry and
7 regulators navigate the complicated analytical
8 environment for products. Consider, for example, the
9 category of products frequently referred to as
10 nonbiologic complex drugs. Applications for generic
11 versions of these drugs have presented challenges to
12 industry and the agency. USP can contribute and has
13 been contributing in a positive way to the development
14 of generic versions of these drugs, and in certain
15 cases USP has been able to bring together scientific
16 experts from the manufacturers and the agency to work
17 collaboratively on these challenges.

18 Through such efforts, common analytical
19 solutions have been identified and agreed upon by
20 manufacturers, and these have led to public standards
21 developments that define critical product quality
22 attributes. It's our understanding that these public

1 standards in turn have been useful to FDA in its
2 approval of certain nonbiologic complex drugs.

3 Moreover, USP standards setting process is
4 iterative to account for changes in innovation. USP's
5 product specific standards are flexible to evolve with
6 the public health needs and advances in quality
7 expectations. USP's standards are reflective of the
8 approved medicine in the marketplace, and evolve as the
9 quality specification for the product evolves. One
10 example is USP's monograph for the drug enoxaparin
11 sodium. This monograph has been revised several times
12 to accommodate subsequent U.S. market entries from
13 different manufacturers for this product.

14 The resolution of these complex scientific
15 issues is challenging, and requires participation by
16 all impacted stakeholders. Early sustained and active
17 engagement by relevant stakeholders in the standards
18 setting process is imperative for the efficient and
19 successful development of a public standard. USP
20 welcomes the opportunity to work with the agency and
21 industry to explore mechanisms to facilitate this work.

22 Number two, USP's standard setting process

1 supports the overall efficiency of the generic drug
2 approval process. USP's processes are built to adapt
3 and respond to stakeholder needs. For example, working
4 closely with the agency and industry, USP created the
5 USP pending monograph process to allow for the
6 development of monographs or monograph revisions for
7 drugs awaiting approval by FDA, to help ensure that the
8 approval of the drug by FDA would be in lockstep with
9 the appearance of the new monograph in the compendia.
10 This new process helps prevent delays in certain drug
11 approvals by reconciling the timing of FDA generic
12 approvals with USP monograph updates.

13 And third, and last but not least, USP stands
14 ready to collaborate even more effectively with FDA and
15 industry to expand access to affordable quality generic
16 medicines. In addition to this very important public
17 meeting, FDA recently announced other policy
18 initiatives designed to enhance patient access to
19 generic medicines. In order to bring generic medicines
20 to the patients who need them, USP is committed to
21 collaborating effectively with FDA and all relevant
22 stakeholders bringing to the table our scientific

1 standards setting process and the great responsibility
2 imparted by our statutory recognition for quality
3 standards.

4 Again, thank you very much for the opportunity
5 to share our comments with you.

6 DR. UHL: Thank you very much for your
7 comments. Related to the aspect of standards, I'm
8 wondering if you could reflect a bit on the specific
9 example you gave, especially enoxaparin and how the
10 monograph had been updated several times. It sounds to
11 me you could analogize that, potentially, to the
12 earlier comments we received about changes in
13 bioequivalence standards and such, and how you might
14 make recommendations to the agency about how we apply
15 evolving standards with the example of enoxaparin. If
16 you don't have anything you want to say off the top of
17 your head, right now, it might be beneficial to hear
18 about that in the docket.

19 MR. FEMIA: Actually, the response to that
20 would be best addressed through the dockets. But, as a
21 predicate statement what I can say is that the -- you
22 know, any and all of these issues kind of start and end

1 with timeliness of commentary to that which appears in
2 the pharmacopeia form. We get requests for revision
3 all the time, for any of our monographs -- any and all
4 of them. When they appear in the PF, we actively
5 encourage and -- to that point, we have a very active
6 program within USP now for stimulating donor
7 participation. Is we really need to have timely
8 feedback from any and all stakeholders -- FDA, any
9 other relevant parties that have interest in that
10 particular monograph need to comment in a very timely
11 manner for PF publications. That's really the
12 cornerstone for any of these evolving monographs, to
13 reflect what's going on in the industry from a
14 regulatory perspective and from an innovative
15 perspective.

16 MR. FLANAGAN: Thank you.

17 MR. FEMIA: Thank you.

18 MS. WORTHY: Good afternoon. I'm Stacey
19 Worthy, the Executive Director of the Alliance for the
20 Adoption of Innovations in Medicine, or Aided Alliance.
21 We're a nonprofit that works to improve access to
22 healthcare, and thank you for the opportunity to

1 provide this public comment. Aimed Alliance supports
2 regulatory policies that accelerate both the
3 development of and access to medical treatments.
4 Guarding patient safety and increasing generic drug
5 development are not mutually exclusive, including when
6 it comes to REMS.

7 First, we recommend supporting efforts to help
8 stakeholders understand the purpose and use of the REMS
9 program. The program limits restrictions only to the
10 most potentially dangerous drugs. For example, the FDA
11 has removed REMS requirements it deems no longer
12 necessary for over 145 drugs already. It also required
13 stricter REMS for certain medications when post-market
14 data showed that these treatments had a known or
15 potential serious side effect not previously
16 understood. Currently, the FDA requires REMS
17 restrictions for 70 medications. Of these, 34
18 individual medications are regulated with elements to
19 assure safe use, or ETASU, the most restrictive type of
20 REMS. Additionally, there are eight drug classes with
21 REMS where both brand and generic versions use a shared
22 distribution system.

1 Yet, allegations persist that REMS safeguards,
2 and especially ETASU with restricted distribution, are
3 overused or are implemented by brand manufacturers to
4 block generic competition. Additionally, REMS has
5 become a convenient target for critics who associate
6 FDA mandated restricted distribution programs with the
7 tactics of some industry bad actors that self-imposed
8 restricted distribution to maximize their profits. To
9 avoid misperceptions, the FDA should support efforts to
10 share information on the purpose and use of the REMS
11 program with stakeholders, including policymakers.

12 Second, generic drug developers must be held
13 to the same safety standards as brand manufacturers, to
14 ensure that patients have more affordable, safe access
15 to higher risk treatments. The purpose of REMS is to
16 first provide treatment options to patients who may
17 otherwise go untreated, and second prevent the
18 dangerous complications these drugs can cause,
19 including severe birth defects and death. Currently,
20 millions of Americans benefit from medications that may
21 have been otherwise unavailable if not for REMS safety
22 protocols. As such, responsible regulatory policy must

1 ensure that generic drug developers are held to the
2 same safety requirements as innovator companies when
3 conducting bioequivalence testing and marketing their
4 products.

5 Third, the FDA should provide guidance on
6 negotiating the sharing of samples for bioequivalence
7 testing. In December 2014, the FDA issued draft
8 guidance explaining how generic manufacturers can
9 obtain samples for REMS drugs with ETASU. It allowed
10 brand and generic drug makers to negotiate the sale of
11 drug samples subject to REMS with ETASU, without fear
12 that the innovator REMS program would be violated.
13 However, it only required generic drug makers to attest
14 to the FDA that they were capable of meeting the same
15 safety requirements as the brand manufacturer.

16 Disagreement over this capability has led to stalled
17 negotiations. To prevent such stalemates, the FDA
18 could provide additional guidance on the terms under
19 which the sharing of drug samples for bioequivalence
20 testing can be negotiated. Such guidance could include
21 standardizing the procedures and controls for safe
22 handling and use of high risk drugs, specifying the

1 quantitative measures to evaluate and validate the REMS
2 programs and methods for filing this information with
3 the FDA.

4 Finally, the FDA should expand the use of the
5 shared REMS system. Shared REMS systems are
6 appropriate when several generic versions of a
7 medication require the same ETASU program. Shared REMS
8 can use a single web portal, for example, to access
9 medication guides, prescribing information and
10 prescriber and pharmacist education platforms.

11 Presently, negotiating each party's responsibilities in
12 implementing a shared REMS system can take a long time.
13 Challenges include agreement on governance and cost-
14 sharing. One possible solution is creating more
15 industry working groups, to develop proposals for the
16 shared REMS system where FDA acts as a facilitator to
17 resolve problems.

18 In sum, the REMS program is an essential tool
19 for advancing patient safety, protecting public health
20 and providing access to lifesaving medications that
21 would otherwise not be available. Therefore, we urge
22 the FDA to balance the need for safe use of potentially

1 dangerous medicines with the importance of increasing
2 the availability of low cost generic drugs. Most
3 importantly, generic drug developers must be held to
4 the same safety standards as brand manufacturers.

5 Our recommendations are laid out more
6 thoroughly in the comment we submitted to the docket.
7 Thank you.

8 MR. FLANAGAN: No questions? This concludes
9 today's presentations. Thank you to all our presenters
10 for sharing your insightful thoughts on ensuring a
11 balance between innovation and access. We will take
12 your comments in addition to the comments submitted to
13 the docket under careful consideration. Thank you very
14 much to everyone who attended today, and to others who
15 were watching remotely. Thank you to Martha Nguyen,
16 Ashley Jones, Trang Tran, Derek Griffing and Phil
17 Bonforte who put together this -- and Tawni Schwemer,
18 who put together this terrific event.

19 Again, the docket will remain open until
20 September 18th. The federal register notice announcing
21 this meeting has instructions for how to submit
22 electronic comments. We'll consider these electronic

1 comments along with the views presented here today. We
2 recognize your passion for the critical issues that
3 were discussed today, and we're impressed by the
4 willingness of so many of you to share your thinking on
5 complex Hatch-Waxman issues. It will take us some time
6 to digest all of the input we have received, and we'll
7 continue to receive until September 18th. But I can
8 assure you that we have been listening carefully, and
9 we'll leverage your insights to identify solutions
10 where possible.

11 Thank you again for joining us today. This
12 meeting is adjourned.

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CERTIFICATE OF NOTARY PUBLIC

I, MICHAEL FARKAS, the officer before whom the foregoing proceeding was taken, do hereby certify that the proceedings were recorded by me and thereafter reduced to typewriting under my direction; that said proceedings are a true and accurate record to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.



MICHAEL FARKAS

Notary Public in and for the

STATE OF MARYLAND

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I, JANE W. GILLIAM, do hereby certify that this transcript was prepared from audio to the best of my ability.

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July 31, 2017



DATE

JANE W. GILLIAM

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