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Public Meeting on Reauthorization of the GDUFA of 2012 06-15-2015

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FOOD AND DRUG ADMINISTRATION (FDA)

PUBLIC MEETING ON REAUTHORIZATION OF THE GENERIC
DRUG
USER FEE AMENDMENTS OF 2012 (GDUFA)

Monday, June 15, 2015

Food and Drug Administration
White Oak Campus
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Reported by: Michael Farkas
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1 A P P E A R A N C E S

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3 Center for Drug Evaluation and Research
(CDER), FDA

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5 CDER, FDA

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Health Service

17 Alan Nicholls, Bulk Pharmaceutical Task Force

18 David Gaugh, RPh, Generic Pharmaceutical
19 Association

20 Gil Roth, Pharma & Biopharma Outsourcing
Association

21 Gabrielle Cosel, The Pew Charitable Trusts

22

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2 Sharon Levine, MD, The Permanente Medical Group,
Kaiser Permanente

3

4 Andrew Bazemore, MD, MPH, Robert Graham Center
Policy Studies in Family Medicine & Primary
Care

5

6 Christopher Topoleski, Government Affairs
Division, American Society of Health-System
Pharmacists

7

8 David Schoneker, MS, IPEC-Americas

9

10 Melissa Authelet, Rochem International

11

12 Perry Cole, Specialty Pharma Association

13

14 James Polli, PhD, University of Maryland School of
Pharmacy

15

16 Gerald Yakatan, PhD, IriSys, Inc.

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

2 DR. PETERS: Morning, everyone. My
3 name's John Peters. I'm the Acting Director of
4 OGD. And on behalf of myself, Dr. Yu, who's the
5 Deputy Director of OPQ, the distinguished panel,
6 and the staff of OGD, I welcome you.

7 Thank you for attending today's Public
8 Meeting on the Reauthorization of the Generic Drug
9 Users Fee Act of 2012, which we lovingly call
10 GDUFA.

11 First, a few brief comments about
12 today's agenda. You'll hear from several FDA
13 officials, including myself, and I promise I'll be
14 brief. When I'm done, Ann Marie Montemurro, the
15 Staff Director of FDA's Office of Regulatory
16 Affairs for the GDUFA staff, will speak briefly
17 about the globalization of the generic drug
18 industry.

19 Then Keith Flanagan, the Director of the
20 Office of Generic Drug Policy in OGD, will provide
21 an overview of GDUFA I. The rest of the morning
22 will be dedicated to presentations from other

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1 federal agencies and trade associations.

2 That should bring us to lunch. And
3 following lunch there will be presentations from
4 other stakeholders and an open comment period.

5 Finally, Mary Beth Clarke, the Director
6 of the Office of Executive Programs in CDER, will
7 make closing remarks and adjourn this Public
8 Meeting.

9 We have a distinguished panel of FDA
10 experts to listen to you and to pay attention to
11 your presentations today. This group consists of
12 our GDUFA II negotiation team.

13 Before I ask the panel members to
14 introduce themselves, I want to thank them and our
15 presenters and all of you in the audience for
16 participating in today's Public Meeting. We value
17 your input and are grateful for your active
18 engagement. We look forward to a very productive
19 rest of your day.

20 So thank you, and would our panelists
21 introduce themselves?

22 MS. CLARKE: Mary Beth Clarke, Director

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1 of CDER's Office of Executive Programs.

2 MR. FLANAGAN: I'm Keith Flanagan, the
3 Director of the Office of Generic Drug Policy in
4 CDER's Office of Generic Drugs.

5 MR. SHERWOOD: Ted Sherwood. I'm the
6 Acting Director of the Office of Regulatory
7 Operations.

8 MS. MONTEMURRO: Ann Marie Montemurro,
9 GDUFA Staff Director, Office of Regulatory
10 Affairs, Office of Medical Products and Tobacco
11 Operations.

12 MS. BOAM: Good morning. I'm Ashley
13 Boam, the Acting Director of the Office of Policy
14 for Pharmaceutical Quality in the Office of
15 Pharmaceutical Quality, CDER.

16 MR. SHIMER: Good morning. I'm Martin
17 Shimer, Deputy Director, Division of Legal and
18 Regulatory Support, FDA Office of Generic Drugs.

19 DR. PETERS: Thank you. Now I'd like to
20 point out three things about GDUFA by way of my
21 comments.

22 First, the agreement was negotiated with

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1 industry and is very specific about the -- what
2 the FDA needs to do, and we're doing it. Keith
3 will walk you through some of the details. We are
4 fulfilling our GDUFA public commitments in
5 performance, and in some ways we are exceeding
6 them. That's my second bullet.

7 In many cases, we're going above and
8 beyond the negotiated agreement. For example,
9 ANDAs that were submitted prior to Year 3 do not
10 have goal dates. This makes it very difficult for
11 industry to make plans for launch or to do other -
12 - make other business considerations.

13 In order to deal with that, we recently
14 rolled out a final plan for what we call target
15 action dates. These are not target completion
16 dates, but are internal aspirational goals that
17 help to give transparency as to the workload
18 planning that's in the FDA for industry's purposes
19 in planning their business. We're starting to
20 share these target action dates with the
21 applicants now as a courtesy.

22 And, third, as we implement GDUFA, we're

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1 running in parallel tracks. We're dealing with --
2 expeditiously dealing with a backlog of pre-GDUFA
3 applications as well as building simultaneously a
4 modern and sustainable generic review program
5 that'll demonstrate, both to industry and to the
6 public, the high-quality and meticulous detail
7 that we dedicate to ensuring quality, affordable
8 generic drugs for the American public.

9 And with that, I'll ask Ann Marie to
10 take the podium.

11 MS. MONTEMURRO: Thank you. Good
12 morning. I'm going to spend some time giving an
13 overview of the globalization of the industry,
14 both as it relates to the importation and drug
15 supply chain, which served as context during the
16 first round of GDUFA negotiations.

17 This globalization and the recognition
18 of a continued need for strengthened oversight of
19 foreign establishments led to some of the
20 commitments in GDUFA specifically related to
21 inspections. I'll also discuss those commitments
22 and describe some of the initial steps the Agency

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1 has taken to address them. I'm so sorry. I forgot
2 to advance my slides.

3 To start, here are some basic facts
4 about globalization of the entire universe FDA
5 regulates -- of FDA-regulated products; not just
6 drugs or generic drugs, but it gives you a sense
7 of the massive globalization we are experiences --
8 experiencing.

9 FDA-regulated products now account for
10 approximately 10 percent of imports into the U.S.
11 FDA-regulated products originate from over 150
12 countries, 130,000 importers, and 300,000 foreign
13 facilities.

14 The globalization of the pharmaceutical
15 market has created tremendous challenges for FDA,
16 including dramatic increases in drug imports,
17 complex and fragmented supply chains, and
18 increasing threats of fraudulent and substandard
19 drugs.

20 Over the last decade, there has been a
21 staggering increase in U.S. imports, and there is
22 now essentially borderless production trade and

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1 consumption of all products FDA regulates. We can
2 no longer distinguish between domestic and
3 imported products in our marketplace.

4 Now, when we just look at drugs, we've
5 all heard the stat that almost 40 percent of the
6 finished drugs marketed in the U.S. come from
7 overseas, and 80 percent of the manufacturers of
8 active pharmaceutical ingredients for U.S.-
9 marketed drugs are located outside the U.S.

10 This chart really puts into perspective
11 some of these stats and demonstrates the growing
12 number of imported human drug products as it
13 depicts -- as it depicts declared human drug
14 import lines through 2015. So that's the red
15 section there. And then the tiny blue sliver
16 there is the number of entries that we examine.

17 And it's not just that imports are
18 growing so quickly, but the complex supply chains
19 has grown as well. Global supply chains are
20 increasingly complex and difficult to trace. From
21 ingredient to manufacturer, from manufacturer to
22 patient, there are threats and vulnerabilities

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1 along the way.

2 Today's supply chains have multiple
3 participants. For example, drug product may go
4 from the manufacturer to a distributor to a
5 repacker to a secondary distributor, all before
6 arriving to its final destination. The
7 fragmentation of the supply chain greatly
8 increases its risk of the unknown with respect to
9 product safety, quality, and integrity.

10 So the globalization challenges relates
11 to imports in drug supply chain are nothing new.
12 In the run-up to the first round in GDUFA, those
13 issues were very much at the forefront, due
14 largely to the heparin tragedy.

15 As a result of both these long-term
16 challenges and the immediate need to respond to
17 heparin with meaningful policy and operational
18 changes, key FDA stakeholders raised concern about
19 the Agency's level of foreign inspection
20 oversight.

21 GAO, for example, had called not only
22 for more foreign inspections to be done, but

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1 specifically noted that what the Agency really
2 needed to do is identify those sites that present
3 the highest risk to public and prioritize
4 inspections, regardless of whether they were
5 foreign or domestic. And in their report, Pew
6 recommended the need for more foreign inspections.

7 So based on those imports from
8 stakeholders as well as results of negotiations
9 with industry, there are a few GDUFA I commitments
10 specifically having to do with inspections,
11 particularly around those related to parity of
12 domestic and foreign inspections and transparency.

13 Two of the commitments that I'll focus
14 here on are that FDA will employ a risk-adjusted
15 inspection model for conducting CGMP surveillance
16 of generic active pharmaceutical and finished drug
17 manufacturers, with the goal of achieving risk-
18 adjusted parity between domestic and foreign CGMP
19 inspections and making inspection classification
20 results publicly available.

21 On the first commitment having to do
22 with parity of domestic and foreign inspections

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1 and conducting more foreign inspections, I'll
2 start by showing this graph, which shows some
3 progress towards increasing the relative number of
4 foreign inspections since the passage of GDUFA.

5 And as you can see here, in 2014, we
6 actually -- it was the first year we actually did
7 more foreign inspections than domestic. And this
8 data represents the number of inspections of self-
9 identified generic drug firms from March -- from
10 fiscal year 2012 through March 30th of this year.

11 I would say that this chart is
12 encouraging, but I also wanted to note that it
13 doesn't give you the full picture of the
14 commitment, which is to conduct risk-adjusted
15 parity with comparable depth and rigor, with
16 "risk-adjusted" being the key word here.

17 FDA is making progress on that
18 commitment by using combined risk models for
19 scheduling inspections with identical risk
20 factors. My colleagues from CDER's new Office of
21 Pharmaceutical Quality have been working
22 diligently on this for several years and can give

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1 you details on the model and risk factors.

2 CDER will use this model when
3 prioritizing inspections for ROA to conduct, and
4 we have worked collaboratively with CDER on this.
5 We are also working together on developing a new
6 standardized inspection approach.

7 With respect to comparable depth and
8 rigor, I will note that FDA always committed to
9 using the same compliance programs and has the
10 same level of training to achieve comparable
11 oversight of foreign and domestic inspections, but
12 there are some unavoidable aspects that make
13 operation of domestic and foreign inspections
14 different.

15 For example, travel constraints on the
16 foreign side and training of new investigators
17 domestically could have some impact on inspection
18 time.

19 But there is additional work that the
20 Agency can do to address the issue of comparable
21 depth and rigor, such as looking at the amount of
22 time spent during domestic inspections and the

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1 time it takes to write up an inspection report
2 once an investigator returns from a foreign trip.

3 ORA, in collaboration with CDER, is
4 carefully studying these factors and devising
5 strategies to address them so we can move even
6 further towards a greater level of comparable
7 depth and rigor.

8 FDA has also responded to the
9 commitments to make inspection classification
10 results publicly available by creating a public
11 database of these results. Inspections are
12 classified to reflect the compliance status of a
13 firm. Classifications are based on the findings
14 during an inspection and Agency review for
15 compliance.

16 This link is to the public database of
17 inspection results. Through this site, the Agency
18 is disclosing inspection information to help
19 improve the public's understanding of how FDA
20 works to protect the public health.

21 Disclosure of the compliance status of a
22 firm helps to provide the public with the

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1 rationale for the Agency's enforcement actions and
2 will also help to inform public and industry
3 decision-making, allowing them to make more
4 informed marketplace decisions and help to
5 encourage compliance.

6 I'll also touch briefly here on a couple
7 of other commitments that the Agency is working on
8 related to inspections: prioritized inspections of
9 establishments that are otherwise approvable but
10 for an outstanding preapproval inspection and
11 studying foreign government inspections and
12 developing a plan for utilizing the information
13 where appropriate.

14 So, for example, the Mutual Reliance
15 Initiative, which was launched in May of 2014, is
16 a strategic collaboration between the FDA and the
17 EU to evaluate whether we have comparable
18 regulatory and procedural framework for
19 inspections of manufacturers of human
20 pharmaceuticals so that we can eventually rely on
21 each other's inspectional information.

22 Strengthening our reliance upon each

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1 other's expertise and resources will greater --
2 will result in greater efficiencies for both
3 regulatory systems and provide more practical
4 means to oversee the large number of drug
5 manufacturers outside of the U.S. and the EU.
6 This evaluation is a work in progress. Efforts are
7 continuing, and the evaluation will go on through
8 fiscal year '16.

9 And, finally, I wanted to give you a
10 brief hiring and training update in support of
11 GDUFA inspection goals. ORA has increased its
12 field staff, with close to 100 new positions.
13 We've hired approximately 80 investigators, who
14 are dedicated to the drug program. These
15 investigators are located throughout the U.S. and
16 are responsible for both foreign and domestic
17 inspections.

18 Sorry. Yeah, can you advance it one
19 more? I'm sorry. The other way. Thanks. These
20 new hires are being trained using -- oh, it's -- a
21 couple more. No, the other way. Keep going. No,
22 no, no, it's the other way. It's almost to the

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1 last slide, so -- okay.

2 These new hires are being trained using
3 a blended learning approach involving Web modules,
4 live webinars, classroom training, and OJT. We
5 are currently -- we currently have three cohorts
6 in various stages of training.

7 And I think I'm at the end. Yeah, so
8 all of these things position us to meet the
9 demands of the global industry. Thank you. And I
10 believe Keith Flanagan will be up next.

11 MR. FLANAGAN: Okay. I'm going to try
12 not to use this clicker. Who should I look to?
13 Tony?

14 FEMALE SPEAKER: Me.

15 MR. FLANAGAN: Okay. Good morning. So
16 I'm going to give you a very long overview of
17 GDUFA I. Next slide, please. And let me start off
18 with the same three high-level points that Dr.
19 Peters made.

20 First is that FDA is fulfilling its
21 GDUFA commitments. We negotiated -- you know,
22 it's a negotiated agreement, and CDER has a strong

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1 track record for fulfilling its negotiated
2 commitments. We take these things real seriously.

3 Congress and our parent agency expect us
4 to fulfill our negotiated agreements. It's the
5 traditional yardstick by which FDA's success and
6 failure on a user fee agreement is measured, and
7 it's the right thing to do. We strive to do what
8 we say we're going to do.

9 Second, in many cases, we're going above
10 and beyond our negotiated GDUFA commitments. So
11 it's a first-time user fee agreement. It's going
12 to be a little disruptive and a little
13 challenging.

14 We listened to industry and other
15 stakeholder concerns, we responded, and we've been
16 very accommodating and very flexible. In many
17 cases, we're already offering a GDUFA 1.5 level of
18 service. While this is a real challenge to do on
19 top of our all -- our pre-existing GDUFA
20 commitments, it too is the right thing to do.

21 And then, last, the GDUFA commitments
22 reflect a design for a modern generic drug

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1 regulatory program, which I'll walk you through in
2 some detail below.

3 So the agenda for my presentation is
4 I'll give you a little background, I'll talk just
5 a little- bitty bit about the nature of GDUFA and
6 user fee agreements. I'm going to provide quite a
7 bit of detail concerning our performance in Years
8 1 and 2. Please bear with me. I tried to dial
9 back the level of detail, but we have to get into
10 some.

11 I'm going to talk about all the things
12 we did to get ready for goal dates for the first
13 time in Year 3. I'm going to talk about the goal
14 dates, talk about how, in many cases, we're going
15 above and beyond our goal dates, and then kind of
16 explain how Years 3, 4, and 5 of this five-year
17 program are going to unfold. And then I'll talk
18 about the expiration of GDUFA.

19 And I think that this is obvious from
20 the way that I laid this out, but basically I'm
21 telling the story of GDUFA chronologically, kind
22 of here's what it was like, here's what's

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1 happening, and here's what's going to happen.

2 So there are a bunch of reasons why we
3 have a GDUFA, why we needed a GDUFA agreement.

4 And my colleague Ann Marie's excellent
5 presentation, she talked about some of the safety
6 and transparency challenges posed by the
7 increasing globalization of the generic drug
8 supply chain and our need to get more boots on the
9 ground overseas and to target high-risk facilities
10 overseas.

11 We also, on the review side, as this
12 graph punches home, had the challenge of OGD being
13 chronically under-resourced and this chronic deep
14 backlog arising over time.

15 In many ways, the generic drug program
16 was sort of the victim of its own success. When
17 Hatch- Waxman passed in 1984, it took a while for
18 a generic drug industry in the United States to
19 gain its footing. It has certainly gained its
20 footing and now started to really push a lot of
21 submissions our way, and we could not keep pace
22 with them; hence, we have a GDUFA.

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1 So GDUFA, like the rest of the FDA
2 medical product user fee programs, is a bilateral
3 agreement. It's negotiated between FDA on the one
4 hand and industry on the other. Industry pays FDA
5 certain agreed-upon fees, and in exchange FDA
6 provides certain agreed-upon performances.

7 After FDA and industry reach agreement,
8 we send it to Congress, who enacts it
9 legislatively. And the bill was signed by
10 President Obama in 2012. At the highest general
11 level, the goal of GDUFA was to promote safety,
12 access, and transparency. Next slide.

13 Okay. So I'm going to try not to swamp
14 you with too much technical detail, but some of
15 these are so technical that unless I give you some
16 detail, you're -- unless you're a generic drug
17 regulatory expert, you're not going to know what
18 I'm talking about. So with apologies I'm going to
19 walk you through with just a little bit of detail.

20 So self-ID and user fee infrastructure,
21 this is one of the earliest GDUFA commitments, and
22 we got it done, thanks in large part to the

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1 leadership of Mary Beth Clarke and Donald Parks,
2 who's sitting in the back, and others at FDA.

3 Basically, we asked generic drug
4 facilities to self-identify and pay fees. This
5 gave us, for the first time, a more complete and
6 accurate inventory of global generic drug supply
7 chain participants. This helps us ensure that all
8 participants in the U.S. market, whether foreign
9 or domestic, are held to consistent, high-quality
10 standards.

11 We -- completing this task is not
12 intuitive. We had to figure out how to do it and
13 then explain it to industry so that we could
14 implement it. We developed and finalized a very
15 detailed guidance to explain what we expected, and
16 then we built a facility database to receive and
17 manage all this data about supply chain
18 participants. And then we had to build a robust
19 user fee program infrastructure to receive and
20 administer the user fees, a significant
21 foundational accomplishment that we got done.

22 The second item up there is complete

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1 response letters. So the deal on this is that,
2 prior to GDUFA, FDA provided applicants with
3 notice concerning their deficiencies on rolling
4 basis in sometimes an ad hoc manner. The complete
5 response letter instead requires FDA to
6 consolidate all reviewed discipline deficiencies
7 into one, as the name suggests, complete response
8 to industry.

9 In the first two years, we issued
10 something like 2,200 complete response letters, I
11 think. And since then we have actually heard from
12 industry that they don't always welcome complete
13 response letters in some circumstances and would
14 prefer that we use alternative vehicles, which
15 I'll discuss below. Nevertheless, the -- you know,
16 the Commitment Letter told us to do it, and we did
17 it.

18 The third thing is easily correctable
19 deficiencies. This requires FDA to notify
20 applicants of easily correctable deficiencies in a
21 timely manner. We're doing that.

22 The next one is the ANDA Refuse-to-

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1 Receive guidance. This basically concerns what,
2 in the new drug space, is called filing review.
3 In the generic space, we call it RTR (ph). For
4 FDA to receive a submission, it must be
5 sufficiently complete to permit a substantive
6 review.

7 Pursuant to GDUFA, we committed to issue
8 a guidance on point to clarify FDA's expectations.
9 We issue -- we developed and issued a draft
10 guidance, received stakeholder feedback, and then
11 finalized the guidance.

12 In addition, we're currently developing
13 additional guidances concerning specific subissues
14 related to RTR policy to provide additional
15 transparency and clarity.

16 The next item is Type II DMF
17 completeness assessments. So let me explain this
18 one. A Type II DMF provides information regarding
19 the manufacturer of a drug substance, a drug
20 product, or an intermediate used in the
21 manufacture of a drug substance or drug product.
22 It is the confidential information of the -- you

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1 know, the API manufacturer, the DMF holder.

2 A different party, an ANDA applicant,
3 can rely on the DMF for purposes of trying to get
4 the ANDA approved, but, again, the material within
5 the DMF is confidential, and FDA can't freely
6 share it with the ANDA applicant.

7 There were numerous improvements that
8 involved us making sure that the left hand of the
9 DMF review process was well-coordinated with the
10 right hand of the ANDA review process, and this is
11 one of them.

12 The completeness assessment evaluated
13 whether information necessary to conduct a full
14 scientific review is present in the DMF. We
15 completed that. It required approximately 300 --
16 3,475 review cycles. But it's done.

17 The GDUFA commitment following that is
18 the DMF available for reference list. This --
19 basically, it means that after we have completed
20 the completeness assessment and found that the DMF
21 contains the necessary information, we put that
22 DMF on a publicly available list. You know, we

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1 post the list.

2 What this does is it enables the DMF
3 holder to better market itself, saying, "Look,
4 we're -- our DMF's in good shape. You prospective
5 business partners should be able to rely on our
6 DMF." And, secondly, it assists ANDA applicants,
7 because they know which DMFs are -- they're ready
8 to go.

9 The last one that I want to talk about
10 is teleconferences. Pursuant to GDUFA, ANDA and
11 DMF applicants can obtain teleconferences
12 concerning first cycle review deficiencies. The
13 long story short on that is that we're fulfilling
14 our commitment on point, but have tweaked how
15 we're managing that program area a little bit
16 going forward.

17 Specifically, we can respond to the
18 applicant's inquiry either by straight-up a live
19 telephone discussed, or, if we earnestly believe
20 that the best way to answer the applicant's
21 question is by providing a written response, we
22 have been providing a written response.

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1 It created some confusion because
2 applicants thought we were providing letters in
3 lieu of a teleconference. So at least on the DMF
4 side, and I think now on the ANDA side -- if it's
5 not done now, it will be soon -- the written
6 responses that go out clarify that the written
7 response is not intended to be provided in lieu of
8 a phone call.

9 So the point is we had a bunch of very
10 specific ANDA and DMF review efficiency
11 enhancements that we had to do pursuant to GDUFA
12 right out of the gate, and we did those. And,
13 stating the obvious, the checkmark means we've
14 done these things. Next slide, please.

15 In addition, we had to get ready for
16 goal dates for the first time. Goal dates began
17 for GDUFA in Year 3, which started October 1st of
18 2014, last year. That's a big deal, and, again, a
19 very significant paradigm shift for us. It
20 requires us to synchronize and coordinate our
21 efforts on our very high-volume, very complex
22 workload in a way that we never have before. So

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1 we needed to build a significant amount -- we
2 needed to enhance our program infrastructure very
3 substantially in order to enable us to do that.

4 So any one of these things would have
5 been a heavy lift. We did them all together.

6 First, our old information systems were
7 fragmented, stovepiped, and used inconsistent
8 terminologies. A lot of people in the generic
9 drug program did their work in homegrown desktop
10 applications that they jerry-rigged to get through
11 the day.

12 We built -- we developed and have
13 implemented an integrated generic drug regulatory
14 review platform that gives us the opportunity to
15 track progress towards goal dates. It reduces the
16 need for manual data entry and integrates our
17 business processes and technology for the first
18 time.

19 Second, we reorganized the Office of
20 Generic Drugs and elevated it to CDER super-office
21 status to make OGD a super-office on par
22 with the Office of New Drugs. Obviously, a

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1 reorganization of the office is a significant
2 undertaking.

3 Secondly, we moved all of OGD's staff
4 from four office buildings in Rockville to the
5 main FDA campus at White Oak, also a significant
6 undertaking. The reorganization and the move were
7 designed to enhance our staff's opportunities and
8 ability to collaborate with the rest of CDER and
9 the Agency.

10 It's a lot easier, a lot, to resolve a
11 sticky issue with a colleague if the colleague
12 works down the hall instead of across town. And
13 we've had so many of these -- it's really enhanced
14 our ability to collaborate, just the physical
15 proximity.

16 The next thing we got done is that we
17 have hired and trained over 1,000 new employees in
18 the generic drug program across FDA. There are
19 GDUFA commitments on point for Years 1, 2, and 3,
20 and we are ahead of schedule. We have completely
21 achieve that goal.

22 I would add that, while we do provide

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1 formal training to new hires, it's been our
2 experience that people learn the best by doing, by
3 mentoring and from on-the-job training, from
4 actual work experience, and that it takes about a
5 year for a new hire to achieve full productivity.

6 The next significant accomplishment to
7 prepare for goal dates is we established and are
8 continually enhancing an Office of Pharmaceutical
9 Quality. My colleague, Ashley Boam at the podium,
10 drives policy for OPQ.

11 A lot of you may have heard the message
12 from FDA going outside the Agency about how OPQ
13 provides the outside world with one voice for
14 quality. The neat thing about OPQ for the generic
15 drug program is it also provides one voice for
16 quality internally. It, for the first time,
17 consolidates all of the quality-related review
18 disciplines into one review package, containing
19 chemistry, micro, DMF, and compliance, which is a
20 really big deal and really big efficiency
21 enhancement for the program.

22 Next, we enhanced our business processes

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1 across OGD, CDER, and the Agency as a whole. Long
2 story short is we did a whole lot of process
3 mapping and a whole lot of process enhancement,
4 which dovetailed very closely with what we did to
5 build new information systems, would especially
6 spotlight the efforts between CDER and ORA to
7 better coordinate our efforts in the generic space
8 going forward.

9 Ann Marie talked about it a little bit,
10 but just to give you one example, you know, this
11 is a well-known kind of hotspot in the program for
12 a long time, where the left hand of scientific and
13 technical review wasn't, in every single case,
14 optimally coordinated with the right hand of
15 inspections and compliance.

16 So what we're doing now for incoming
17 submissions with goal dates is the people in CDER
18 and ORA who need to make determinations as to
19 whether and which inspections may be required to
20 take action on a submission, do those
21 determinations very rapidly together upon
22 submission of the ANDA so that we can timely plan

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1 for, conduct, and receive the results of
2 inspection. That means that the inspection work
3 is proceeding on a parallel track to the review
4 work that will substantially enhance efficiency.

5 The next business process -- although
6 these are by no means the only ones, just ones
7 that I particularly want to flag -- are first
8 generics- related improvements. So this is going
9 to seem like gobbledygook unless you're a Hatch-
10 Waxman lawyer or live in this space all the time,
11 so bear with me for just one moment. I'm going to
12 get through this slide, and then I'm going to try
13 to explain the technical issues in layman's
14 language.

15 Try. I'm going to try. Okay. So
16 pursuant to GDUFA, FDA agreed to expedite the
17 review of first- to-file Paragraph IV ANDAs,
18 especially to avoid forfeiture and also to
19 expedite the review of submissions that maybe
20 become eligible for approval, as the result of no
21 blocking patents, exclusivities, or stays. This
22 is a continuing obligation from the start to the

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1 finish of GDUFA.

2 Okay. So this is a complicated, but
3 important, provision. This commitment refers to
4 an important set of ANDAs known as first generics.
5 They are often blocked from FDA approval by
6 patents and other protections against competition
7 that Congress created to incentivize development
8 of new medicines. ANDAs that qualify as first
9 generics are just that, the first ANDAs that are
10 no longer blocked by patents or these other
11 incentives.

12 They are important because they can open
13 the market to generic competition for the first
14 time. They can dramatically improve access to
15 affordable quality medicines.

16 First-to-file Paragraph IV, or P4, ANDAs
17 is shorthand for a special subset of first generic
18 ANDAs. Specifically, a P4 ANDA applicant is one
19 who challenges the brand's patents. The Hatch-
20 Waxman law incentivizes these challenges in order
21 to keep weak brand patents from frustrating
22 competition. The incentive is P4 ANDAs can be the

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1 only generics on the market for 180 days after
2 approval.

3 One requirement is that P4 ANDAs be
4 ready for tentative or final approval, from a
5 scientific perspective, within 30 months of
6 submission. If they're not ready, they lose their
7 shot at 180 days of market protection. Next
8 slide, please.

9 The purpose of the very important GDUFA
10 commitment on P4 ANDAs is to honor the Hatch-
11 Waxman law's intent. We need to try our best to
12 make available the reward Congress created for
13 challenging brand patents. One hundred eighty
14 days of market protection can enable applicants to
15 recoup their investments, grow their businesses,
16 and thus further expand consumer access to
17 generics.

18 Toward this end, we made a number of
19 significant program improvements. Among other
20 things, we opened a docket and considered
21 stakeholder feedback. We established a patent and
22 exclusivity team within the Office of Generic

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1 Drugs. It proactively identifies, tracks, and
2 facilitates timely approval of issues related to
3 first generic approvals.

4 We also built a team of experienced
5 Hatch- Waxman Regulatory Counsels. They analyze
6 legal issues and document decisions in order to
7 ensure timely action. We trained review
8 disciplines and regulatory project managers
9 concerning first generics. And we're enhancing
10 our computer systems to ensure real-time
11 information supports (inaudible).

12 We need all of this first generics
13 program infrastructure. The law on point is
14 notoriously complicated. Numerous factors, such
15 as the outcome of patent litigation, are outside
16 of FDA's control. The legal landscape can change
17 rapidly and without our knowledge. We must be
18 proactive, attentive, and nimble.

19 Our program improvements are paying off.
20 In the past few months, we have timely approved
21 six first generic Abilifys, five tablets and one
22 orally disintegrating tablet; a first generic

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1 Fusilev; and a first generic Enablex. In the past
2 few weeks, we timely approved first generic
3 Lotronex; Zyvox, in multiple dosage forms; Tygacil
4 (ph); Vagifem; and Integrilin.

5 The thing that I would add -- can you go
6 to the next slide, please? The thing that I would
7 add before moving on is that we can only approve
8 approvable submissions. So if there's -- if
9 there's rat droppings and mold and data integrity
10 problems at an API facility, we can't approve the
11 ANDA. If there are problems with the scientific
12 and technical content of the submission, we can't
13 approve the ANDA. We can only approve approvable
14 submissions, which I'll discuss in greater detail
15 below.

16 Thank you for letting me go through that
17 deep dive on first generics. I saw that your --
18 some of your faces were kind of glazing over, and
19 I apologize for the level of detail, but it's
20 very, very important, and I wanted to walk through
21 it.

22 The deep dive on first generics is over.

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1 Let's return kind of back to where we were in the
2 chronology. In GDUFA Years 1 and 2, we built
3 program infrastructure to help us hit goal dates.
4 Goal dates started in Year 3 of the program. Goal
5 dates are a very powerful tool to improve the
6 timeliness and predictability of review.

7 Brand biopharmaceutical companies and
8 medical device companies get them under PDUFA and
9 MDUFA, respectively. Once you get used to goal
10 dates, it's hard to do without them. Next slide.

11 So I'm going to walk you through where
12 we're at on the Year 3 goals. So the Year 3 goal
13 for original ANDAs is FDA must take action on 60
14 percent of Year 3 original ANDAs within 15 months
15 of submission. So for an ANDA submitted October
16 1, 2014, the goal date does not accrue until 15
17 months later, in December of 2015.

18 The last submission ANDA in Year 3 could
19 be submitted September 30th, 2015. And so the
20 goal date for that submission won't accrue until
21 15 months later, which I think is December 2016,
22 after the presidential election. So we have a lot

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1 of time still to work, even on the very first Year
2 3 ANDAs that came in, but we feel confident that
3 we're on the right track.

4 On the pre-GDUFA backlog, that is all
5 ANDAs -- ANDA amendments and prior approval
6 supplements that were pending in our inventory as
7 of October 1, 2012, the day of GDUFA enactment.
8 Our GDUFA goal is that we must take action on 90
9 percent of this bucket of submissions by the end
10 of Year 5 of GDUFA I. We are way ahead of
11 schedule on that commitment. We are currently at
12 77 percent.

13 In addition, although I didn't put the
14 slide in to show the dramatic trend, we have
15 essentially eliminated the prior approval
16 supplement and other supplement backlogs, not only
17 for the GDUFA backlog, but also for Year 1 and 2.
18 So we are way ahead of schedule on that.

19 On prior approval supplements, a prior
20 approval supplement seeks approval of a major
21 change related to the safety, effectiveness, and
22 quality of an approved drug product. For Year 3,

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1 our goal is we must take action on 60 percent of
2 PASs not requiring inspection within 6 months.

3 I was a little skeptical about this, but
4 some of my colleagues have scrubbed the data and
5 strongly insist that we're currently at 100
6 percent. We'll validate that number for final
7 performance reporting to Congress, but, in any
8 event, we're crushing that goal.

9 On the amendment goals, I'm not going to
10 put a slide up explaining all the different
11 amendment goals because it's extremely complicated
12 and would take 15 minutes just to explain the
13 amendment metric goals. We issued a guidance on
14 point to provide clarity.

15 As with the original ANDAs, it's too
16 soon to tell, but we're confident. The reason
17 it's too soon to tell is mainly because we just
18 haven't gotten that many amendments. Amendments
19 refers to amendments to Year 3 original ANDAs.
20 It's not any amendment that comes in.

21 The next metric goal concerns controlled
22 correspondence. Controls are basically questions

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1 from industry about how to develop products. They
2 promote transparency and access by clarifying
3 FDA's expectation. The goal is we've got to
4 respond to 70 percent of these within four months
5 of submission, in general, and we're currently at
6 at least 95 percent. So we're also doing great on
7 that goal.

8 We have a teleconferences goal, at least
9 for ANDA CR teleconferences. I talked about that
10 above. We have metric -- a specific metric goal
11 for the first time in Year 3, and the goal is
12 we've got to try to provide 200 teleconferences.

13 I apologize to my colleagues who are
14 going to receive these calls, but I need to flag
15 that we have only received 25 requests for
16 teleconferences on the ANDA side. And so if
17 applicants have such requests, they should not shy
18 away from placing them. Obviously we can only hit
19 the goal if people ask for the teleconferences.
20 The next slide, please.

21 So I want to -- I have a pause point to
22 talk about the big picture on the GDUFA metric

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1 goals. And although I really should have labeled
2 this -- this slide is using the goal -- the goals
3 for original ANDAs as an example because it
4 illustrates the larger points that I want to make.

5 Does this have a laser pointer on it?

6 We're going to find out. It does? Okay. So the
7 -- we talked about -- if you're on a webcast, I
8 don't know if you can see the laser. The laser is
9 pointing at the pre-GDUFA backlog. So the metric
10 goal for the backlog is that we've got to take
11 action on 90 percent of everything in that giant
12 bucket of maybe 2,866 or so submissions by the end
13 of Year 5. Individual submissions in that bucket
14 don't get goal dates. The bucket as a whole has a
15 goal date.

16 Then we have goals for each ANDA that
17 comes in the door, Year 3, 4, and 5, and the goals
18 get tougher each year. Then for Years 1 and 2 of
19 the program, we have to do a good job on first
20 generics, and we have a maintenance and
21 productivity obligation, which I'll discuss in
22 some detail below, but there's no goal dates, as

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1 Dr. Peters pointed out, on any of the pre-Year 3
2 submissions. So next slide, please.

3 Okay. So the long story short is that
4 while we spent a lot of -- well, FDA has spent a
5 lot of time building program infrastructure to
6 enable us to hit goal dates, industry has strong
7 concerns regarding productivity and communications
8 for the pre-Year 3 submissions, which lack goal
9 dates. That's about -- that's maybe 85 percent or
10 so of our workload. Some of those submissions are
11 long-pending, and applicants want them approved as
12 soon as possible. But, as I just walked through,
13 they lack short-term GDUFA goals.

14 The -- this was all sort of -- there was
15 a little buzz in the background on this bucket of
16 issues, and then we started to hear much more
17 forcefully from industry and other stakeholders
18 following issuance of what we call the
19 communications with industry MAPP. MAPP, M-A-P-P,
20 stands for Manual of Policies and Procedures. It
21 is an internal CDER policy that is visible to the
22 public.

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1 The background on this communications
2 with industry MAPP is prior to GDUFA, applicants,
3 either directly or through consultants, could poke
4 around OGD, other parts of CDER, and other parts
5 of the Agency informally to inquire concerning the
6 status of their submissions and also informally to
7 advocate to expedite review of the most
8 commercially significant submissions, kind of the
9 shake the tree.

10 The challenge for us was, first, that
11 that was very resource intensive for our guys, who
12 had to drop their review, supervisory management,
13 or other work to respond to those calls. Two, it
14 gave rise to an appearance of differential
15 treatment for similarly situated applicants. And,
16 three, that wasn't always pursuant to an optimal
17 business process and wasn't always optimally
18 documented.

19 So when we issued the MAPP, it basically
20 said, "You can't call whoever you want in OGD.
21 You can only call the RPM." We basically stand by
22 that. We believe that the RPM, the regulatory

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1 project manager, should be the main point of
2 contact for a submission.

3 The challenge is that the new policy did
4 have the result of degrading communications
5 transparency concerning deficiencies and the
6 status of submissions. Industry's perspective --
7 and Mr. Goff (ph) or others can correct me if I
8 get this wrong later, but I don't think I got it
9 wrong -- industry's perspective was, "Look, we
10 paid a lot of money into this program, and for you
11 to provide less communications, worse
12 communications, not more and better, really
13 doesn't meet our expectations and, in addition,
14 really hurts us commercially, because it makes it
15 much harder for us to plan important product
16 launches and do other business planning."

17 FDA agreed with many of these
18 criticisms. Since then we've had a candid,
19 spirited consultation with GPhA, its member
20 companies, and other stakeholders to try to
21 pinpoint industry's exact pain points and develop
22 the most impactful enhancements we can make going

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1 forward to address that.

2 Okay. So now we're getting into the
3 kind of above-and-beyond section of my
4 presentation. So these are things we agreed to do
5 to enhance communication's transparency, even
6 though they're not in the GDUFA Commitment Letter.
7 They're often a heavy lift for us, but they're the
8 right thing to do, so I'm going to walk through
9 each of them.

10 Complete responses pending inspection,
11 as I discussed above, the GDUFA Commitment Letter
12 requires us to issue complete response letters.
13 The challenge is that we have a lot of submissions
14 in our workload, and from time to time the
15 scientific and technical review is complete, but
16 the compliance- and inspection-related work is
17 not.

18 In that case, we heard strong requests
19 from industry that, while it would be better to
20 have the compliance work done, if it's not, they
21 wanted their deficiencies as soon as possible so
22 they could move the submission closer to approval

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1 instead of waiting for a complete package later.

2 So we agreed to provide completer
3 responses pending inspections to applicants. We
4 have done that for about --one -- approximately
5 1,300; is that right? Approximately 1,300 times,
6 we've done that, even though it conflicts with the
7 GDUFA commitment and really degrades our ability
8 to make progress on the GDUFA backlog metric.

9 We're doing it because it's the right thing to do
10 and it helps submissions move closer to approval.

11 Secondly -- and this is another big one
12 -- where, under Ted Sherwood's leadership -- and I
13 don't see his face, but also with help from Dr.
14 Lawrence Yu and the Office of Pharmaceutical
15 Quality, the review disciplines in OGD and in OPQ
16 have been issuing informational requests to
17 applicants on a rolling basis.

18 What this means is that when individual
19 review disciplines discern deficiencies that are
20 not major deficiencies, they will very promptly
21 alert the applicant and request that the applicant
22 rapidly respond with information to dispose of the

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1 question.

2 The idea is that doing this iteratively
3 can drive submissions closer to approval in the
4 current review cycle. Basically, the deal is that
5 if you're an applicant, you would rather have us
6 try and crank through all the deficiencies we can
7 in the current review cycle and arrive at an
8 approval instead of taking the first round of
9 deficiencies, consolidating them into a complete
10 response, sending them to you, and then waiting
11 for you to get back to us and start another review
12 cycle.

13 So the thing that I need to stress is
14 that obviously this is only for deficiencies that
15 are not major. If you have a major deficiency, we
16 -- our hands are tied. We've pretty much got to
17 give you a CR, and there's nothing we can do about
18 it.

19 This is a response to industry's request
20 for more rapid information concerning deficiencies
21 in the current review cycle. I don't remember the
22 exact numbers, but we issued more than 700 of

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1 these in April, nearly 600 of them in May, and
2 continue to crank them out right now.

3 The third major initiative is target
4 action dates. So as Dr. Peters alluded to, a
5 target action date is FDA's internal aspirational
6 deadline for action on a pre-Year 3 submission.
7 We are starting to notify applicants of their
8 target action dates.

9 This is a very significant undertaking.
10 We are going to try to hit all our target action
11 dates. We will potentially miss some of them. But
12 the very, very strong feedback we got from agency
13 -- from industry was, "Look, a lot of imperfect
14 information concerning the status of our pre-Year
15 3 submissions is better than a very small amount
16 of 100 percent reliable information."

17 So that's the way that we're doing it.
18 I think Mr. Sherwood and Dr. Peters and others are
19 working to train a lot of people in the generic
20 drug program on how to implement target action
21 dates. I'm not going to walk you through the
22 details, but there are other significant things

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1 we're doing to assist with communications
2 regarding review status to help companies plan
3 their launches. These things rely on the target
4 action dates. We're training the RPMs on that
5 right now.

6 None of these things were part of GDUFA,
7 but we heard that people were having difficulties,
8 and we try -- we're trying to be flexible, and
9 we're trying to be very accommodating, even though
10 it is novel, arguably extraordinary, for FDA to do
11 all this extra stuff on top of implementing a
12 first-time user fee agreement. Next slide,
13 please.

14 So in addition to improvements to
15 communicating review deficiencies and
16 communicating the status of submissions, we're
17 also agreeing to provide essentially a GDUFA 1.5
18 level of service with respect to productivity for
19 the pre-Year 3 ANDAs.

20 And notwithstanding our actual
21 negotiated commitment, which I'll discuss in just
22 a moment, FDA is going to strive to take action on

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1 all pre-Year 3 submissions before the end of GDUFA
2 I, and we're going to pursue approval rather than
3 action on pre-Year 3 submissions whenever
4 feasible.

5 We think that this is good for the
6 public health because consumers get access to more
7 affordable quality medicines. It's good for
8 industry, obviously, because approvals mean they
9 can market the products. And it's good for FDA
10 from an efficiency perspective because when we
11 finally approve a submission, it's out of our
12 workload forever. It doesn't come back for
13 another review cycle. Next slide, please.

14 So this is the negotiated commitment for
15 Year 1 and 2 submissions. FDA said it would
16 aspire, to the extent possible, to maintain levels
17 of productivity at least similar to pre-GDUFA
18 levels while hiring and training incremental staff
19 necessary to achieve the program performance
20 goals, building necessary systems, and
21 implementing outlined program changes in Years 1
22 and 2 of the program.

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1 So it's an explicitly aspirational
2 maintenance of productivity obligation. The point
3 is that we'll try our best, but we have a lot of
4 other commitments to build program infrastructure
5 to facilitate goal dates. Next slide, please.

6 As this "Approvals by Fiscal Year" chart
7 shows, our approvals, our productivity, are in
8 line with pre-GDUFA levels. Next slide, please.

9 So on our workload, we have a couple
10 challenges. The first challenge is that --
11 concerns submission volume.

12 So in the GDUFA Commitment Letter,
13 there's an explicit assumption, there's a
14 projection, that industry would submit
15 approximately 750 ANDAs per year. The actual
16 number of ANDAs submitted in fiscal year '12 --
17 I'm not a thousand percent sure about 1,025, but
18 it's over a thousand. The actual for fiscal year
19 '13 was 968, and actual for fiscal year '14 was
20 1,473.

21 We received -- approximately 635 ANDAs
22 were submitted in June 2014 alone. So not to

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1 state the obvious, but two things you should take
2 away from this. One is that we received about
3 twice as much work as we planned and budgeted for
4 pursuant to GDUFA. And second is, as we think
5 about things that we're going to need to improve
6 in GDUFA II, we probably need a much better
7 workload projection.

8 The other big challenge in addition to
9 submission volume is submission quality. So it
10 usually takes us about four review cycles to
11 approve an ANDA.

12 There's a saying in the generic space,
13 "File first, develop later," although I heard from
14 an industry veteran last week that I got that
15 wrong; that it's actually "File first, fix later."
16 It refers to the common practice of applicants,
17 especially first filers, submitting ANDAs just
18 complete enough to be received, then improving the
19 submission's quality iteratively using FDA's
20 review process.

21 At the end of the day, submission
22 quality is the applicant's responsibility. Now,

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1 over time, industry will improve the quality of
2 its submissions, and -- it's a two-way street --
3 FDA will improve the clarity and consistency of
4 its review process. But it's not going to happen
5 overnight.

6 Before we move to the next slide, I'd
7 also note that there -- of our workload right now,
8 there are about 1,100 submissions that are pending
9 industry. We've already taken action on them, and
10 we are waiting. That's all we can do. We're just
11 waiting, either for time to pass on the TA or for
12 industry to get back to us with a complete
13 response on our complete response. The next
14 slide, please.

15 So I think Mary Beth may allude to this
16 in her closing remarks, but CDER obviously has
17 considerable experience with user fees. And we
18 had a similar experience with PDUFA when it kicked
19 off. I say "we," but it was 1993, so I wasn't
20 here.

21 But the first year of PDUFA, the first
22 cycle approval rate for original NDAs and BLAs was

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1 27 percent. By the end of PDUFA IV, it had risen
2 to 67 percent, although I want to very amply
3 caveat this. Dr. Woodcock has said that our --
4 this number may go as high as 86 percent right
5 now. I need more information to clarify exactly
6 what she's talking about.

7 But the point is that, over time, as FDA
8 and industry learn from experience and each user
9 fee agreement targets the most impactful
10 improvements, those improvements accrete over
11 time. Submission quality improves, the review
12 process improves, and we're able to approve more
13 submissions in the first review cycle. Next
14 slide, please.

15 So there are -- we walked through kind
16 of Year 1 and Year 2 commitments, getting ready
17 for Year 3 goal dates, kind of above and beyond on
18 the pre-Year 3 workload, but now's a good time to
19 pause and remember that GDUFA is not only about
20 review matters. There are other very, very
21 important commitments. And I don't want to repeat
22 Ann Marie's excellent presentation, but we are on

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1 track to fulfill our inspection-related
2 commitments, which will improve access, safety,
3 and transparency. Next slide, please.

4 There's also very important GDUFA
5 Regulatory Science commitments. We are also
6 fulfilling these commitments. Dr. Lionberger's
7 (ph) in the front row. He and his staff held a
8 regulatory -- conducted a regulatory science
9 meeting June 5th, and I certainly don't want to
10 repeat all of his content, but we have 62 external
11 research projects underway, a lot of internal
12 research.

13 I have a paragraph that I have to read,
14 because when I talk -- when I improvise and talk
15 about science, it always is a disaster, so I'm
16 going to read this paragraph.

17 "Regulatory science is a very important
18 part of modernizing the generic drug program. It
19 enables industry collectively to fund research to
20 address unmet public health needs. The research
21 yields transparency concerning FDA's expectations,
22 ultimately promoting access. One of our

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1 regulatory science priorities is studying the
2 therapeutic equivalents of complex products. Our
3 work here, and the work of GDUFA Regulatory
4 Science grantees, is creating pathways for
5 development of dosage forms with unique
6 characteristics, inhalers and topical patches, for
7 example. Much of the research is still in the
8 early phases, but we expect that the results will
9 eventually translate into approval of new
10 affordable generic drugs that will be broadly
11 accessible to the public."

12 So what is next? In Years 3, 4, and 5
13 of the program, our review metrics tighten. Each
14 year, we need to produce more actions more
15 rapidly. There will be up months and down months,
16 but overall productivity on pre-Year 3 submissions
17 will continue to increase.

18 I note that our April productivity, the
19 number of -- particularly the number of approvals
20 and TAs approached record levels. May was also
21 very good. In June so far, we're off to a very
22 good start. I think we have a combination of 34

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1 approvals and TAs combined, which potentially puts
2 us on track to another record month of
3 productivity. But it may not always be a
4 graceful, you know, steady line. It's going to --
5 could bounce a little, so please roll with the
6 punches with us.

7 We're also going to have a very, very
8 strong focus on target action dates and related
9 communications improvements, particularly more
10 communications coming out of our regulatory
11 project management staff. We'll have a continuing
12 strong focus on first generics. We want to avoid
13 first-to- file P4 forfeitures and pursue timely
14 generic approvals.

15 So, looking ahead, GDUFA I expires on
16 September 30th, 2017. That is nine months into a
17 new Congress and a new administration. That is a
18 very short window in which to develop and pass a
19 bill. With that time line in mind, FDA will be
20 ready to start GDUFA II negotiations this fall.
21 We'll have a docket open through July 15th, and we
22 sincerely welcome your comments. More on that

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1 below. Next slide, please.

2 So, again, FDA's perspective on GDUFA I
3 is that we are doing what we said we would. First
4 things first is we've got to fulfill our
5 negotiated commitments. That's how it works.
6 It's important to CDER institutionally. We do
7 what we say we're going to do, we honor our
8 commitments, we keep our word.

9 Second, even though it is challenging,
10 we heard what industry and other stakeholders
11 said, and we're making significant adjustments in
12 the communications and productivity spaces and
13 essentially providing a GDUFA 1.5 level of service
14 that goes way above and beyond our negotiated
15 commitments. And, in doing all of this, we're
16 building a modern generic drug regulatory program.

17 One big challenge is that, by design, we
18 build program infrastructure in Years 1 and 2, and
19 then you don't see the productivity, you don't see
20 the output, you don't see the benefits until later
21 in the program.

22 We totally grasp that applicants have

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1 paid in hundreds of millions -- that stakeholders,
2 all kinds of payers, have paid in hundreds of
3 millions of dollars, soon to be almost a billion
4 dollars, and have not yet seen all the benefits
5 materialize.

6 But, at the same time, we know that
7 people who are submitting ANDAs in Year 3 see that
8 that system works, and we are confident that once
9 people get used to goal dates, they will want to
10 preserve them.

11 So if we -- not to dwell on it, but if
12 we do not timely reauthorize the program, we'll
13 have reductions in force, we'll have severe
14 business disruption, and that will result in
15 reduced access to affordable quality medicines.

16 So, in closing, I would just make one
17 additional closing remark, which is that, at the
18 end of the day, FDA and stakeholders, we think,
19 are aligned on the big things. We all want more
20 safety, access, and transparency. So we truly do
21 welcome your comments. The docket's open. And we
22 look forward to working with you to design the

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1 best path forward for GDUFA II.

2 I think -- Martha?

3 MS. NGUYEN: Hi. Good morning,
4 everyone. My name is Martha Nguyen, and I lead the
5 Division of Policy Development in the Office
6 of Generic Drug Policy. We're going to take a
7 break in a few minutes, but before we do that, I'd
8 like to go over just a few logistics to keep this
9 meeting moving smoothly.

10 If you haven't already done so, please
11 sign in at the registration desk. It helps us
12 keep track of the number of attendees and lets us
13 be able to contact you afterwards if there are any
14 follow-up bits of information.

15 There's also an opportunity at the
16 registration desk to sign up for the GDUFA
17 listserv, where you'll receive email announcements
18 of significant announcements related to GDUFA.

19 Today's agenda includes a 15-minute
20 break, which we'll have now, and a one-hour lunch
21 break. We will not break in the afternoon, so
22 please plan accordingly if you're like me and get

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1 the munchies around three o'clock.

2 For any members of the media who are
3 present, FDA press officer Kris Baumgartner is
4 available to help you. Kris is raising his hand in
5 the far back there. Please direct all media
6 questions to him.

7 The times listed on the agenda are
8 approximate, and if we finish one session ahead of
9 schedule, we'll move right into the next part of
10 the agenda. We'll try to end the meeting today at
11 five o'clock, if not earlier.

12 After each group of presentations this
13 morning, the panel will have an opportunity to ask
14 questions. No participant may interrupt the
15 presentation of another participant, and only the
16 panel may ask questions after the presentations.

17 I'll announce the first speaker of each
18 set of speakers, but not subsequent ones, so
19 please approach the podium over here in the order
20 shown on the agenda and state your name and
21 affiliation before you start your remarks.

22 After the trade association

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1 presentations, we'll break for lunch, and after
2 lunch are presentations by other stakeholders.
3 And here the panelists will have an opportunity
4 after each presentation to ask clarifying
5 questions.

6 After the stakeholder presentations,
7 we'll move to the open comment period. If you
8 signed up at the registration desk this morning,
9 look for your name on the list of speakers, which
10 we'll project onto the slides. And, as with the
11 morning presentations, please state your name and
12 affiliation before you start your comments. We'll
13 allow as many speakers as time permits.

14 At the end of the day, Mary Beth Clarke,
15 the Director of the -- CDER's Office of Executive
16 Programs, will make closing remarks and adjourn
17 the meeting.

18 The transcript of this meeting will be
19 transcribed -- or, I'm sorry, the record of this
20 meeting will be transcribed, so please remember to
21 use the microphone when speaking. The transcript
22 itself will be acceptance through regulations.gov

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1 and posted on FDA's GDUFA website about 30 days
2 after the meeting. Any comments that aren't
3 presented today can be submitted through
4 regulations.gov to the docket for this meeting.

5 Now we'll take a 15-minute break. There
6 is a kiosk serving coffee in the lobby, and
7 restrooms and vending machines are located through
8 the lobby to the right. We'll see you at 10:40.
9 Thank you.

10 (Whereupon, a break was taken.)

11 MS. NGUYEN: Now we'll hear
12 presentations from other federal agencies. Before
13 I invite Dr. John Coster to the podium, I wanted
14 to let you know that Dr. Chester Bernie Good from
15 the Department of Veterans Affairs was scheduled
16 to speak today, but was unable to make it. So we
17 have his prepared remarks, and we'll enter them as
18 part of the docket for the meeting today.

19 Dr. Coster?

20 DR. COSTER: Thank you very much. Good
21 morning, everybody. I'm John Coster. I'm
22 Director of the Division of Pharmacy at the Center

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1 for Medicaid and CHIP Services, CMCS, which is
2 part of the Center for Medicare and Medicaid
3 Services. So I'm a pharmacist and appreciate the
4 opportunity to be here to talk to you about the
5 importance of generic drugs to the Medicaid
6 program.

7 While I'm just here representing the
8 Medicaid program in theory -- I wouldn't dare say
9 I'm representing Medicare -- but I would say that
10 most of my comments also apply to the Medicare
11 drug programs. You know, Medicare operates a very
12 large prescription drug program, Part D. They
13 also operate Medicare Advantage Plans, and also
14 CMS operates the Marketplace programs, which are
15 run by CCIIO.

16 So I would say that my comments would
17 apply to almost all the programs that CMS operates
18 in terms of the importance of generic drugs for us
19 managing our program and agree with the comments
20 made already this morning that the programs that
21 we operate need a steady, sure, reliable supply of
22 generic medications.

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1 I can get this right. Okay. So just a
2 little background, again, CMS, Centers for
3 Medicare and Medicaid Services, operates the
4 Medicare program, the Medicaid program, and the
5 Exchange programs. If you look at where Medicaid
6 falls in terms of federal spending, it's about 9
7 percent of the budget. It's the third largest
8 domestic program in the federal budget.

9 According to our own financial reports,
10 total Medicaid assistance payments totaled about
11 \$500 billion in 2014. Now, as you know, Medicare
12 is primarily operated by the federal government,
13 but Medicaid is a federal state program. So the
14 states operate the Medicaid programs under federal
15 rules, and what we do is we match Medicaid
16 spending based on a certain percentage that the
17 state gets. It's anywhere from 50 to 80 percent.

18 All state Medicaid programs cover
19 prescription drugs, even though it is still an
20 optional benefit. Prescription drugs accounted
21 for about 3 percent of the about \$500 billion by
22 now in payments, or about \$15 billion, but that's

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1 only on the fee-for-service side. That doesn't
2 include payments that Medicaid makes for drugs
3 provided by managed care organizations. And right
4 now Medicaid is about 75 percent in managed care.

5 So we have prescription drug spending in
6 Medicaid, both for patients in the fee-for-service
7 program as well as the managed care program, where
8 the overwhelming majority of our beneficiaries are
9 enrolled.

10 As you know, Medicaid is the low-income
11 program. It's for individuals who have low
12 income, mostly adults, children, disabled, dual
13 eligibles. It helps to provide healthcare
14 coverage, including prescription drugs, for about
15 70 million low-income Americans.

16 And, as you often hear in the news,
17 Medicaid and education are the top competing in
18 most states for how much they spend most of a
19 particular line item in most states' budgets.

20 So Medicaid is a very important part of
21 states' budgets. Medicaid -- you know, states are
22 always looking for ways to better manage and

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1 control Medicaid spending.

2 Pharmacy coverage is optional under
3 Medicaid, but every state currently provides
4 prescription drug coverage, both for their fee-
5 for- service and managed care populations. It's
6 an important and growing part of Medicaid
7 spending.

8 That is clear to me as director of the
9 division and became clearer even this year, as
10 states struggled to control some of the costs of
11 the new drugs that came on the market, such as the
12 HCV drugs, which offer great promise, but created
13 a lot of angst for many state Medicaid programs in
14 terms of how they were going to pay for those new
15 drugs.

16 The use of generic drugs has been and
17 continues to be an important strategy for most
18 states to control their drug costs, and that
19 includes the Medicaid Managed Care Organizations,
20 who use generic drugs as part of their overall
21 cost containment strategies.

22 Now, what are the specific ways that

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1 state Medicaid programs use and promote generic
2 drugs? Well, there's three major ways. First,
3 most state Medicaid programs create Preferred Drug
4 Lists, and these are lists that the states use,
5 and they try to steer beneficiaries, physicians,
6 and pharmacies to prescribe drugs on the Preferred
7 Drug Lists.

8 Under Medicaid law, if a manufacturer
9 enters into a rebate agreement with CMS, then the
10 state has to cover all the drugs of that
11 manufacturer's, with certain exceptions.

12 Except states can create Preferred Drug
13 Lists, and they create these Preferred Drug Lists
14 basically to make sure that patients are getting
15 the best drug, but that they're also getting the
16 most cost-effective drug.

17 So there can be a category of brand-name
18 drugs that have been on the market, and the states
19 can try to drive a bargain with the manufacturers
20 to steer to the best brand of that -- in that
21 particular class, but when the first generic comes
22 to market, the state will generally then try to

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1 drive a bargain to steer patients to that generic
2 drug in that class. Doesn't mean patients can't
3 get the nonpreferred drug, but they try, of
4 course, to steer them to the drug that's going to
5 be the best for them and the most cost-effective.

6 Second, generic drugs allow states to
7 create new reimbursement limits. Once a certain
8 number of generics come on the marketplace, CMS is
9 able to set what's called a Federal Upper Limit
10 for generics, and the states set what are called
11 Maximum Allowable Cost. So it allows them to
12 reduce the reimbursement because, as a result of
13 the new generic coming on the market, you have
14 greater price competition, the prices go down to
15 the pharmacies, and then, you know, the states can
16 pay the pharmacies less.

17 And just, again, as an aside --
18 sometimes you assume everyone knows how these
19 mechanisms work -- Medicaid is a payer, so we are
20 reimbursing pharmacies in the overwhelming
21 majority of cases, for the drugs that are
22 dispensed to Medicaid patients. Medicaid, unlike

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1 other programs in the federal government, is not a
2 direct purchaser. We're a payer.

3 The third way that generic drugs benefit
4 Medicaid is it allows states to charge decreased
5 co-pays for Medicaid patients. States don't want
6 to charge Medicaid patients high co-pays. They
7 have some discretion in the law to charge nominal
8 co-pays. To the extent that generics are on the
9 market, it allows them to decrease the co-pays
10 that they could impose on Medicaid patients, which
11 are nominal to begin with.

12 So generic drugs benefit Medicaid
13 substantially. It helps to promote cost savings
14 through the use of generic drugs. It allows
15 competition so that states can reduce the
16 reimbursement that they pay to pharmacies,
17 although, you know, states try to set
18 reimbursement policy to encourage the use of
19 generic drugs. And it allows states to set lower
20 co-pays for Medicaid beneficiaries within the law.

21 So first in terms of promoting cost
22 savings, patent expirations of brand-name drugs

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1 creates opportunities and large savings for
2 Medicaid because generics represent a lower-cost
3 alternative. States maintain Preferred Drug
4 Lists, drugs for which no prior authorization is
5 required. For most classes of drugs, the generic
6 drug is the preferred drug.

7 When it comes to price, there's a big
8 difference between generic and brands. On
9 average, the cost of generic is 80 to 85 percent
10 lower than the cost of a brand-name product. And
11 in 2010 alone, the FDA -- the use of FDA-approved
12 generics saved about \$3 billion every week. This
13 is a global number, not just for Medicaid.

14 State Medicaid programs quickly
15 recognize the availability of generics. Our
16 states monitor the use and the approval of generic
17 drugs by the FDA. We have also -- many states
18 have contractors that help them administer their
19 programs, and these contractors monitor the
20 availability of generic drugs. And once generics
21 come on the market, states will adjust their drug
22 payments in response to falling market prices.

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1 So generics promote competition. The
2 faster you can get generics to the market that are
3 safe and effective, the faster it can promote
4 competition among the pharmacies that are buying
5 the drugs, the faster Medicaid can reduce its
6 reimbursement.

7 This is especially significant, given
8 the recent changes in reimbursement, including the
9 launch of CMS' NADAC, National Average Drug
10 Acquisition Cost. This benchmark was created to
11 help states better reimburse pharmacies for
12 generic and brand drugs to move away from the
13 flawed AWP reimbursement, which has been around
14 for a long time.

15 It also allows us, as I said, to set
16 Federal Upper Limits for generic drugs. We need
17 at least three generics on the market to set a FUL
18 for a particular multiple-source drug. So to the
19 extent that the Agency improves more generics,
20 safe and effective generics in a faster manner, we
21 can set Federal Upper Limits, and that saves
22 taxpayers money.

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1 So one example of the difference between
2 the cost of a brand and generic for Medicaid --
3 and this is from our NADAC file, our National
4 Average Drug Acquisition Cost file. The NADAC for
5 the drug Tricor, which is a cholesterol-lowering
6 drug, the brand name is \$7.10. The generic
7 equivalent is \$1.35.

8 So you see the huge difference between
9 the two and the reason why, for example, when the
10 generic comes on the market, the state would
11 prefer this particular generic over Tricor. A
12 patient could still get Tricor if they needed it
13 under prior authorization, but the goal would be
14 to steer patients to the generic equivalent.

15 Now, every year, CMS does a survey of
16 the prescribing habits of -- the utilization of
17 state's drugs. We do a drug use review survey
18 under federal law. States are required to have a
19 drug use review program, a prospective,
20 retrospective, educational intervention program to
21 assure that drugs are being used appropriately.

22 We do a survey of this -- of the state's

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1 activities in drug use review every year, and one
2 of the questions we ask is the generic utilization
3 percentage. So for the most recent DUR report
4 from 2013, states were asked what is their generic
5 utilization percentage in terms of number of
6 prescriptions dispensed, total prescriptions on
7 the bottom, number of prescriptions dispensed with
8 a generic, and it ranged anywhere from 66 to 89
9 percent, with an average of about 79 percent.

10 So for the overwhelming majority of
11 prescriptions dispensed by Medicaid, most of them,
12 the overwhelming majority are dispensed with
13 generics. However, given the difference in price
14 between brands and generics, there's about a 1 to
15 5 difference. If you look at states' spending on
16 generic drugs, it's much different. It's from 9
17 to 30 percent, with an average of about 22
18 percent.

19 So the states are doing all they can to
20 promote the use of generic drugs. And even with
21 the push to increase the use of generics and the
22 increased availability of generics on the market,

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1 it's still the overwhelming majority of spending
2 is for -- is for brand-name drugs, as you might
3 guess, given how much more expensive they are.

4 If you look at the map, this shows you
5 the distribution of states in terms of their
6 spending on generic drugs, and it varies all the
7 way from a high of 42 percent to 10 percent.

8 And why the difference? It could be for
9 any number -- any number of reasons. Could be
10 more of the patients in a particular state are --
11 fewer patients are in fee-for-service, but the
12 ones that are in fee- for-service are the high-
13 cost utilizers of brand-name drugs. It could be
14 some states that prefer brands. It sometimes
15 happens that when a generic comes to market, the
16 manufacturer of the brand will offer a deep
17 discount to that state for the use of the brand
18 over the generic, and it becomes more cost-
19 effective for the state.

20 But, on balance, you'll see that the
21 overwhelming majority of prescriptions are written
22 for generics in states, the average being about 80

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1 percent, with the average spending being about 20
2 to 22 percent.

3 So the last three years, you can see the
4 number of prescriptions dispensed as a generic has
5 gone up from 74 to 80. The amount spent on
6 generics has also increased, some would say
7 because some prices of generics have gone up.
8 Others would say because the states are using more
9 generics.

10 Cost savings in the U.S. from generics -
11 - again, this is a global number -- in 2013
12 reached about \$239 billion. Generic products
13 saved the U.S. health system nearly \$1.5 trillion
14 over the past ten years. And CMS, without a
15 doubt, is the largest payer of prescription drugs
16 anywhere. I mean, combine Medicare, Medicaid, and
17 Exchange plans. So we're a huge purchaser, huge
18 payer, of prescription drugs and generics in
19 particular.

20 I'm going to skip over this slide
21 because I think I addressed this already, and I'm
22 -- because I'm getting the red light.

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1 And just one last -- the slide on cost-
2 sharing savings, as I said, Medicaid patients pay
3 nominal co-pays for all their prescriptions, but
4 if a generic is available and can be designated as
5 a preferred drug, the cost sharing is nominal only
6 up to -- up to -- not -- doesn't mean the states
7 have to charge this -- up to \$4.

8 So, again, I want to thank you for
9 inviting, for the perspective of CMS in
10 particular, CMCS. We support the use of all
11 drugs, appropriately, brand and generic, of
12 course, but it's really important for us to have
13 an adequate supply of safe, effective generic
14 drugs, and we support the work of the Agency in
15 reauthorizing GDUFA.

16 I think I'll introduce my colleague,
17 Admiral Schweitzer.

18 ADMIRAL SCHWEITZER: Thank you, John.
19 And I want to thank you very much. My name is
20 Rear Admiral Pam Schweitzer, and I'm with the
21 Public Health Service, and I'm really happy to be
22 -- have the opportunity to participate in this

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1 Public Meeting. As the Chief Pharmacy Officer, I
2 recognize the importance of GDUFA and welcome the
3 opportunity to express my support and to share the
4 perspective from a couple of our pharmacy
5 programs.

6 And I should say as a side note, as we
7 prepared for this -- as we prepared for this
8 meeting, we actually got together all the federal
9 services, but because I'm Public Health Service,
10 I'm representing that group. But we also included
11 the DHA, the Defense Health Agency. They were
12 part of this too, and they actually provided
13 comments, which the Public Health Service also
14 agreed with.

15 So I just wanted to let you know that
16 the comments I'm sharing are really with the other
17 -- our other federal partners too.

18 So the U.S. Commissioned Corps
19 pharmacists, we work in a variety of federal
20 agencies, including the Indian Health Service, an
21 agency within HHS. And there we serve several of
22 the -- the underserved population in there.

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1 And the Bureau of Prisons is another
2 agency, and that's within the Department of
3 Justice. And besides providing clinical pharmacy
4 services, both of these agencies also fill or
5 purchase, fill, and dispense prescriptions to
6 their respective beneficiaries.

7 The Indian Health Service provides
8 healthcare for 2.2 million American Indians and
9 Alaska natives who are part of 566 federally
10 recognized tribes in 35 states. And some of the
11 data that you're going to see here is from the
12 Indian Health Service National Supply Service
13 Center, which actually coordinates and manages
14 distribution supplies of items to the Indian
15 Health and Tribal Health facilities.

16 The Bureau of Prisons, on the other
17 hand, provides healthcare to 208,000 inmates, and
18 we obtained the data from them from the Logistics
19 Support Department there at the BOP.

20 Both of these agencies use the VA
21 Pharmacy Prime Vendor program to purchase
22 pharmaceuticals and supplies, and both agencies

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1 have robust formulary management processes to
2 ensure that they provide the most value, both
3 clinically and economically, to their agencies.

4 The formulary committees, they provide
5 pharmacoeconomic analysis, with evidence-based
6 clinical review and usage to determine which
7 product or group of products provide the most
8 value. Regardless of where a drug is manufactured,
9 knowing that an FDA-approved generic drug is held
10 to a high- quality standards is critical and
11 important consideration when adding that drug to
12 the formulary.

13 The agencies are funded through
14 Congressional appropriation to provide the health
15 needs of their respective populations. So that
16 means there's -- the price of the drug is not
17 passed along to the patient. There are no co-pays
18 or deductibles for these patients. And so it's
19 really, really critical that generics play a vital
20 role in these agencies with their really limited
21 budgets.

22 Although this is not under the FDA

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1 purview, we wanted to let you be aware of a unique
2 situation for federal pharmacy. And this is
3 really more for your situational awareness.
4 Federal pharmacy is subject to the Trade
5 Agreements Act, TAA, which provides authority to
6 waive the Buy American Act for covered products
7 from countries that have signed an international
8 trade agreement with the United States or that
9 meet with certain criteria.

10 It affords designated and qualifying
11 country end products equal consideration with
12 domestic products for acquisition above \$200 and
13 \$2,000 in covered federal supply group and
14 restricts the acquisition of end products from
15 noneligible sources.

16 So the reason why I'm telling you this
17 is because absent from that list of designated and
18 qualified countries are India and the People's of
19 China -- Republic of China, who are major
20 pharmaceutical manufacturers and among the top
21 pharmaceutical exporters.

22 This increased commercial trend of

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1 moving products to non-TAA-compliant countries
2 represents a growing challenge for the federal
3 pharmacy sector. The Indian Health Service and BOP
4 and DHA end up having to purchase equivalent items
5 from more expensive compliant competitors or
6 sources. So it would be important for us to
7 increase -- always increase drugs production in
8 U.S. or TAA trade agreement-compliant countries.

9 Both agencies participate in the -- as I
10 mentioned, the VA Prime Vendor, and they look at
11 their data -- we looked at their data for the past
12 12 months. And even though both report their data
13 a little bit differently, by calendar year and
14 fiscal year, you can see the trends.

15 In the Indian Health Service -- I guess
16 I need -- yeah, Indian Health Service, 27.6
17 percent of the \$364 million drug budget is spent
18 on generics. And the drug -- generic drugs
19 accounted for 58 percent of the \$12 million total.

20 And if you look at the trend from
21 calendar year 2011 to calendar year 2014, the
22 generic expenditures increased by 44.7 percent.

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1 And the total units purchased increased by almost
2 21 percent.

3 And then a similar trend was over in the
4 Bureau of Prisons. About 15 percent of their \$100
5 million total drug budget was on generics, and the
6 generics accounted for about 38.7 percent of the
7 total 2.4 million packages. And of all their
8 prescriptions dispensed, 84 percent of them are
9 the generic products. So -- and then their trend
10 too for 2014, they had a 9.8 increase in the
11 generic expenditures since 2013.

12 So you can see how important these
13 generics are for these agencies and how it's
14 really important for them to have a continued
15 pipeline of safe and effective generics.

16 So in -- as far as -- we can go to the -
17 - how do I do the next slide? There, thanks. As
18 far as the benefits, we had a little discussion on
19 this too, and we felt it was really, really
20 important -- or it is known that the confidence
21 that the drugs purchased abroad have the same
22 standards as purchased from U.S. manufacturers,

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1 that was really important for us.

2 And also we -- in reviewing, we had a
3 chance to notice that, in the fiscal year 2013
4 GDUFA Performance Report, that FDA has made, just
5 over the -- that first year, significant dent in
6 the GDUFA backlog of applications. And this was
7 quite impressive knowing that the challenge of
8 putting together resources and infrastructure in
9 such a short time to implement a project of this
10 magnitude. So we wanted to commend the FDA for
11 that.

12 Some of our challenges that we've
13 experienced and that we wanted to pass along were
14 the -- due to the shortages and the increased
15 prices due to some of the situations of the --
16 implementing the GDUFA. And a lot of it was
17 related to the overseas inspections and then not
18 being able to have some of the drug product
19 available, and we know that that will eventually
20 be changing and improving over time.

21 And then also, another big challenge for
22 us for a consolidation of product lines within the

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1 generic pharmaceutical industry, and that also
2 resulted in shortages and increase in prices.

3 And for some of the drugs, there's just
4 not enough manufacturers making the product. And
5 if there's a raw materials shortage or a
6 production issue, then everyone -- the whole
7 nation feels it. And so we wanted to pass that on,
8 because part of our recommendations are going to
9 be related to having more competition.

10 We -- as far as the improvements in the
11 program, we wanted to recommend that the FDA -- or
12 we wanted to commend the FDA for the tremendous
13 amount of work that has been accomplished with
14 GDUFA program in less than three years. We
15 support the goals of GDUFA, and it's vital that we
16 maintain availability of low- cost, high-quality
17 generic pharmaceuticals.

18 Some of our recommendations are we
19 wanted to provide comments, more current comments
20 on the Performance Report from GDUFA, and if
21 there's -- it's available in these next 30 days,
22 we would love to read it and provide comments on

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1 that if it is available from the FDA.

2 The other comments are really around
3 incentives. We were hoping that here would be
4 incentives put in place to expand the product
5 lines, including TAA-compliant countries, and also
6 incentives that would allow manufacturers to be
7 able to get in the game if they have fewer product
8 lines, so the smaller companies.

9 And then also the manufacturers for
10 inexpensive -- or incentives for manufacturers to
11 produce or manufacture the less-expensive products
12 -- things like penicillin that used to be pennies
13 are now very costly.

14 The program should also be adaptable in
15 case there's fewer generics on the market. And
16 then we also felt pretty strongly about if this
17 program can be expanded to the biosimilars.

18 So, in conclusion, generic drugs are an
19 important part of improving health outcomes, and
20 it's critical that there be a process for generic
21 drugs to be approved and made available to the
22 public in a timely, safe, consistent, and

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1 efficient manner.

2 And I'd like to thank the FDA for the
3 opportunity to provide suggestions. And we are
4 very happy and proud to be part of this program.
5 Thank you.

6 MS. NGUYEN: Thank you, Dr. Coster and
7 Rear Admiral Schweitzer. Are there any questions
8 from the panel?

9 MS. CLARKE: John, this is a question
10 for you about the Federal Upper Limit. You
11 mentioned that there need to be at least three
12 generics for that to be set. As more generics are
13 approved for any one given product, does that
14 Federal Upper Limit continue to be recalculated,
15 or is -- do they stop the calculation after the
16 first three?

17 DR. COSTER: That's a good question.
18 When we get our final rule out on Federal Upper
19 Limits, which would be hopefully sometime soon,
20 what -- the way we calculate upper limits is you
21 have to have, really, three listed in the Orange
22 Book. So it's generally the reference product,

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1 which is, you know, innovator multiple source, and
2 two other therapeutically equivalent generics. So
3 it's three or more.

4 The Federal Upper Limit is calculated in
5 theory every month. So we recalculate it every
6 month to keep up with changes in price. So when
7 the fourth or fifth generic comes out in that
8 class and the price, you know, has more -- and the
9 -- there's more competition in the market, the
10 price in theory could drop. So we recalculate the
11 upper limit every month.

12 If there's fewer than three, then we
13 take the Federal Upper Limit off. So it's --
14 again, it's very important that we have a
15 consistent supply of generics on the market.

16 The states generally will set what's
17 called a MAC, when there's two generics. When
18 there's -- well, the innovator and the generic,
19 they'll generally set a MAC, and their MACs tend
20 to be more aggressive than the FULs. But it all
21 goes in saying that for reimbursement policy,
22 whether it's a MAC or a full, we need to have a

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1 consistent supply of generics listed in the -- in
2 the Orange Book.

3 MS. NGUYEN: Any other questions? Okay.
4 Next we'll hear from the trade associations, from
5 the Bulk -- from representatives of the Bulk
6 Pharmaceutical Task Force, the Generic
7 Pharmaceutical Association, and Pharma & Biopharma
8 Outsourcing Association. First is Alan Nicholls.

9 MR. NICHOLLS: Good morning. My name's
10 Alan Nicholls. I'm the Chair from the Bulk
11 Pharmaceutical Task Force. For those not familiar
12 with this group, Bulk Pharmaceutical Task Force is
13 an affiliate of SOCMA and is an association for
14 manufacturers of active pharmaceutical
15 ingredients, also known as APIs, excipients and
16 pharmaceuticals intermediates. The Bulk
17 Pharmaceutical Task Force participated in the
18 GDUFA negotiations as a representative for the
19 domestic API industry.

20 Bulk Pharmaceutical Task Force's
21 assessment of GDUFA so far is that it is and will
22 continue to be of benefit to the generic

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1 pharmaceutical industry and its suppliers. But we
2 think it's very important that the FDA meets those
3 three-to-five-year -- Years 3 to 5 ANDA review
4 metrics that Keith presented earlier this --
5 today.

6 And we think that progress made in the
7 inspection parity between domestic and foreign
8 facilities is a very positive step in progressing
9 the safety and quality of the U.S. drug supply
10 chain.

11 Now, I've titled this "Unintended
12 Consequences" of GDUFA that need to be fixed. And
13 we've seen several aspects of GDUFA program that
14 have resulted in what I call "unintended
15 consequences." And our group recommends changes be
16 made to performance goals and the fee payment
17 schedule prior to reauthorization of GDUFA. This
18 should result in a lower and more equitable cost-
19 sharing arrangement.

20 The changes that we're talking about
21 here are associated with the following six issues.
22 First is the surveillance inspection program

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1 frequency, and this is an item that we raised with
2 the FDA at the last Public Meeting in September on
3 GDUFA.

4 The second one is facility fees while
5 pending approval of generic drug submissions.
6 Third is excessive user fees for the group of
7 products we call bulk pharmaceutical ingredient
8 manufacture; the split between the -- the fee
9 split between facility fees and application fees;
10 the large fee carryover that currently exists;
11 and, finally, small business fee waiver.

12 So the first of those, surveillance
13 inspection frequency. One of the goals agreed
14 with industry and enshrined in the GDUFA
15 Commitment Letter was to achieve parity of U.S.
16 and foreign surveillance inspections. As
17 discussed earlier, the FDA's required to get
18 parity of inspection by the year 2017, which is
19 Year 5 of GDUFA.

20 Now, the FDA's made very good progress
21 of this, witnessed by the -- earlier this year's
22 May Office of Inspector General's report, and this

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1 was the data for 2013, whereas you see the split
2 there for -- whereas it's not a parity. We would
3 not expect it to be a parity yet, but it is
4 certainly a whole lot more foreign inspections
5 than were prior to GDUFA.

6 So good kudos to the FDA for starting
7 off on a good foot there. And this is supported
8 by the Health and Human Services Annual Report on
9 Inspections and Establishments for 2014, which you
10 see an increase over the 2013 numbers in the last
11 slide. You see that increase for foreign
12 inspections.

13 But if you look there, you'll see for
14 domestic inspections, they decreased, and also the
15 total number of inspections decreased. And this
16 was something that was never discussed or
17 contemplated in GDUFA, that the total number of
18 inspections would actually decrease.

19 And our concern is that the increase in
20 foreign inspections has been done at the expense
21 of domestic inspections, and this is not by chance
22 in the HSH (sic) budget justifications for 2015.

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1 It said that there would be a 40 percent decrease
2 in U.S. inspections starting in fiscal year 2014.

3 Now, the Bulk Pharmaceutical Task Force
4 doesn't really have an objection for domestic
5 reduction in inspections, but this can -- as long
6 as the -- this doesn't result in -- or the FDA can
7 be assured there's no reduction in drug safety and
8 quality.

9 But this does have an unintended
10 consequence, that many foreign countries require
11 API manufacturers to have been successfully
12 inspected within the last three years, and the
13 Commitment Letter for GDUFA said that the FDA will
14 be guided by inspecting API facilities on a three-
15 year cycle.

16 A result of this requirement by foreign
17 countries is there's a delayed -- can be a delayed
18 reauthorization of Finished Dosage Form drugs from
19 what is put out by drug manufacturers who are our
20 customers.

21 And also, of course, the most -- the
22 facilities with the best compliance histories will

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1 be the most affected because they will be the ones
2 that will have the least inspections. In fact, if
3 you do the maths, you can see that half of the
4 U.S. API manufacturers may not receive an
5 inspection within that promised three-year cycle
6 or that committed three-year cycle that was in
7 GDUFA.

8 If, as we believe, the FDA's going to
9 continue down this path of reduced inspections,
10 then we need support from the Agency in the way of
11 either negotiating with those countries that have
12 these requirements in the form of, say, bilateral
13 agreements or that we could get a letter from the
14 FDA quoting our GMP status, even if we hadn't been
15 inspected within the last three years, or that the
16 FDA provides GMP certificates, as do the European
17 countries, and this was something that was
18 requested by the Bulk Pharmaceutical Task Force in
19 GDUFA I negotiations and was rejected by the
20 Agency.

21 So we need some support there, and we're
22 saying that unless the FDA provides a more

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1 imminent solution, these actions need to be
2 incorporated into the GDUFA II goals.

3 Now, as a result of reduced domestic
4 inspections compared to the commitment letter, we
5 believe also the FDA should adjust its original
6 hiring plan for expanding the inspection cadre,
7 and this should correspondently result in a
8 reduced user fee for GDUFA II. So we think that
9 there are savings for all here.

10 Moving on to the second item, facility
11 fees while pending approval of generic drug
12 submissions. Now, Finished Dosage Form and API
13 facilities have to pay fees while awaiting
14 approval for an ANDA, prior approval supplement,
15 or amendments under GDUFA. And collectively these
16 are called generic drug submissions.

17 The current -- I'm told that the current
18 average approval time for an ANDA is 46 months.
19 This has resulted in hardships for applicants of
20 greater than \$640,000 while awaiting approval.
21 And that is often greater than the value of the
22 new business they're applying for.

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1 So payments made during the approval
2 time have been an unexpected consequence of being
3 a hindrance of new business and a competition,
4 because people are taking a second look at whether
5 they want to be part of an ANDA application when
6 they think they're going to have to wait for so
7 long to get the approval. And it posed a barrier
8 to entry for -- certainly for small and fledgling
9 companies.

10 We think the case for elimination of
11 these fees is -- now outweighs the original reason
12 for the inclusion, and that reason was to
13 encourage the preparation of quality generic drug
14 submissions.

15 While expense is expected to decline in
16 future years as ANDA and prior approval
17 supplements approval times decrease, you'll
18 remember from Keith's number that the requirements
19 get tighter on the FDA as we go through the
20 number, up to Year 5, when it's 90 percent within
21 ten months.

22 We still propose the removal of this

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1 penalty, and that's what it is, as the approval
2 time will not -- will always remain uncertain for
3 any individual applicant, and the delay is not
4 always caused by that applicant.

5 Third one, excessive user fees for bulk
6 pharmaceutical ingredients. In this context, I'm
7 referring to APIs blended with one or more
8 excipients. These BPIs are then subsequently
9 converted into Finished Dosage Form products, you
10 know, such as tablets and other dosage forms. And
11 under GDUFA, BPIs are defined as Finished Dosage
12 Forms, and they're not.

13 Manufacturers have to pay both API and
14 Finished Dosage Form facility fees, and this can
15 be up to \$320,000 for -- on this year's basis.
16 Frankly, the margins for the manufacturers for
17 these products are just not commensurate with this
18 level fee. And we also suggest that neither the
19 FDA's resources require to regulate this type of
20 operation -- so expensive.

21 Bulk Pharmaceutical Task Force proposes
22 that the BPI manufacturer pay a fee equal to the

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1 API fee instead of the Finished Dosage Form fee.
2 So, for example, if APIs and BPIs were made in
3 different facilities, each would pay the same fee.
4 If API and BPI were made in the same facility, the
5 manufacturer will pay twice the API fee.

6 The bottom line result is that it's over
7 \$200,000 savings, regardless of the location of
8 the facilities, whether they make them in the same
9 facility or different facilities, or whether it's
10 domestic or foreign. We think it's just fair in
11 that case. And this isn't -- these products are
12 just not commensurate with the fee level.

13 The split between facility and
14 application fees. The GDUFA fees are set up for
15 70 percent to come from facility fees and 30
16 percent to come from application fees. However,
17 the number of facilities registered has been
18 lower, but the number of applications have been
19 higher than expected. And the actual fee ratio is
20 actually close -- very close to 60 to 40 in each
21 of the years we have data for.

22 This has also resulted in over-

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1 collection of \$18.6 million in 2014 from the
2 higher-than-expected ANDA submissions, whereas
3 facility fees have escalated if you look at the
4 data here, the data for API fees, facility fees,
5 and Finished Dosage Form facility fees for the
6 three years '13, '14, and '15.

7 And the last column there, I call
8 adjusted, and this is adjusted what the fees for
9 2015 would have been if they'd been calculated on
10 a 60/40 ratio for the -- instead of the 70/30
11 ratio. And each API facility would have had to
12 pay \$7,800 less, and for each Finished Dosage Form
13 facility, the saving would have been over \$36,000.

14 Now, this doesn't come free, because if
15 you take it off of the facility fees, you've got
16 to pay for the -- you've got to take it from the
17 application fees. And application fees for ANDAs
18 prior approval supplements and the one-time fee
19 for a DMF would all increase by 33 percent.

20 However, we consider that we would
21 prefer 40 percent instead of 30 percent of the
22 fees come from new business applications, because

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1 you can budget for that. And these are one-time
2 payments. We say it's better one time than once a
3 year.

4 Next item is the fee carryover.
5 Currently, the fee carryover from the first two
6 years of GDUFA is a whopping \$277.5 million.
7 That's almost a year's fees. You see the
8 carryovers from the first year and the second
9 year, and that is from the GDUFA financial report.

10 Now, we recognize that a carryover is
11 anticipated in Years 1 through 3 because of the
12 time required of the hiring process. Even so, we
13 opine that the original baseline cost estimate for
14 GDUFA of \$299 million a year was too high. And we
15 suggest that user fees for GDUFA II should be
16 reduced so as to better align with the actual
17 needs of the agreed program.

18 And, finally, small business fee waiver.
19 This was discussed under GDUFA I, but no waiver
20 was enacted. Because of the higher-than-expected
21 GDUFA fees, the absence of a waiver or discount
22 for small business has resulted an unintended

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1 barrier to business entry and to the competitive
2 (sic) of small business entities.

3 A quarter of a million dollars is a
4 large amount of money to pay for a fee for a small
5 business, and that's for the fee -- current fees
6 for Finished Dosage Form manufacturers. And it
7 has been a deterrent to people entering the
8 market.

9 And I saw the last speaker was on about
10 improving competition and getting more folks
11 involved. Well, it's not happening because of the
12 extent of the fees. So we propose that a fee
13 reduction for small business at least be
14 considered for GDUFA II.

15 And that's the presentation. Thank you
16 very much for your attention. And do questions
17 come now or later? Later. Okay. Thank you.

18 I'm walking away with the

19 MR. GAUGH: Oh. You can run them for me
20 if you want to.

21 MR. NICHOLLS: Yeah.

22 MR. GAUGH: Thank you. Good morning,

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1 and thank you to the FDA panel for holding this
2 Public Meeting. I'd like to address now, for the
3 Generic Pharmaceutical Association -- my name is
4 David Gaugh. I'm Senior Vice President for
5 Sciences and Regulatory Affairs at GPhA. And my
6 comments are going to be representative of our
7 entire industry.

8 So GPhA represents the manufacturers,
9 distributors of finished generic pharmaceutical
10 products; manufacturers and distributors of bulk
11 pharmaceutical chemicals; and suppliers of other
12 goods and services. Our members manufacture more
13 than 90 percent of all generic pharmaceuticals
14 dispensed in the U.S., and their products are used
15 in more than three billion prescriptions every
16 year.

17 And it's been stated earlier, but
18 generics represent approximately 86 percent of all
19 prescriptions dispensed in the United States,
20 while only accounting for about 27 percent of the
21 healthcare spend for those products.

22 This is a list of our full members. So

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1 we have both full regular members, and we have
2 associate members. The associate members are
3 those that do not do finished products. So these
4 are our finished products companies. We have
5 about 34.

6 I want to note that the majority of our
7 company representatives are here today, so while
8 they're not going to be speaking in front of you,
9 they are here to allow me to present for them and
10 represent their views on behalf of their
11 companies.

12 First I thought I would start with the
13 FDA mission, because I think it's important and
14 critical to what we're doing with GDUFA. And I
15 know Keith and others kind of didn't go over it
16 exactly, but they went through the process.

17 So FDA is responsible for protecting the
18 public health. FDA is also responsible for
19 advancing public health by helping speed
20 innovation that makes medicines more effective,
21 safer, and more affordable.

22 And, further, the Office of Generic

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1 Drugs is responsible for providing regulatory
2 oversight to expedite the availability of safe,
3 effective, and high-quality generic drugs to
4 patients.

5 We are committed to maintain the
6 public's confidence in an agency that continues to
7 meet the ever-changing need for public health,
8 which we also heard that echoed by a couple of our
9 future -- past speakers.

10 Now let's take a second and look back
11 and how we got to where we are, so kind of the
12 who, the how, and the what. And before I go into
13 the current GDUFA actions, I thought it would be
14 important to go over these.

15 So the why. And this is a direct quote
16 from Dr. Hamburg in 2011, that "We are at
17 something of a tipping point Looking ahead, it is
18 clear that the FDA will not be able to make ends
19 meet with current resources, and more approvals
20 will be delayed because of lack of inspectional
21 resources."

22 The how: "FDA and industry jointly

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1 negotiated GDUFA which started in October 1 of
2 2012 as a five-year program with industry paying
3 annual inflation adjusted fees of \$299 million
4 through September 30th of 2017."

5 And the what -- the what, I think, are
6 the most important pieces of GDUFA. So the three
7 key aims of the GDUFA goal are safety, to ensure
8 that industry participants are held to consistent
9 high-quality standards and inspected, using a
10 risk-based approach, with foreign and domestic
11 parity.

12 Access, to expedite the availability of
13 low- cost, high-quality generic drugs, most
14 importantly increasing predictability and
15 timeliness to the approvals.

16 And, finally, transparency, improve
17 FDA's communications and feedback with industry in
18 order to expedite products access as well as
19 enhance FDA's ability to protect Americans in the
20 complex global supply environment by requiring
21 identification of facilities that manufacture both
22 finished fill (ph) and APIs.

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1 And also note a quote up here from Dr.
2 Woodcock. And I think it's important that these
3 three tenets are very important to what we're
4 doing, because approval of drug applications is
5 not a new phenomenon. So it's been around since
6 1984 with Hatch-Waxman. The idea of GDUFA was to
7 be an add-on to have improvements to what we
8 already had.

9 So with that, let's go through some
10 status checks of GDUFA and where we are today. So
11 we, of course, have to acknowledge that some very
12 good foundational activities have occurred, and we
13 knew that it would take at least two years for
14 that. That's why there were no metrics in the
15 first two years of GDUFA.

16 And the Agency has done a very good job
17 now in Year 3 of meeting the application metrics
18 that were built into GDUFA. So as we look forward
19 three, four and five -- Years 3, 4, and 5, we are
20 hitting the marks that we wanted to. But
21 execution is still lacking. And on the backlog,
22 in Year 1, Year 2 applications, at this point, we

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1 are still seeing lags in those pieces and
2 components of GDUFA.

3 To date, approximately \$621 million has
4 been invested into the program, which has resulted
5 in decreased transparency, decreased certainty for
6 industry, and decreased access for patients. The
7 next round of investments, \$299 million, is coming
8 soon, which is really in the next three months.

9 FDA met GDUFA goals to hire new staff,
10 bring on more than 950 hires as a result of GDUFA.
11 So we have 950 new hands, if you will, to work
12 through the progress of GDUFA.

13 And, as such, industry has experienced
14 unforeseen pain during the foundational building
15 periods for the new OGD and GDUFA program, and
16 patients have experienced delays in accessibility
17 and products at the first available date.

18 Status check on the goals -- goal of
19 improved transparency. So as I mentioned earlier,
20 one of the three key tenets of GDUFA was enhanced
21 transparency, improving FDA's communication and
22 feedback with industry in order to expedite

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1 product access.

2 However, communications and feedback are
3 not occurring, placing industry in the dark,
4 unable to plan for the future and provide patients
5 with the medications that they need, which is
6 counter to the purposes of Hatch-Waxman.

7 While industry has noticed an
8 improvement in the increased information request,
9 overall feedback with project management staff
10 continues to suffer. Also, FDA has revised its
11 internal communications MAPP, which Keith alluded
12 to earlier, which significantly limits the FDA
13 staff in how much they may share with applicants.

14 GPhA firmly believes that neither FDA
15 nor industry anticipated meaningful communications
16 processes would essentially be shut down and
17 remain extremely limited for the first half of the
18 GDUFA cycle. As part of GDUFA -- and as Keith
19 alluded to earlier, we're kind of now in GDUFA 1.5
20 -- FDA agreed to provide industry with target
21 action dates and information requests for all pre-
22 October 1, 2014 filings. While we thank the

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1 Agency for agreeing to provide these actions, we
2 have yet to see significant resolution.

3 Status check on improving access and
4 more timely approvals. Since passage of GDUFA,
5 OGD's median review time to approval has continued
6 to rise. When the program was negotiated in 2011,
7 the median time was 30 months. Since then, median
8 review times have increased to 31 months in 2012,
9 36 months in 2013, and we're at an estimated --
10 what we believe to be somewhere north of 42 months
11 in 2015 -- or in 2014, excuse me -- and probably
12 even more than that in 2015. And I say "probably,"
13 and we're estimating because we have not seen the
14 fiscal year '14 Performance Report, which we note
15 at the bottom of this, so those are estimated
16 numbers.

17 Overall approval numbers -- and these
18 approval numbers include both tentative and final
19 -- are down as well -- 619 in 2012, 535 in 2013,
20 500 in 2014, and we are looking so far this year,
21 fiscal year '15, at 346.

22 So first generic continued to miss

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1 approvals on earliest legally eligible date as
2 well, which is counter to the Hatch-Waxman
3 purposes. Overall, filings compared to approval
4 dates show a continued increasing gap, with the
5 submissions being at around 2,600 and the
6 approvals at around 1,100.

7 So how does this affect serious patient
8 and market impact? In the last year and a half,
9 it is estimated that U.S. healthcare system lost
10 over \$3 billion in savings due to first generic
11 approval delays. Collectively, these first
12 generic applications have experienced median
13 approval times, well above what I'd just mentioned
14 on the previous slide, now at 50 months.

15 Increasing healthcare costs impacts
16 access to pharmaceuticals for key patient
17 populations. Timeliness and the number of generic
18 approvals have a direct impact on the drug price
19 competition. We heard that from a couple of the
20 previous presenters, and namely the Hatch-Waxman
21 Act, which was historically provided the framework
22 to allow for more than a trillion dollars in

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1 savings to the U.S. healthcare system.

2 Post-GDUFA, value of 180-day exclusivity
3 likewise continues to erode as companies are
4 forced to forfeit their exclusivity due to review
5 delays.

6 Keith mentioned earlier the regulatory
7 science funding, which was also -- or is part of
8 the negotiation into GDUFA, and it allowed for \$20
9 million to be allocated of the \$299 million per
10 year to the Regulatory Science Initiatives.

11 To date, no industry suggestions
12 provided by GPhA has been implemented. No
13 transparent process is in place for consideration.
14 We did just have a public meeting last year, as
15 we've had the two previous years, and we greatly
16 appreciate that, but, as I'd mentioned in that
17 meeting on the 5th of June, we would like to see
18 more collaboration between industry, who is paying
19 these fees, and the Agency as they go forward in
20 looking at new programs and new priorities.

21 Additional emphasis needs to be ensured
22 that proper and meaningful scientific dialogue

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1 exists for the development of complex generic
2 drugs.

3 In conclusion, patient access to generic
4 pharmaceuticals are in jeopardy unless and until
5 improved GDUFA implementations are made by the
6 FDA. Uncertainty leads to drug shortages, drug
7 price increases, and market disruption, which we
8 heard from a couple of the previous presenters.

9 Communications with industry and
10 formation of a true partnership are critical.
11 Patients in the U.S. healthcare system deserve to
12 see immediate improvements in transparency and
13 approvals of the backlog and Year 1, Year 2
14 applications.

15 Industry and Congress continues to await
16 FDA's 2014 Performance Report, as I'd mentioned
17 earlier. And, finally, GPhA welcomes the
18 opportunity to continue to work with the Agency to
19 ensure the key purposes of GDUFA, improved access,
20 transparency, and safety are achieved as intended.
21 Thank you very much.

22 MR. ROTH: Hi. My name's Gil Roth. I'm

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1 the President of the Pharma & Biopharma
2 Outsourcing Association. It's a new trade group,
3 for those of you who aren't familiar with it, that
4 represents CM -- whoops, wrong direction -- CMOs
5 and CDMOs within the pharma and biopharma space.

6 The main mission for putting the group
7 together was to provide a voice, to provide
8 advocacy within the legislative, regulatory, and
9 general business areas for this sector of pharma.

10 And our companies -- well, our members
11 are listed here -- they run the gamut of contract
12 services, drug development solutions, and other
13 manufacturing activities, both for commercial and
14 development scale drugs. About a third of them
15 are present at the meeting today. Almost all of
16 them are affected by GDUFA in one way or another,
17 generally on the final dosage form side,
18 particularly the primary packaging and contract
19 manufacturing areas.

20 Now, the thing to understand about CMOs
21 and CDMOs, the industry's been around for more
22 than 30 years, and it's really coming into its own

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1 and maturing at present, and I think having an
2 association like this is helping to bring us
3 along.

4 According to PharmSource, an information
5 consultancy that covers this industry, CMOs and
6 CDMOs were involved in more than 44 percent of the
7 NDAs that were approved last year. The numbers on
8 the generic end are a little tougher to parse, but
9 we think they're involved in approximately 15
10 percent of generic drugs that are manufactured,
11 and that covers both the contract manufacturing as
12 well as the primary packaging, which is also
13 subject to Finished Dosage Form fees.

14 Let's see. Now, our goals under PDUFA
15 (sic) are the same as yours. We weren't around
16 when GDUFA I was being negotiated. We want to be
17 part of the negotiations going forward to make
18 sure that this part of the industry is represented
19 and that our viewpoint is taken into account.

20 We want the same things you do: safety,
21 access, and transparency. We want timely review
22 of ANDAs so that our -- well, my member companies

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1 can get to work making these drugs. We want the
2 inspection to be -- want inspections to be done of
3 our manufacturing sites, and we also want enhanced
4 communication with FDA and OGD.

5 We've talked about -- well, the past
6 speakers have talked about other areas of
7 communication that are being adjusted under GDUFA.
8 We'd love to see more involvement in understanding
9 when drugs are, well, ready for their target
10 action dates, and we want to contribute to the
11 regulatory guidance going forward and ultimately
12 have a seat at the negotiating table.

13 Now, the GDUFA facility fees, again, the
14 previous speakers have talked about them quite
15 extensively. From our companies, they're facing
16 the final dosage form facility fees, and those
17 climbed from 175 to 220 to 247 for domestic
18 facilities.

19 Our take is that a flat fee isn't fair
20 ultimately for some of our companies that might
21 have a single generic client that they do one week
22 of work for per year, and they're paying the same

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1 facility fee as a dedicated in-house generic
2 facility that's working three shifts a day,
3 cranking out a lot of generic product.

4 So in the next version of GDUFA, we'd
5 like to see some sort of adjustment, some way of
6 recognizing the realities of what contract
7 manufacturers do and the way that their finances
8 and economics differ from that of in-house generic
9 companies.

10 Similarly, as Alan Nicholls pointed out,
11 the lack of a reduction or waiver and not having
12 authority to issue that for small businesses
13 really does create a disproportionate impact on
14 small manufacturers, and that's both CMOs and on
15 the generic side.

16 Now, we talk about the potential impact
17 of these fees and what they can mean, particularly
18 for contract manufacturers. We might see that
19 some of them are in a position where they have to
20 exit the generic space, where these facility fees
21 outweigh the contracts that they have with their
22 clients, especially if they have a small number of

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1 generic clients at a facility. Some of them may
2 choose not to renew generic contracts. Others may
3 end up cancelling existing deals.

4 We have some members -- well, I've heard
5 some anecdotes of companies that are waiting for
6 their first generic approval -- CMOs, I mean --
7 for whom they've paid final dosage form facility
8 fees year after year after year, with no income
9 coming yet from a contract. That's outweighing
10 the value of the deal that they had in place
11 initially, and it's very difficult to adjust these
12 after the fact.

13 Some CMOs may not be able to bring in
14 generic clients into their new, very good
15 manufacturing facilities, given that introducing a
16 single client is going to trigger this fee and not
17 make that contract feasible. Some of them would
18 need to bring in five or ten clients, ultimately,
19 to be able to offset what they're paying in
20 facility fees.

21 And so, as we have mentioned before,
22 reduced competition means fewer manufacturing

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1 options for generic clients, and because of the
2 nature of the facility fees being a fixed pie
3 (ph), that's going to increase the fees on the
4 remaining facilities that are in place. That's
5 going to create a vicious cycle, a barrier to
6 entry for anyone coming in.

7 And we'll see potentially that small
8 scale products, the ones that are done at these
9 small runs with a single CMO, and orphan drugs may
10 become scarce and more expensive if those
11 contracts expire and these companies choose to
12 exit the manufacturing space for them. And that
13 could lead potentially to drug shortages in
14 critical areas, particularly in sterile
15 injectables.

16 Now, also, I'm not sure about that
17 vicious circle. I was checking out the self-
18 identified facilities list over the weekend to see
19 what the numbers were like for final dosage form
20 companies and packagers, both of whom are, again,
21 subject to these fees, and they appear to have
22 dropped.

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1 And the deadline was June 1st, so I
2 don't know if the self-identified facilities list
3 as-is is currently final. But if it is, then the
4 2015 -- sorry, fiscal 2016 list of facilities is
5 dropped 55 dosage form makers and another 33
6 packaging companies, which, again, is going to
7 increase the fees on the remaining facilities in
8 place. If I'm incorrect about that, please let me
9 know if the list is going to be updated further.

10 Now, the PBOA has a few recommendations
11 and suggestions for how GDUFA II could work, at
12 least in terms of the facility fees. Our
13 preferred option is that we see something more
14 like PDUFA, in which facility fees are part of the
15 drug filer's application rather than being levied
16 directly on individual sites. And, again, the
17 reason for that is the economics of these sites
18 are very, very different from contract
19 manufacturers to in-house drug makers.

20 We'd like to see GDUFA also establish
21 facility fee tiers, that the ANDA holders have a
22 different set of facility fees than the contract

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1 manufacturers, who do not have ANDAs of their own.
2 As such, you could create categories within the
3 self- identified facilities list that would be
4 able to help identify CMOs versus an in-house
5 manufacturer.

6 I'm not sure how your data is structured
7 and how that could be put together, but
8 conceivably in the years going forward, we could
9 create an additional checkbox where a company
10 that's listed as a drug manufacturer could say
11 whether it owns an ANDA or not. If it doesn't,
12 then it's a CMO.

13 We'd also like to see a small business
14 exemption brought into GDUFA II, empowering FDA to
15 offer some sort of relief to smaller companies and
16 allow them to compete within this marketplace.

17 General suggestions -- and I'm sure
18 there'll be more as we go further and deeper into
19 negotiations -- is that CMOs and CDMOs get
20 notified as part of the target action date letters
21 when they're issued.

22 As our previous speakers have a minimum,

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1 they say, of 46 months for review times for ANDAs,
2 some of these -- the people who first set up the
3 deals that the generic companies may have left,
4 personnel at the CMO may have left, when a generic
5 company knows there's going to be a potential
6 action on its drug, it'll help if the CMO is aware
7 also and if the API maker is aware so that there's
8 enough time to build up and to get an
9 infrastructure in place to actually be able to
10 launch the drug.

11 It's great that, you know, under GDUFA
12 1.5, that this initiative is going to happen, but
13 if it can be inclusive of the CMOs and CDMOs, it's
14 going to facilitate the manufacture of these drugs
15 in a timely and effective manner.

16 Also -- and this is a small point --
17 there are transparency issues where, in a few
18 instances, some of our companies have ended up on
19 the self- identified facilities list without
20 actually self- identifying. They've been included
21 as secondary manufacturers on someone's ANDA and
22 as such have shown up and been handed a bill for

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1 \$250,000.

2 We would like some sort of pathway in
3 place that would enable them to appeal the fee,
4 basically, if their facility does not make
5 generics, if they do not intend to make generics.
6 Some of the points that were brought up by the
7 Bulk Pharma Task Force are also, I think, very
8 applicable for our companies in terms of paying
9 closer to approval and not paying before an
10 application has been sitting for several years on
11 your side.

12 So that is a little bit of the PBOA's
13 perspective. I hope to work with you guys as the
14 GDUFA II negotiations begin. It's an important
15 sector of this industry. I know that 15 percent
16 number might not sound huge, but it's critical to
17 being able to produce these drugs safely, cost-
18 effectively, and, you know, in a timely manner.

19 So thank you very much for your time.

20 MS. NGUYEN: Thank you. Are there
21 questions from the panel for any of the trade
22 associations?

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1 MS. CLARKE: I have a question, I think,
2 that is -- started with Alan's presentation, and I
3 think Gil also referred to it, which is when you
4 mentioned what I believe are new facilities who
5 would be paying the fee for the first time while
6 waiting for ANDA approval, because if -- they
7 wouldn't be -- otherwise they wouldn't be new.

8 I think we would be very interested if
9 you could share with us as much -- as many
10 specifics, both in number and the types of firms
11 that are experiencing this. We are often
12 challenged with real-time because intelligence
13 data about what is going on in the marketplace.
14 So we would appreciate as much data as you feel
15 that you can share on behalf of those companies.

16 MS. NGUYEN: Please submit the
17 information to the docket.

18 MALE SPEAKER: Yes.

19 MS. NGUYEN: Thank you.

20 MR. FLANAGAN: Thanks, gentlemen. I
21 have a question for Mr. Gaugh. One of the slides
22 says in the last year and a half, it's estimated

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1 that the U.S.

2 healthcare system lost over \$3 billion
3 in savings due to first generic approval delays.

4 Are these submissions that met FDA's
5 scientific and technical requirements for approval
6 and, you know, all were relied on facilities that
7 were acceptable? But these submissions were all
8 approvable, but FDA dropped the ball.

9 MR. GAUGH: From that standpoint, yes.
10 So this is a survey of our member companies, and,
11 as far as we can tell from the information, which,
12 as you can imagine, is confidential information
13 with each company, that they were to that level
14 and point, but for approval, yes.

15 Meeting the requirements except for FDA
16 approval; is that what you're asking?

17 MR. FLANAGAN: Could we see the
18 aggregate -- could we get a better look at the
19 data?

20 MR. GAUGH: I can -- we can give you
21 some better data. We'll put it in the docket.
22 Absolutely.

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1 MR. FLANAGAN: And does it -- from an
2 access perspective, does it include the cost to
3 consumers of ANDAs that were approved, but never
4 marketed because of settlement agreements, or is
5 it only limited to approval issues?

6 MR. GAUGH: Just approval issues. So
7 this is the brand staying on the market with no
8 competition, yes.

9 MR. FLANAGAN: Thanks.

10 MR. GAUGH: Uh-huh.

11 MR. SHIMER: Actually, I also question,
12 kind of to follow up on Keith's. On Slide 7, you
13 discuss accessibility of generics, obviously post-
14 approval, and you talk about first available date.

15 So I was wondering what -- in this
16 slide, in the general idea here behind your
17 definition of first available date, because there
18 are often instances wherein the first available
19 date is a Hatch-Waxman date, but that doesn't lead
20 in to acceptance of the drug product.

21 So what is meant in this slide by first
22 available date?

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1 MR. GAUGH: We can give you a better
2 definition that we'll put to the docket, but first
3 legally available date would be whether it's a
4 patent challenge, so it's Day 1, Day 181, or, if
5 there are no patents, they're legally eligible to
6 be launched at that date, but they just haven't
7 been approved.

8 MR. SHIMER: So that won't always
9 correlate to accessibility, though?

10 MR. GAUGH: Correct.

11 MR. SHIMER: Thank you.

12 MR. GAUGH: No. And we can get a more
13 robust definition to the docket too. Thank you.

14 MR. SHERWOOD: There's been some
15 discussion about the number of receipts, and
16 certainly the fact that they've been outpacing the
17 approvals. Does GPhA or any of the trade
18 associations have any background information on
19 why that number has increased from sort of the
20 general estimates at the time that GDUFA I was
21 being prepared?

22 MR. GAUGH: Well, a couple things to

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1 think about. So remember this: data was looked at
2 back in 2009, '10, and '11 for the negotiations
3 that occurred back in 2011. That's one issue. So
4 you had to work off of what history you had at
5 that point in time.

6 A second and I think important piece
7 that we need to consider is the 2014 stability
8 guidance that went into place in June, which
9 required three stability batches versus one
10 stability batch. So companies did a yeoman's job,
11 if you will, to get that work done, and the
12 filings filed before the June -- I believe it was
13 June 21st of '14, or maybe it was 23rd.

14 So 600 and some-odd filings occurred
15 that one month. I think we'll find in 2015, as
16 we're tracking right now, the number will be
17 significantly lower than 1,400, and probably even
18 lower than 1,000, the way it's tracking at the
19 moment.

20 MR. SHERWOOD: And this is for all of
21 the associations. You know, there's been some
22 discussion about the impact of the fees on small

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1 business. Have you seen that your associations
2 are losing members as people are dropping out of
3 the generic arena?

4 MR. GAUGH: (Inaudible) not from GPhA's
5 perspective, no.

6 MR. NICHOLLS: I'm certainly aware of
7 companies that said they were not going to
8 participate. I mean, they were looking at this,
9 and they withdrew from the potential market. Yes,
10 we did lose a couple members (inaudible).

11 MS. NGUYEN: Any further questions from
12 the panel? If there are no further questions,
13 we'll break for lunch. We'll resume in one hour,
14 at 12:55. The coffee kiosk is now serving lunch.
15 Thank you.

16 (Whereupon, a lunch recess was taken.)

17 MS. NGUYEN: Good afternoon, and welcome
18 back to the Public Meeting on Reauthorization of
19 GDUFA. First on the agenda for this afternoon are
20 stakeholder presentations.

21 Unlike this morning, we will provide an
22 opportunity for the panel to ask questions after

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1 each presentation. So after your presentation, I
2 ask that presenters remain at the podium to
3 provide an opportunity for question and answer.
4 And if the person who is listed on the agenda
5 after could approach the podium after Q&A is over,
6 that would be great.

7 So first for this afternoon, we have
8 Gabrielle Cosel from The Pew Charitable Trusts.

9 MS. COSEL: Hi. Thank you very much.
10 And I apologize. I think it was my fault that we
11 are a few minutes late starting, so my apologies,
12 everyone.

13 My name is Gabrielle Cosel. I manage
14 Drug Safety Initiatives at The Pew Charitable
15 Trusts, which is an independent nonpartisan
16 research and policy organization dedicated to
17 serving the public.

18 We're glad to have the opportunity to
19 speak today about the General Drug User Fee
20 Program and its importance to public health.
21 Patients rely on generic medicines every day, from
22 chemotherapy to antibiotics. They are essential to

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1 our health system. And not only do patients need
2 access to these drugs, they need them to be safe
3 and of good quality.

4 The first and landmark Generic User --
5 Drug User Fee Agreement supported both access to
6 and quality of generic medicines. To support
7 access, the agreement included metrics to hasten
8 the review of generic drug applications as well as
9 new staff to conduct reviews.

10 And to support quality and safety, the
11 agreement provided resources and a mandate for FDA
12 to conduct more frequent inspections of overseas
13 drug- manufacturing facilities.

14 As was discussed earlier this morning,
15 the complexity and geography of our drug supply
16 chain really has changed significantly over recent
17 decades. Our drugs and their ingredients are
18 increasingly sourced from foreign countries,
19 creating oversight challenges for both the
20 industry and for the FDA.

21 Insufficient oversight increases the
22 risk that substandard drugs enter the drug supply

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1 chain and harm patients. Perhaps the most well-
2 known example of this occurred in 2008, when
3 dozens of adverse events in the U.S., including
4 some deaths, were linked to an adulterant in
5 heparin, a widely used blood thinner. The drug was
6 made by a U.S. company that was sourcing active
7 and precursor ingredients from a complex upstream
8 supply chain in China.

9 Investigations revealed that somewhere
10 in that supply chain, the correct active
11 ingredient was replaced by a substance with toxic
12 effects known as over-sulfated chondroitin
13 sulfate, which standard tests then in use were
14 unable to detect.

15 Adulterated heparin exposed a number of
16 significant supply-chain management problems on
17 the part of the manufacturer and the FDA. The
18 U.S. manufacturer began receiving heparin from a
19 new Chinese plant in 2004, but didn't conduct its
20 own audit of the plant until 2007, relying instead
21 on an earlier assessment by a different company.

22 FDA approved the plant as a supplier

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1 without conducting a preapproval inspection, in
2 part because the Agency confused the plant with
3 another in its database. When the Agency finally
4 inspected the plant after the adverse events
5 occurred, its inspections found a number of
6 manufacturing quality issues, including poor
7 control of incoming raw materials.

8 So one of FDA's most important tools for
9 ensuring the safety of drugs sold in the U.S.,
10 whether they're made here in this country or
11 whether they're made overseas, is the inspection
12 of factories to verify compliance with good
13 manufacturing practice standards.

14 The volume of drugs destined for the
15 U.S. makes it impossible to test samples of all
16 products before they reach patients. And while
17 FDA inspections alone cannot guarantee quality,
18 the expectation of an inspection is a critical
19 driver of compliance.

20 Despite our increasing reliance on
21 overseas production plants, historically, the FDA
22 inspected them much less frequently than those in

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1 the U.S., about every nine years on average,
2 compared with every two to three years
3 domestically.

4 But the FDA's inspection program is now
5 changing as a result of GDUFA and additional
6 supply chain provisions in the Food and Drug
7 Administration Safety and Innovation Act of 2012.

8 FDASIA's Title VII placed all
9 manufacturing plants, whether foreign or domestic,
10 on a single risk- based inspection schedule.

11 Meanwhile, the GDUFA agreement provided FDA with
12 additional funds to inspect foreign generic drug
13 facilities and established a goal for FDA to reach
14 inspectional parity between foreign and domestic
15 plants by fiscal year 2017.

16 In fiscal year 2014, FDA conducted 993
17 total inspections of foreign human drug
18 establishments and 1,869 inspections of domestic
19 human drug establishments. But subcounts of GMP
20 surveillance inspections were much more similar.
21 FDA conducted 780 GMP inspections of domestic
22 plants and 757 GMP inspections of foreign plants.

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1 And this is both brand and generic combined. In
2 prior years, these numbers were farther apart.

3 I think it's also important to note that
4 there is a range of manufacturing quality in all
5 countries. There are well-run plants in emerging
6 economies doing high-quality manufacturing, and
7 there are also U.S. facilities with quality
8 problems. For example, many of the drug shortages
9 in the U.S. that the U.S. is grappling with today
10 have been linked with sterile production issues at
11 domestic finished drug plants.

12 When these plants are faced with a need
13 to quickly move production to another line or
14 update production equipment, they often need to
15 get FDA approval. And GDUFA can help provide FDA
16 with the resources and staff it needs to allow
17 expedited applications and plant inspections to
18 ameliorate shortage situations.

19 Drug shortages continue to plague the
20 U.S. healthcare system. We -- while new drug
21 shortages have begun to decline, thanks in part to
22 the work of the FDA, a legacy of ongoing drug

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1 shortages persists. In 2012, the U.S. experienced
2 over 450 shortages, according to the GAO.

3 And it goes without saying that
4 shortages can have disastrous impact on patients,
5 interrupting or delaying treatment, forcing use of
6 second- or third-choice medicines that may be less
7 effective or have worse side effects. And they
8 also affect the healthcare providers that have to
9 devote staff and resources to identifying new
10 sources of supply, rationing supplies, and
11 communicating contingency plans throughout the
12 health system, which is certainly expensive.

13 I wanted to make one other point since
14 some mentioned increasing costs of generic drugs
15 in the context of drug shortages, and I wanted to,
16 you know, also make the counterpart point, that
17 many older generics are -- still are very low-
18 margin products. And ideally our market and
19 regulatory system would reward high-quality
20 production and supply resiliency. And it may be
21 that paying more of a premium could be justified
22 if purchasers have confidence that it makes --

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1 that it will result in reduced supply
2 interruptions.

3 So, in conclusion, we strongly support
4 the continuation of the GDUFA program. Funding
5 support timely review of drug applications will
6 help ensure patient access to safe and high-
7 quality generic medicines and help mitigate drug
8 shortages.

9 We also support continued inclusion of
10 resources and performance goals for FDA foreign
11 inspections in GDUFA II. These are important
12 drivers of essential oversight activities that
13 protect patients. Thank you.

14 MR. FLANAGAN: Thank you.

15 DR. LEVINE: Good afternoon. I'm Dr.
16 Sharon Levine. I'm from The Permanente Medical
17 Group in Northern California, part of Kaiser
18 Permanente. And I want to thank you for the
19 invitation and the opportunity to speak today.

20 I'm a pediatrician and a member of the
21 leadership team of The Permanente Medical Group,
22 and for the last 15 years have been responsible

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1 for pharmacy and therapeutics, drug use
2 management, and prescription drug policy for the
3 medical group and part of Kaiser Permanente's
4 oversight and management of prescription drugs.

5 Kaiser Permanente is one of the largest
6 integrated delivery systems in the country, caring
7 for ten million members in eight states in the
8 District of Columbia.

9 And we really appreciate the opportunity
10 -- the timely opportunity to provide feedback on
11 the reauthorization of GDUFA, which is intended to
12 strengthen the generic drug market by increasing
13 patient access to affordable generics through an
14 improved ANDA process and ensuring the quality of
15 generic drugs available to the American public
16 through manufacturing oversight.

17 We want to compliment the FDA on what is
18 remarkable progress since 2012 in meeting the
19 goals and commitments made under GDUFA and
20 strongly support your efforts to strengthen and
21 improve the program with GDUFA II.

22 My remarks today reflect our experiences

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1 as part of our system with a large pharmacy
2 service, which serves both as a purchaser of drugs
3 and a dispenser of drugs.

4 Our pharmacies dispense 93 million
5 prescriptions a year, operate 363 outpatient
6 pharmacies, 36 inpatient facilities, 5 central
7 fill mail order pharmacies, infusion centers, and
8 a specialty pharmacy. We employ 8,600 pharmacy
9 professionals nationwide.

10 Our 2014 prescription drug spend was
11 \$5.8 billion, of which 5.4 billion was for
12 outpatient drugs. And my -- some of my comments
13 today are actually informed by observations on
14 feedback from our generic drug suppliers.

15 The availability of quality generics in
16 a healthy and competitive generic market for
17 traditional small-molecule drugs has historically
18 resented in -- resulted, sorry -- resulted in
19 substantial savings for consumers and cost
20 avoidance for health systems. Those savings
21 represent the promised benefit to consumers, the
22 promised return to consumers, in exchange for

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1 government-granted monopoly rights provided to the
2 manufacturer of the innovator molecule through
3 patent and exclusivity protections. And the
4 impact is substantial.

5 A branded prescription is typically 25
6 to 28 times the cost of a generic prescription.
7 Generics represent a growing proportion, as we've
8 heard, of total drug volume, approaching 80
9 percent across the country, up from 70 percent
10 only five years ago.

11 The availability of quality generics has
12 played a critical role in the last five years,
13 from 2008 to 2013, and dampening the overall rate
14 of increase in drug costs.

15 Kaiser Permanente has long been an
16 industry leader in generic utilization, and, in
17 2014, 90 percent of the drugs dispensed by volume
18 were generics, and our physicians prescribe and
19 our pharmacists dispense generic drugs 99.2
20 percent of the time when an AB generic is
21 available.

22 The savings to our program have allowed

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1 us to invest in care delivery, to moderate prices
2 for our members, and to -- and to invest in
3 quality initiatives for the benefit of our
4 members.

5 Looking forward, we have concerns about
6 the sustainability of the model. Fewer
7 blockbuster drugs are coming off patent in the
8 next few years, limiting the number of potential
9 market entrants.

10 Between 2010 and 2014, the value of
11 branded drugs coming off patent is estimated to be
12 about \$102, \$103 billion. Looking forward from
13 2015 to 2019, the projected value is about \$66
14 billion, a 35 percent decline. This really
15 heightens the importance of maximizing
16 opportunities for entrance into the generic
17 market.

18 Consolidation of drug -- generic drug
19 manufacturers threatens competition and is very
20 likely to contribute to limiting the number of
21 suppliers and products in each category and to
22 increasing the prices of generics.

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1 GDUFA was designed to accelerate access
2 to safe and effective generic drugs and to lower
3 cost to industry. Fees collected under GDUFA are
4 meant to provide more resources to accelerate
5 market approvals and increase risk-based
6 inspections, both of which are key to ensuring a
7 reliable supply of quality generic product.

8 Inspections of manufacturing sites, as
9 we've heard all day today, has improved, and
10 specifically for sites outside the U.S., which is
11 of critical importance given the global nature of
12 our drug supply.

13 To the extent that those fees have led
14 to more and better-trained inspectors, the program
15 has had a tremendously positive impact on the
16 quality of generic medications marketed within the
17 U.S.

18 As providers of care, we strongly
19 support the FDA's efforts to ensure that all drugs
20 are manufactured up to the highest standard of
21 safety and quality. Stepped-up inspections have
22 uncovered issues with CGMP compliance, which has

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1 resulted in products being removed from the
2 market. This appropriate action has also,
3 however, contributed to shortages of drugs,
4 leaving physicians and patients scrambling to find
5 alternative therapies, potentially less-effective
6 alternatives, and, in some cases, interruption of
7 therapy with significant potential health impact.

8 In addition to safety and quality-based
9 removals, there are a number of other factors
10 affecting drug availability. FDA data show a
11 growing number of drug shortages, and according to
12 the Generic Pharmaceutical Association, we've gone
13 from 70 shortages in 2006 to more than 200
14 reported shortages in 2010, and, over the last
15 year, 77 percent of the shortages were in
16 parenteral products, a nontrivial issue.

17 According to the University of Utah's
18 Drug Information Service, as of May 2015, the
19 number of drugs currently in short supply is 265,
20 a 74 percent increase over the last five years.

21 In our own program, the top drug
22 categories hit by shortages were anti-infectives,

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1 CNS agents, oncology drugs, endocrinology agents,
2 and cardiovascular drugs, and many of these are
3 generics that have long been used, like digoxin
4 and nitroglycerin injection for cardiac care;
5 oncology products, like docetaxel; and anti-
6 infectives, including piperacillin and ribavirin.

7 Limitations in the supply of generics
8 we've experienced over the past 12 months are due
9 not just to regulatory action, but to
10 manufacturer-imposed limitations and, to some
11 extent, increased demand exceeding supply.

12 Teva's exit from the market created a
13 strain on the supply of sumatriptan. An FDA
14 consent decree limited Bedford's ability to
15 release Famotidine Injection. FDA action limited
16 the supply of active pharmaceutical ingredients
17 for hydroxychloroquine, azathioprine, and
18 magnesium sulfate. And there's been an increased
19 demand for acetaminophen with codeine due to the
20 shift of hydrocodone to Schedule II.

21 Whatever the reason, providers and
22 patients are left scrambling for safe and

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1 effective substitutes, and we're competing amongst
2 ourselves for scarce supply, and pricing often
3 goes up when there's scarce supply.

4 In some circumstances, if we can
5 anticipate the shortages, we can warehouse
6 additional supply to safeguard against disruptions
7 in care, but these defensive strategies are short-
8 lived and not terribly effective. For some drugs,
9 such as IV gamma globulin, when there was a
10 shortage, we had to prioritize access to available
11 supply, identifying those patients in greatest
12 need, and stretching out the interval between
13 therapeutic infusions.

14 Shortages involving oncology agents have
15 created significant problems beyond cost and
16 inconvenience. It can have significant health
17 consequences.

18 We believe there is room to improve the
19 ANDA process. As the frequency of drug shortages
20 has increased, the time for ANDA approvals, as
21 we've heard, has also increased. Some of our
22 vendors now are estimating approval times of 40

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1 months or so, and we have seen estimates of median
2 approval times from University of Utah's Drug and
3 -- Drug Information Service for up to 42 months
4 for a variety of drugs, ranging from antibiotics
5 and oncology drugs to saline.

6 Focusing on increasing the speed of ANDA
7 approvals could help alleviate shortages.

8 Recently, FDA has begun to prioritize action on
9 approvals of medications in short supply, and one
10 potential approach to this might be to look at a
11 discounted fee system to incentivize manufacturers
12 to submit ANDAs and/or fast-track ANDAs for
13 medications where there are known shortages and
14 anticipated shortages.

15 And backlogs in shortages create new
16 challenges in managing supply. When there's a
17 limited number of manufacturers, the supply is
18 vulnerable to disruption from regulatory action,
19 shortage of raw material, or disruptions in the
20 supply chain, such as a longstanding strike on the
21 West Coast last year, which interfered with drug
22 supply and requires defensive strategies, which,

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1 as I've said, are of limited use for short period
2 of time.

3 A slow rate of ANDA approvals also
4 creates the potential to shift market incentives
5 towards using scarce manufacturing capacity for
6 higher-priced drugs, a perverse incentive. A
7 manufacturer who believes an ANDA will not be
8 approved in a timely manner may decide to invest
9 resources in manufacturing capacity elsewhere,
10 making other opportunities to generate revenue
11 more attractive.

12 Significantly increasing prices on
13 already approved products, or acquiring a product
14 and substantially increasing its price, will
15 quickly generate revenue, as we've seen with drugs
16 long in use, with no patent or regulatory
17 exclusivity in effect, and the price hikes are
18 both steep and sudden, often.

19 Isuprel and Nitropress, two drugs used
20 in cardiac care, were purchased earlier this year,
21 with no changes in formulation and substantial
22 increases in price, 525 percent for Isuprel; went

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1 through two acquaintances in a very short period
2 of time, from \$44 to \$1,200, from Hospira to
3 Marathon to Valeant. No change in the drug, just
4 a big change in the price.

5 Nitropress' price increased 212 percent,
6 also as a result of an acquisition. These aren't
7 isolated incidents. Other companies are buying
8 drugs they view as undervalued and increasing the
9 prices. With high demand and few, if any,
10 regulatory barriers, where are the competitors to
11 these drugs? What are the barriers to entry?

12 Long approval times can mean revenue
13 opportunities or, from a consumer perspective or
14 patient perspective, higher prices for the
15 existing limited number of approved drugs until
16 new agents enter the market and compete on price.

17 And most alarming is that escalating
18 prices for long-established generics, like the
19 doubling of the price for lisinopril or the
20 quadrupling of the price for doxycycline, are
21 driving overall pricing up, much like what is
22 occurring in the branded market.

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1 Even now, in some markets, there are
2 newly approved generics that are a price --
3 approaching the price of the brand drug, like
4 aripiprazole. The promise of generics has been
5 that the eventual availability of lower-cost drug
6 is a -- an earned payback to consumers for
7 government-granted monopoly. What we are
8 experiencing recently feels like a clear violation
9 of that promise.

10 Prices for generics have increased in
11 some cases by extraordinary amounts: tetracycline,
12 52 percent in one year; phenobarbital, 340
13 percent; thiothixene, 1,500 percent; and naproxen
14 sodium, over 3,200 percent within a year.

15 In a particularly chilling example --
16 chilling to the physician community, to the
17 provider community -- is colchicine, a drug used
18 literally for many, many decades for the treatment
19 of gout, grandfathered by the FDA.

20 And when an entrepreneurial company
21 submitted an NDA for the drug that had no NDC,
22 because it had been grandfathered, in 2009, based

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1 on a very small trial, no new information, no new
2 research, no change to the drug, a new brand drug
3 was created, Colcrys, with the remainder of the
4 generics -- there were multiple generics. It was
5 a very competitive market for colchicine. The
6 price of the drug in wide use went up a factor of
7 50, from 9 cents to \$4.85 a tablet.

8 We strongly recommend that the FDA
9 consider ways to enhance ANDA approvals, in
10 particular, where pricing and shortages can
11 threaten patient access by offering incentives in
12 the form of fee waivers, potentially discounts,
13 and/or fast-track approvals to enter market
14 segments most vulnerable to shortages or where
15 there are two or fewer products available, and
16 where the drugs are critical, such as oncology.

17 Thank you very much for the opportunity
18 to provide this testimony.

19 MR. SHERWOOD: Do you have any sort of
20 feeling on the number of generics it takes to have
21 active in the marketplace to keep the cost down?

22 DR. LEVINE: Well, what we saw with the

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1 statins was the more generics that entered the
2 market, the more generics that were available, the
3 lower the prices. Certainly two is not enough.
4 Somewhere higher than three or four.

5 MR. SHERWOOD: Okay. Thank you.

6 MS. CLARKE: Thank you.

7 DR. BAZEMORE: Good afternoon. I'm
8 Andrew Bazemore. I'm a family physician and the
9 director of the Robert Graham Center for Policy
10 Studies in Family Medicine & Primary Care. And
11 I'm probably the least expert member of this group
12 presenting to you this afternoon.

13 I come, again, as the director of a
14 center with interest in primary care policy.
15 You'll see in our long list of topics nothing that
16 relates to pharmacoepidemiology. But I also wear
17 a hat as a practicing doctor and one that
18 recognizes that, as my patient's advocate, that I
19 have demands that I prescribe safe, efficacious
20 pharmaceuticals, again, the highest-quality
21 medical care and a sensitivity to their medical
22 and financial circumstances. And I too am seeing

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1 an increasing array of my patients coming in and
2 speaking to the rising costs of generics.

3 I thought when the Walmart \$4
4 prescription list came out not too long ago, in
5 this age of \$4 formularies, that my patients would
6 see an era in which their drug costs would only go
7 down and down and down, and in recent years have
8 been surprised to see something a little
9 different.

10 And so in preparation for this talk,
11 which I was asked to present only last week, been
12 asking colleagues around the country as well as
13 some in my practice what they're seeing and also
14 asked some of my staff if they'd help me review a
15 2015 public data release to better understand, at
16 least on the Medicare side, the Part D
17 prescribing.

18 It certainly helped me to be reminded
19 that we have, in Part D, 36 million people, 68
20 percent of our Medicare beneficiaries, enrolled,
21 with an expenditure of around \$64 billion in 2013,
22 and that, in this data release, we were able to

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1 learn about the drug names, total cost, total
2 prescriptions, and prescribing data by provider
3 using their NPI, specialty, and geographic
4 location.

5 It was enlightening to me to see that
6 we're seeing a rise in generic prescribing, very,
7 you know, again, encouraging. Our claim counts in
8 2013 reveal that the top ten drugs accounted for
9 over 300 million claims, whose total cost was a
10 little over 4 billion, whereas the top ten by
11 costs were all brand-name drugs. Their claim
12 count was about 55, 54.5 million, and a total bill
13 of about \$18.7 billion.

14 Among the drugs that I prescribe most
15 commonly, I took a particular interest in two of
16 the top ten drugs on the list, Nexium and Crestor,
17 although I'm familiar with all these and also
18 familiar, because I hear about it on week-to-week
19 basis from my patients, of the relative cost of
20 these drugs and also, in an age of consumer-
21 directed advertising, the range of information
22 that they're coming in to my office with on proton

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1 pump inhibitors and statins in particular.

2 The -- you know, again, despite the fact
3 that we have an increase in national generic
4 dispensing rate, which has gone from 65 percent in
5 2007 to a little over 3 in 4 in 2013, we've seen
6 the cost go up from 62 billion to 103 billion
7 during that time period.

8 And as, again, my colleagues have
9 mentioned, it's the single-source prescribing,
10 it's the consolidation of the industry that I'm
11 hearing more and more about that leaves me
12 concerned.

13 Also trying to understand why my
14 patients are increasingly -- whether through their
15 formularies or personal choice -- moving towards
16 brand selection over other generics within the
17 same class when there's a therapeutic substitution
18 opportunity available and, obviously, the brand
19 selection over chemically equivalent generic
20 versions or generic substitution as well.

21 So it leaves me, as a primary care
22 provider, wondering, you know, again, how to help

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1 my patients who are struggling with costs to move
2 where possible towards generic substitution and
3 therapeutic substitution where it's medically
4 appropriate.

5 The, again, evidence behind this, given
6 the FDA approval process, which includes a review
7 of scientific data on manufacturing, ingredients,
8 performance, as you know, and, again, forces us to
9 -- or allows us to be able to tell our patients
10 that the generic drugs that are approved by the
11 FDA contain the same active ingredients, are
12 identical in strength, dosage, form, and route of
13 administration; treat the same conditions; similar
14 rates of absorption; and have the same
15 requirements for their identity, strength, purity,
16 and quality under same strict standards of
17 manufacture are clear.

18 Yet in these particular cases, I --
19 again, I was reminded that I -- we have really no
20 evidence for anything but equivalency in the world
21 of prescribing statins. There is no branded
22 statin with a proven safety advantage. There's no

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1 equal head-to-head comparison that took equivalent
2 doses; few differences really found for outcomes.
3 There's some differences as we raise our dose for
4 outcomes, but achievable often between a generic
5 and a brand name.

6 And this is really on a top five list
7 from my internal medicine colleagues, four for
8 cost-cutting. They have create a "Choosing
9 Wisely" campaign that focused in particular on the
10 proton pump inhibitors that I'm able to use in
11 conversations with my patients, not only looking
12 at the generic alternatives, but whether they
13 should be on some of the highest-cost drugs in the
14 first place.

15 If you look at the opportunities for
16 savings, though, it's abundantly clear that when
17 you are picking a generic such as omeprazole
18 versus its comparison agent, Nexium, an isomeric
19 equivalent, that when you look at the cost, back
20 to my \$4 drug list, for omeprazole, they're
21 looking at a co-pay frequently of around \$4, \$42
22 for Nexium, cost per day of around 45 cents versus

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1 nearly \$8.

2 And if we go all the way down to the
3 bottom, a potential savings of nearly a billion
4 dollars per annum, just from making that one
5 switch for the entire program.

6 Similarly for Crestor, we're looking at
7 a difference in cost per month of \$162.60 versus
8 about \$20 for atorvastatin. We're looking at a
9 co-pay, again, difference of \$42 versus \$4, and a
10 substantial cost per day, cost per day adjusted
11 difference, and a savings with generic that adds
12 up to over a billion dollars per annum for the
13 program.

14 So this is -- this is very interesting
15 to me for many reasons, in particular that I face
16 these patients on a day-to-day basis. I'm well
17 aware of their adherence problems; of the fact
18 that, as I add up more and more meds, which, with
19 a rapidly aging population with increasing
20 comorbidity, is the standard and is the new norm,
21 that my patients are much more likely to stick
22 with their prescription drug treatment plans if

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1 they're using these lower-cost generics in place
2 of brand-name drugs; that that adherence alone
3 explains a lot of decreasing hospital stays in
4 patients for whom are successfully treated and
5 less Emergency Department visits as well as better
6 adherence when they leave the hospital on new
7 medications in addition to its cost to the
8 healthcare system.

9 And, again, I started from the start I
10 am a non-expert in the GDUFA, beyond knowing what
11 it means and what I believe it stands for, but
12 insofar as it generates resources that allow FDA
13 to reduce their backlog of applications, cut their
14 average time required to review generic drug
15 applications for safety, and increase their risk-
16 based inspections, it's good for my patients with
17 these increasing comorbidities.

18 So as a practicing physician, we
19 certainly are in a time where it makes sense,
20 despite increasing generic prescribing rates, to
21 see this backlog that we've just heard about
22 reduced through faster approval processes from the

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1 FDA, to FDA calls for more manufacturers, where
2 generic prices are rising from no competition.

3 I also run a travel clinic and have
4 conducted work in rural Honduras for many, many
5 years. I'm very familiar with the tropical
6 diseases and have been shocked to see, over a one-
7 year period -- actually, over a two-year period --
8 a drug, albendazole, used to treat parasitic
9 infections, rise from a daily dose cost of about
10 \$6 to my patients, particularly with a growing
11 number of immigrants in our country, being an
12 important medication, to \$120 -- again, from \$6 to
13 \$120 -- over a two-year period; to see captopril,
14 a med that I've used since I was a resident back
15 in the 1990s, rise by 2,800 percent from November
16 2012 to November 2013; clomipramine rising from 22
17 cents to \$8.32 a pill.

18 And these are just a few of the examples
19 which Sharon has given you in far greater detail
20 that, again, I'm seeing on a day-to-day basis.

21 We have obligations as well to continue
22 to educate our patients and to educate our

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1 colleagues and to push for closer scrutiny of the
2 advertising and information that our patients are
3 deriving from it and to scrutinize the influences
4 around CME.

5 However, here today to speak, certainly
6 on behalf of any process that would reduce the
7 time from application to approval for these
8 generic drugs to combat the negative effects of
9 growing consolidation on behalf of our patients.
10 Thank you.

11 MR. SHERWOOD: You have any stories on
12 the consequences of these rising costs on the
13 patients themselves?

14 DR. BAZEMORE: So stories of the cost --
15 of the consequences on the patients themselves?

16 MR. SHERWOOD: Yes.

17 DR. BAZEMORE: You know, I hear them
18 just about weekly. I actually practice now in
19 Fairfax, but I have been practicing in community
20 health centers, and I think it's in the safety net
21 where you're seeing some of the biggest problems.

22 On the one hand, we have the \$4 drug

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1 list; on the other hand, we have limits of the \$4
2 drug list. And for my patients who really have
3 month-to-month, 30, 40 percent of their disposable
4 income going to food, medications, and almost
5 nothing left over for housing, this is a huge,
6 huge consequence for them.

7 So in downtown D.C., I hear many, many
8 stories of the negative consequences of some of
9 these generic prescriptions, so -- rising.

10 MS. CLARKE: Thank you.

11 DR. BAZEMORE: Thank you.

12 MR. TOPOLESKI: Good afternoon. My
13 name's Chris Topoleski, and before I begin, I just
14 want to say that we did not hold a conference
15 call, but I'll be covering the exact same two
16 topics that everyone else has. I'll be speaking
17 about drug shortages as well as increasing prices.

18 Again, my name is Chris Topoleski. I
19 serve as ASHP's Director of Federal Regulatory
20 Affairs. ASHP represents pharmacists who serve as
21 patient care providers in acute and ambulatory
22 settings. The organization's more than 40,000

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1 members include pharmacists, students, and
2 pharmacy technicians.

3 For more than 70 years, ASHP has been on
4 the forefront of efforts to improve medication use
5 and enhance patient safety. I appreciate the
6 opportunity to present the views of ASHP on the
7 performance of the Generic Drug User Fee program,
8 or GDUFA, and additional initiatives that the FDA
9 should consider when negotiating a reauthorization
10 of the Act with lawmakers.

11 FDA's public health mission is to ensure
12 the safety and effectiveness of drugs, biologics,
13 and medical devices. No other agency or private-
14 sector entity serves the vital public health
15 purpose in our society.

16 ASHP believes that the allocation of
17 sufficient federal resources to the FDA to meet
18 its mission is a necessity and that those funds
19 should primarily be through federal
20 appropriations. ASHP strongly supports increased
21 funds for the Agency and is working to achieve
22 that through our works with the Alliance for a

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1 Stronger FDA.

2 Drug user fees do not replace the need
3 for increased appropriations from Congress.
4 However, ASHP does recognize that with the
5 Agency's increasing backlog of generic drug
6 applications, the passage of GDUFA in 2012
7 represented an important and viable means to help
8 bring safe and effective generic drugs to market.

9 My comments today will focus on the
10 current state of GDUFA and potential improvements
11 to the program that would improve patient access
12 to needed medications in a way that emphasizes
13 safety.

14 As I already noted, the FDA should be
15 primarily funded through federal appropriations.
16 However, for many years prior to the passage of
17 GDUFA, ASHP encouraged the FDA to consider
18 requiring user fees for generic drugs.

19 Poor-quality applications take valuable
20 time away from the generic drug reviewers that
21 need to focus their attention on accurate and
22 complete applications for needed generic drugs

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1 that will be marketed and sold in the U.S.

2 ASHP also recognizes the challenges
3 associated with reviewing and approving complex
4 generic drugs, such as inhalers and topical
5 agents, and GDUFA crated additional resources to
6 address the expertise and added time necessary to
7 review and approve applications for these agents.

8 ASHP believes that the implementation of
9 GDUFA, currently in its third year, has been very
10 successful. The initial authorization of any new
11 federal program requires a period of planning and
12 building up of resources. To that end, the Agency
13 has exceeded their recruitment goals in the first
14 two years of the program, hiring over 1,000 new
15 employees to meet the goals.

16 Additionally, the FDA has enhanced their
17 IT systems, issued guidance to industry on ANDA
18 submissions, and significantly increased the
19 number of applications reviewed each year compared
20 to pre-GDUFA, reducing the backlog in
21 applications.

22 The Agency has been incredibly

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1 transparent in public in what they have
2 implemented to achieve the five-year goals of
3 PDUFA (ph), as noted by numerous presentations,
4 public meetings, and outreach efforts to educate
5 and inform industry participants and other
6 stakeholders.

7 So now future directions. Hospitals and
8 health system pharmacists appreciate the role that
9 generic manufacturers and the FDA play in helping
10 to ensure that there are adequate supplies of
11 medically necessary drug products. This is very
12 important, as drug shortages of medically
13 necessary products can have a catastrophic effect
14 on patient safety.

15 FDASIA, passed in 2012, gave the FDA
16 more powers to prevent and resolve shortages,
17 including requiring manufacturers to provide
18 advance notice to the Agency of potential
19 shortages and allowing the FDA to speed up
20 approvals of manufacturing upgrades.

21 The FDA has stated that it prevented
22 over 100 shortages last year by working closely

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1 with manufacturers following notification.

2 However, the number of drugs in short
3 supply in the U.S. has risen 74 percent from 5
4 years ago, to about 265, according to the
5 University of Utah's Drug Information Service.
6 These drugs range from antibiotics and cancer
7 treatments to very basic items, such as sterile
8 saline.

9 While the FDA may not be able to compel
10 a manufacturer to continue to make a product, it
11 will be important for the FDA to continue to
12 prioritize applications for medically necessary
13 products that are in short supply and to use
14 generic drug user fees to enhance Agency efforts
15 to prevent drug shortages.

16 As we are all well aware, generic drugs
17 bring the promise of significant savings over
18 their brand-name counterparts. In the ten-year
19 period between 2003 and 2012, generic drugs
20 generated \$1.2 trillion in savings to the U.S.
21 healthcare system.

22 However, generic prices for some drugs

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1 have been moving up for some time. Many drugs
2 have doubled in price over a relatively short
3 period of time, with extreme examples of price
4 increases of more than 1,000 percent or more for
5 commonplace drugs. These drugs include oral solid
6 doses that used to be pennies on the dollar.

7 These types of changes in drug prices,
8 along with new products coming to market, have
9 been negatively impacting patient access to needed
10 medications.

11 Regardless of the reason for these price
12 increases, ASHP recognizes the frustration and
13 challenges that it's presenting to pharmacists,
14 patients, and the time demanding -- resulting from
15 managing these situations.

16 We have engaged in discussions with
17 policymakers on Capitol Hill, but believe that the
18 FDA should explore ways in which to examine and
19 study this trend using the resources of GDUFA.

20 While drug pricing is often out of the
21 scope of the Agency, we believe the FDA does have
22 an opportunity to discuss reasonable pricing

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1 decisions with manufacturers during the
2 application process.

3 So, in conclusion, GDUFA has increased
4 the quality of generic drug submissions, enhanced
5 communication between the FDA and manufacturers,
6 increased staff dedicated to reviewing
7 applications, and significantly reduced the number
8 of drug applications in backlog.

9 The program should be reauthorized in
10 2017 and include goals to address the growing
11 number of drug shortages and increasing the price
12 for certain generic drugs.

13 On behalf of the over 40,000 members of
14 ASHP, I thank you for the opportunity to present
15 these comments. We look forward to working with
16 the Agency on the reauthorization of this
17 important program. Thank you.

18 MS. CLARKE: Thank you for your
19 comments.

20 MR. TOPOLESKI: Thank you.

21 MR. SCHONEKER: Hi, I'm Dave Schoneker.
22 I'm representing the International Pharmaceutical

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1 Excipients Council of Americas. We're
2 an organization that represents the makers, users,
3 and distributors of pharmaceutical excipients,
4 pretty much the entire industry: generics,
5 innovator companies, OTCs.

6 And I'm here to talk to you about
7 something a little different than what we've been
8 talking about, but something that's going on
9 behind the scenes that has a lot to do with some
10 of the major issues that have been discussed by
11 some of the other speakers.

12 I'd like to talk a little bit about some
13 proposals that we plan to meet -- make in our
14 written comments here related to the Inactive
15 Ingredient Database and how to handle the safety
16 of inactive ingredients.

17 As earlier mentioned by various
18 speakers, IPEC believes that GDUFA should address
19 timely review of applications, increased
20 innovation, and cost containment with the Inactive
21 Ingredient Database and related policies, such as
22 the RTR and Controlled Correspondence Guidances

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1 have given us a number of issues.

2 Improvements are needed related to how
3 to handle new excipients and how they're
4 evaluated. IPEC has been having meetings
5 routinely with various groups within the Agency,
6 working together with GPhA, and we actually had a
7 meeting with some of your toxicologists back on
8 June 4th to talk about some of the issues related
9 to novel excipients. So, with that, I'll get into
10 the presentation here.

11 There's a need for new and novel
12 excipients. We have innovative and novel drug
13 technologies that are key to improving public
14 health, developing high- quality drug products,
15 and advancing manufacturing science in the
16 pharmaceutical industry. These are key goals that
17 Janet Woodcock emphasizes in almost every talk
18 I've heard her talk.

19 Well, to explore these types of
20 innovative systems and develop formulations, which
21 can address difficult drug substance property
22 issues, such as poor solubility and permeability,

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1 and enhance the use of advanced manufacturing
2 techniques, the availability of high-quality
3 inactive ingredients, excipients, having unique
4 performance capabilities designed for purpose is
5 critical.

6 To get into things like continuous
7 manufacturing and other advanced techniques that
8 can help control costs and make better products,
9 more improved productivity, the old excipients
10 we've been using for a hundred years just aren't
11 going to make it. We have a need for many new
12 materials.

13 So currently, outside the inclusion in
14 an NDA or ANDA, there is no regulatory pathway or
15 process for the Agency to independently review the
16 safety of new or novel excipients.

17 All other ingredients in many related
18 areas have a regulatory pathway: food additives,
19 cosmetic ingredients. Even APIs with a DMF Type
20 II Completeness assessment have some sort of a
21 regulatory pathway to get looked at or qualified
22 or reviewed in some manner. We don't have that

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1 for excipients. There is no process outside of
2 putting it into a drug application and seeing what
3 happens.

4 This current process of essentially
5 having to find someone to become the guinea pig,
6 to be the first one on the block to try a new
7 excipient or what may not really be a new
8 excipient, as I'll talk about in a minute, but
9 some minor modification in the current situation,
10 simply is not working. It's not working because
11 of the regulatory risks that are involved.

12 Now, these regulatory risks are not
13 safety risks. They're regulatory risked based on
14 the uncertainty of timing, of what the use of a
15 new or novel excipient might mean in terms of the
16 timing of the review or the questions that you
17 might get. Rarely does it have anything to do with
18 any real risk related to safety of these
19 materials. Most excipients are materials that are
20 commonly used at much higher levels in foods and
21 other related areas.

22 Now, the lack of an independent FDA

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1 excipient safety review process is really
2 hindering drug development and innovation in both
3 generic and innovative drugs. No one is willing
4 to be that guinea pig.

5 I have many experiences, and our members
6 throughout IPEC have many experiences, where new
7 materials have been developed that could really
8 enhance the drug manufacturing process, the
9 formulations, solve problems, and basically people
10 try these materials, they love them, they say,
11 "Oh, my God, this can solve all these problems
12 that we have. Go away and come back after somebody
13 else uses the material first."

14 And so what happens is ten years go by,
15 and nobody goes first, and that material that
16 could solve all those problems never gets used.
17 This is a reality with the current system.

18 What that means is that many drug
19 manufacturers end up settling for developing drug
20 products which are -- I'll call them good enough,
21 but not necessarily the best or at the lowest
22 cost.

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1 So the establishment of an independent
2 process for FDA to review the safety of new or
3 novel excipients is critical for both innovative
4 and generic drug development.

5 Members of IPEC-Americas plan to propose
6 in our written comments a number of options for
7 FDA to consider, which could lead to enhanced
8 innovations in the pharmaceutical industry, both
9 innovator and generic companies.

10 We'd like to have these options to be
11 included in the GDUFA and PDUFA reauthorization
12 negotiations, which will take place over the
13 coming months. Now, I'll speak a little bit about
14 how we might see that could work in the next few
15 slides.

16 First, I'd like to define what do I mean
17 by a new or novel excellent? Because, when we say
18 that, everybody usually jumps right to the bottom
19 of this list and talks about, oh, new chemical
20 entity type of excipients. Well, obviously that
21 needs all kinds of safety data. That needs all
22 kinds of review, just like a new drug.

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1 But that's not how novel excipients are
2 defined by FDA. FDA defines a novel excipient as
3 basically anything that doesn't have a prior
4 precedence of use in the route of administration
5 of interest, you know, in a previously approved
6 drug.

7 Now, this includes things like new
8 grades of an existing family of related
9 excipients, of existing excipients. Okay? This
10 typically means that very little safety assessment
11 is needed.

12 In the past, these never were really
13 looked at as a new excipient, but over the last
14 few years, FDA reviewers have been looking at
15 different grades of, let's say, the same polymer
16 as if it was a new excipient, expecting to see
17 full safety data on each and every grade, which is
18 simply ever going to happen, nor would any
19 toxicologist ever recommend that that kind of work
20 be done and waste those animals. But yet it's
21 defined as a new or novel excipient, to some
22 degree in the same way as a new chemical entity,

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1 in terms of regulatory status.

2 We also have new co-processed
3 excipients, which are things where we take two or
4 more excipients and physically combine them.
5 There's no chemistry involved.

6 And, basically, with those materials,
7 you can assess the safety of those materials
8 rather easily by looking at some analytical data
9 and doing a safety bridging argument to show that
10 you didn't create any chemistry, and you can
11 bridge back to the safety of the individual
12 component, many of which have been around for a
13 long time.

14 I've had experiences with a material
15 that is simply a spray-dried version of cornstarch
16 and pre-gelatinized cornstarch, but because it's
17 a co-processed excipient and we've got all the
18 analytical data to show that there's no chemistry
19 involved, no one will touch that material.

20 Eight years have gone by. No one has
21 approved it yet. This is cornstarch and pre-
22 gelatinized cornstarch. There's no risk involved,

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1 yet many of these materials can solve huge
2 problems in the industry and improve products --
3 processes and reduce cost.

4 Next on the list we have new uses of
5 existing excipients. This would be an excipient
6 that's been around for a long time, but possibly
7 somebody wants to use it at a higher level of use
8 -- in a -- in -- in a previously used route of
9 administration, but wants to use it at a higher
10 level of use. I'm sorry. I got mixed up there.
11 Or they want to use it in a new route of
12 administration.

13 Well, many of these materials, again,
14 have been used at much higher levels, in related
15 oral applications in food, for instance, if it's
16 an oral drug, et cetera.

17 Next we have new chemically modified
18 grades of an existing excipient. Here you start
19 to get a little bit more going on. There's some
20 chemistry happening, but maybe not all that much.
21 And then finally we get to a new chemical entity
22 type of excipient.

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1 Well, the key thing about this list is
2 to understand that the level of safety assessment
3 that's needed increases as you go down the list,
4 starting at the top, where there's not really much
5 risk at all, all the way to where there's more
6 risk at the bottom.

7 If we look at this in a little different
8 manner, we think about the amount of safety data
9 necessary to look at each one of these different
10 types of novel excipients, and you can see how the
11 curve starts to exponentially go up.

12 Well, the bottom line is there's quite a
13 difference in the amount of safety data that's
14 needed to look at a new chemical entity type
15 excipient versus something like a new grade of an
16 existing family of polymers, for instance.

17 So what is it we're talking about? IPEC
18 will propose concepts for consideration in our
19 written comments, such as the use of Type IV or V
20 DMFs for submission of inactive ingredients safety
21 information, including studies in bridging
22 arguments. We like to have those DMFs be reviewed

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1 independently by FDA experts to do a safety
2 assessment of those DMFs outside of a drug
3 application. A DMF holder would indicate the
4 intended types of use and levels of which they
5 intend to sell that product into the industry for.

6 The usefulness of a GDUFA or PDUFA type
7 user fee system could provide resources to FDA for
8 these independent safety assessments, and industry
9 is willing to talk about new user fees here if, in
10 fact, we could -- could achieve some sort of an
11 independent process with a reasonable time line.
12 There's huge benefits to be had.

13 We would see this review end up in a
14 published list of excipients which have undergone
15 this independent assessment and consider --
16 probably not the right word is "endorsed" there,
17 but I would say "qualified" is a better word,
18 something that FDA has qualified as having
19 appropriate safety data to be used in the intended
20 use and the intended use level.

21 We're not looking for an approval. We
22 understand that that would still happen in the

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1 individual drug in the context of use. But
2 something that would allow companies to know that
3 this material safety data has been qualified at a
4 level that's reasonable.

5 There's many other similar programs out
6 there in different arenas. In the food arena,
7 you've got the FDA GRAS notification process,
8 which is a similar type of thing, for food
9 additives. We've got the FEMA process for
10 flavors, the CIR process for cosmetic ingredients.

11 And we also have become aware, after our
12 meetings with your toxicologists last week -- or
13 two weeks ago -- about a biomarker qualification
14 process that you have, which is kind of similar to
15 the type of thing that we're talking about here,
16 and that's something more recent that you've
17 developed kind of to do the same thing that we're
18 talking about here, how to develop a way to get
19 innovation through the process.

20 So I'm going to switch gears now and
21 talk a little bit about that first category that I
22 talked about on the types of excipients, and I'm

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1 going to talk about what we call the family
2 approach for inactive ingredients safety
3 assessment.

4 The current Inactive Ingredient Database
5 and the policies regarding its use are
6 insufficient at the current time to support
7 efficient drug development and approval.

8 The database has a lot of problems. The
9 policies and the guidelines that have been
10 developed through GDUFA have actually created huge
11 confusion in the marketplace and much uncertainty,
12 which has created numerous RTRs for reasons that I
13 think, if I went into the details, you would
14 shudder at why we're spending time and you're
15 spending time on some of these issues.

16 Some of these policies continue to
17 create confusion and have resulted in longer
18 review times for generic drug applications.

19 IPEC-Americas believes that there are
20 several things that can be done to make the
21 process more efficient and help the Agency and the
22 industry meet GDUFA commitments.

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1 The current practice of requiring
2 toxicology data for each and every grade of an
3 inactive ingredient is not substantiated by
4 scientific rationale and is not aligned with a
5 risk-based approach.

6 In fact, no other regulatory agency that
7 I'm aware of looks at things like a family of
8 polymers and expects to see data for each and
9 every grade. This is always done by bracketing.
10 This is standard toxicology 101 you do with these
11 types of families by having studies at various
12 brackets to minimize the amount of animals that
13 are being used in the testing.

14 We believe that utilizing a family
15 approach during a safety review of these related
16 grades of excipients can lead to a more efficient
17 review and reduction of FDA resources without
18 compromising patient safety.

19 The safety testing, as I mentioned, of
20 excipients within a related family is normally
21 performed using a bracketing approach, and the
22 same data must be used to evaluate all grades

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1 within the family, and, in fact, the same data
2 always will.

3 Right now, what's happening is FDA keeps
4 requesting data for many of these circumstances
5 and re-reviewing the same data over and over and
6 over again for each grade of the excipient family.
7 There won't be any additional data. Nobody in
8 their right mind would do more studies on some of
9 these materials that have no safety risk. So it
10 ends up with being reduction work on behalf of the
11 Agency and holding up drug development in
12 different ways.

13 So IPEC-Americas has been meeting with
14 FDA's IID Expert Working Group since 2011, and
15 we've supplied significant information to FDA to
16 justify the use of a family approach to excipient
17 safety assessment for related excipient grades.

18 We've been working on this since 2011.
19 We still don't have a decision on it yet. A
20 decision is needed as soon as possible to accept
21 this family approach. Otherwise, these issues
22 will impact the amount of redundant and non-value-

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1 added FDA resources used to evaluate these
2 excipients under GDUFA.

3 Hopefully, this can get resolved within
4 GDUFA I, but certainly if not, we certainly need
5 to have it resolved in GDUFA II, not that we want
6 to wait that long.

7 We recognize and we applaud the FDA for
8 their recent work at updating and improving
9 information listed in the Inactive Ingredient
10 Database. We know there was a lot of work to be
11 done. The database had some issues. There's been
12 a huge amount of effort, I believe funded by some
13 of the GDUFA funds from recent years to get that
14 database in better order, but it's still a long
15 way from where it needs to be.

16 As was discussed a little bit earlier,
17 you're improving many of your systems. This is
18 one that definitely needs improvement, and we
19 believe a modern database with improved
20 capabilities is needed to support improved drug
21 development and more efficient FDA reviews and
22 that this new database must have the capability to

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1 include maximum daily intake information.

2 IPEC-Americas believes that provisions
3 to build and maintain a new, improved IID database
4 should be considered as part of the GDUFA and
5 PDUFA reauthorization and should be funded by
6 GDUFA and PDUFA fees. We also plan to be involved
7 in similar types of discussions during the PDUFA
8 meetings that are coming up next month.

9 Thank you very much for your attention
10 today, and I'm open for any questions.

11 MR. SHERWOOD: Do you have any general
12 idea on volume of these independent safety
13 assessments? Do you think that could be put
14 forward to the Agency if we were to pursue one of
15 these venues?

16 MR. SCHONEKER: Well, that's one of the
17 areas that obviously we would need to work
18 together on. You know, there's many of these
19 situations out there. Many of them don't come to
20 fruition now because there's no pathway.

21 So what we're really doing is talking
22 about a way to open the ability to innovate for

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1 the excipient companies. Right now, there's only
2 a few companies developing new chemical entity
3 excipients, and I know that most of them are just
4 about ready to stop doing it because they've done
5 an investment with no payback, and these materials
6 will not continue to exist unless we have some
7 sort of a pathway.

8 Now, we believe that some of these
9 concepts, if handled appropriately, could open the
10 door for much innovation, especially with things
11 like co-processed excipients, et cetera, that
12 really can solve a lot of these problems, improve
13 productivity, and the quality of the drug
14 products.

15 So we think this is -- again, there's
16 only going to be a limited number of new chemical
17 entity excipients coming through because of the
18 amount of toxicology. That's why I wanted to
19 define these. That's a limited number. But all
20 these other materials and having the ability to
21 assess higher levels of use, et cetera, those are
22 huge benefits that we think there would be a

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1 significant number of people coming through
2 wanting to get this type of a qualification
3 process done.

4 Do I know what those numbers would be?

5 No, not yet. Part of what we're looking at is
6 trying to figure that out, hopefully together with
7 you guys, to figure out something that would be
8 workable for you and workable for industry.

9 MR. FLANAGAN: Thanks for your
10 presentation. I'm going to ask you to educate me.
11 So my question's not -- like, I'm not playing
12 dumb. I really don't know what you're -- I really
13 need to learn more about one aspect of your
14 presentation.

15 So it sounded to me like the idea was
16 that generic manufacturers are reluctant to use
17 novel excipients because they haven't yet been
18 qualified or endorsed by FDA. Is that basically
19 accurate in the generic space?

20 MR. SCHONEKER: Yes, because I think,
21 you know, right now, what happens is one of the
22 first checks that happens when somebody submits an

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1 ANDA is you have people that check the ingredients
2 against the Inactive Ingredient Database to see
3 whether there's a prior precedence of use.

4 And it may say "yes" -- even if it's
5 there, it might say it's approved only at this
6 level in a particular route of administration. So
7 if it's above that level, okay, now it's defined
8 as a novel excipient. And if somebody has not
9 submitted all the safety data upfront, that
10 results in an RTR.

11 And that's where the rub comes. And so,
12 you know, what happens is nobody will do anything
13 to try to, you know, innovate unless they have no
14 ability to solve the problem some other way.

15 MR. FLANAGAN: And what is the
16 therapeutic benefit produced by excipient
17 innovation? Because, in most cases, when we're
18 reviewing generics, we're not looking for novelty
19 or innovation. We're looking for sameness.

20 MR. SCHONEKER: Right. Well, and,
21 again, innovativeness here is a little different
22 than when you're thinking about innovative drug.

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1 Okay? We're talking about trying to find ways to
2 be able to be the same, but do it better. Okay?
3 In many cases, it comes down to the manufacturing
4 of the material.

5 If you want to move towards more
6 advanced manufacturing techniques, continuous
7 processing, that type of thing, it makes a big
8 difference, whether you can have something that's
9 designed for purpose versus something that might
10 vary all over the place based on natural type of
11 things.

12 Additionally, when it comes to
13 formulations, especially if you look at oral drug
14 formulations, you're allowed to have different
15 excipients, as long as you have the same
16 bioequivalence.

17 So people get to that sameness endpoint
18 through the use of various different methods that
19 can mean better formulations, higher-quality
20 tablets, that type of thing, even though it still
21 has the same bioequivalent.

22 MR. FLANAGAN: Do you think that -- it's

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1 hard for you to predict, and if you don't know,
2 then you don't know -- but do you think your
3 proposals would have such a positive impact on
4 access that other -- that other GDUFA fee payers
5 would welcome them instead of viewing them as
6 draining resources away from other objectives
7 that' be more impactful from a public health and
8 access perspective?

9 MR. SCHONEKER: That's a very good
10 question, and I would have to say I absolutely
11 believe most of the generic drug industry would
12 love if we could have a process like this.

13 We get asked all the time, "What can we
14 do? We want to use it at a higher level of use.
15 We want to use this co-processed excipient. It
16 could really make a benefit and keep our cost down
17 and make a better-quality tablet that's less
18 friable or, you know, works better." In many
19 cases, the solubility of a drug is a problem, and
20 sometimes this can make it more consistent and
21 less variable.

22 So there's many of those types of

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1 properties that the industry would love to have,
2 and I can tell you, from the excipient
3 manufacturer's perspective, these are the
4 discussions we have with our customers every day,
5 but we don't have the ability of solving the
6 problem because, unless there's a pathway to break
7 down this uncertainty barrier, they won't go
8 there, and instead they'll develop something and
9 try to get by with materials that might vary more,
10 that, you know, somehow make it good enough to get
11 through.

12 So when we think about and when you
13 hear, you know, Janet's vision for, you know, 21st
14 century initiative and quality by design and
15 everything else, we're getting by with good enough
16 when we could be trying to be the best in many
17 cases, and that's a reality in the industry. I'd
18 be willing to guess that many people in the room
19 would say that. Okay.

20 MS. CLARKE: Thank you for your
21 comments.

22 MR. SCHONEKER: Thank you.

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1 MS. AUTHELET: Good afternoon. My
2 name's Melissa Authelet. I'm from Rochem
3 International. My colleague Marco is sitting
4 there enjoying the reserved seating for
5 presentators. He'll be available to answer
6 questions, but I'll be presenting.

7 Rochem International, really quickly, is
8 a product development and sourcing API company.
9 We're located on Long Island, New York.

10 Okay. So my presentation is for
11 redefining the API and FDF definitions that are in
12 GDUFA. So I'm going to start out with my proposal
13 for a suggestion of how we think that the new
14 definitions should be if they were revised,
15 explain how the definitions as they currently
16 stand conflict with the goals of GDUFA, and then
17 also provide a actual real-life example that we've
18 encountered to really show how this affects the
19 industry.

20 So we'd like to propose to remove
21 Definition C of a Finished Dosage Form, which
22 currently is "Any combination of an active

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1 pharmaceutical ingredient with another component
2 of a drug product for purposes of production."

3 We believe that this definition really
4 is and should be considered an API definition. So
5 to remove that and then add a clause into the API
6 definition, Definition A, as you can see in bold,
7 is what we would be proposing to be added,
8 something along the lines of "or only for the
9 purposes of further production" when it comes with
10 mixing an API with other substances and not just
11 be for it to be unstable for shipping or
12 longevity, but also for the purposes that it would
13 be -- have to go through further manufacturing
14 processes before it's actually considered a final
15 dosage.

16 So this is what it would look like if
17 the FDF Definition C is removed. It would still
18 have A and B, but then API Definition A would be,
19 in bold, added "or only for the purposes of
20 further production" if we were to mix an API with
21 another substance.

22 So the industry is told that the goals

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1 of GDUFA -- here's two quotes from the GDUFA
2 website. "The law requires industry to pay user
3 fees to supplement the costs of reviewing generic
4 drug applications and inspecting facilities

5 So we agree with that, and we think that
6 that should be in place. Second, "Self-
7 identification is required for two purposes," the
8 second of these being that "Self-ID is a central
9 component in an effort to promote global supply
10 chain transparency. And the information provided
11 through self-ID will enable quick, accurate, and
12 reliable surveillance of generic drugs and
13 facilitate inspections and compliance."

14 So self-ID, with the current definitions
15 of API and Finished Dosage Form, puts a lot of API
16 manufacturers who mix an API with one or more
17 excipients to then be considered a finished
18 dosage. So these facilities are self-IDing under
19 an API and also a finished dosage facility, as
20 Alan Nicholls had talked about earlier.

21 So this is falsely categorizing and
22 artificially creating more manufacturing sites and

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1 inflating the number than there actually is.
2 Especially with how global our generic drug supply
3 chain is, it's -- where not every FDA -- not every
4 facility is going to be FDA inspected as soon as
5 they self-ID.

6 So you wouldn't know that the
7 manufacturer only does APIs and a additional
8 blending step and not actually a full Finished
9 Dosage Form until you actually set foot on the
10 facility. And that could not be -- and that could
11 maybe be for two or three years down the line,
12 after they've -- after they're part of a
13 submission.

14 So facility fees are intended to cover
15 costs of inspections, but Finished Dosage FDF
16 Definition C would have those API manufacturers
17 paying both the API fee and the finished dosage
18 facility fee when, in actuality, there's only
19 going to be one inspection, and it's going to be
20 the same depth and time that a API facility
21 inspection would be.

22 So -- and then it negatively affects the

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1 API manufacturers who fall into this definition
2 because they have to pay two facility fees for one
3 site and one inspection and possibly only one
4 generic drug.

5

6 To touch on PDUFA, we were told when
7 this was being established that GDUFA was designed
8 to build on the success of PDUFA. Just to remind
9 you that PDUFA defines a Finished Dosage Form as
10 one in which is approved for administration to a
11 patient without substantial further manufacturing.
12 The way that final dosage is defined in GDUFA is
13 that further manufacturing does occur in FDF
14 Definition C.

15 Establishment fees under PDUFA, it
16 states that each establishment is only assessed
17 one establishment fee for each year, even if
18 there's multiple applicants -- multiple
19 applications for that facility.

20 We're not endorsing that a true API
21 manufacture and finished dosage facility who are
22 in the same location should not pay both fees.

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1 We're saying that they should be assessed and pay
2 the fee that is accurate to them.

3 So this is our example that I've brought
4 to really show how this negatively affects API
5 manufacturers and the industry as a whole. So
6 this example is for an oral solid dosage tablet.
7 It's been a generic for over probably 15 to 20
8 years. There's nothing new, nothing novel, but
9 it's being negatively affected by these GDUFA
10 fees.

11 So the API manufacturer is a foreign
12 facility. They manufacture the API. They blend
13 it with microcrystalline cellulose and povidone
14 k30, again, not a new or novel excipient. They
15 package into -- bulk powder into drums. They're
16 25-kilo drums that -- you know, this is a foreign
17 facility, so it's imported into the United States.

18 By law, all of the drums have to state
19 on them "For Further Manufacturing Use Only."
20 These drums -- these 25-kilo drums cannot be sold
21 to hospitals or pharmacies or doctors' offices.
22 It's just for further manufacturing.

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1 The finished dosage manufacturer is
2 domestic in the U.S. As I stated, it's imported
3 here. The finished dosage manufacturer then takes
4 this blend, blends it with additional excipients,
5 and then compresses it into tablets, also coats
6 the tablets, does finished dosage release testing,
7 and then packages and labels for consumer level.

8 So you can see how much more detailed an
9 inspection of this final dosage manufacturer would
10 be compared to the API manufacturer.

11 But right now, as the GDUFA definitions
12 stand, the API manufacturer must pay an API and
13 FDF manufacturer facility fee every year, and the
14 finished dosage manufacturer only pays one
15 facility fee.

16 So the total for fiscal year 2015 for
17 this manufacturer, who has yet to see -- yet to
18 gain approval, so this is just paying fees without
19 actually it being on the market, is over \$300,000
20 for just fiscal year '15. The finished dosage
21 manufacturer pays \$247,000 in fiscal year 2015.

22 So total facilities paid for one oral

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1 solid dosage tablet, generic, is over half a
2 million dollars, and this is without approval,
3 because facility fees have to be paid before
4 approval when it's time of submission.

5 So over a course of, if we were lucky,
6 24 months that it received approval, both these
7 facilities would be paying over a million dollars
8 before the generic drug even gets on the market.

9 So essentially there's two
10 manufacturers, but there's actually three facility
11 fees being paid; three facility fees being paid
12 for only two inspections.

13 So, again, this is our proposal for how
14 we would work around a new definition for an API
15 and FDF. In closing, the current definitions are
16 not meeting the intention and spirit of GDUFA
17 through inaccurate reporting of facilities, their
18 actual manufacturing processes, multiple fees
19 being paid for one manufacturing process, and one
20 FDA inspection.

21 So I hope you can take our suggestions
22 into consideration. Thank you.

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1 MR. FLANAGAN: I think there's -- just a
2 comment rather than a question, but I would just
3 let you know I think there is a recognition that
4 there's situations where there's some fee double-
5 counting, where a product hasn't yet been
6 approved, where it's a small company, and the
7 small company has paid a big fee several years in
8 a row. And, you know, that doesn't make sense, so
9 we'll be talking about that.

10 MS. AUTHELET: Okay. Thank you.

11 MR. SHERWOOD: Again, do you have any
12 idea what the volume of these, you know, sort of
13 double- counting situations are?

14 MS. AUTHELET: For fiscal year '16, the
15 self-ID that recently came out, it was over 100
16 that had the same manufacturing site that were
17 both registration desk as an API and FDF
18 manufacturer.

19 We do believe that if there's actually
20 an API plant and there's a finished dosage plant
21 on the same campus and they're registered the same
22 identification facility number, we do believe they

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1 should pay both fees because those are
2 manufacturing processes that are actually
3 occurring. But in a lot of examples that we've
4 come across, as the one that I've shown, that is
5 actually not the case.

6 MR. FLANAGAN: I assume that the answer
7 is no, but I -- we might as well poke around. So
8 do you have any idea of -- of those hundred, do
9 you know how many of -- do you by any chance know
10 how many of those are small companies that have
11 paid the fee a couple times, but are not
12 associated with any approved products at all?

13 MS. AUTHELET: No, I don't have that.
14 Sorry.

15 MS. CLARKE: Thank you for your
16 comments.

17 MS. AUTHELET: Thank you.

18 MR. COLE: Good afternoon. Thank you
19 for this opportunity to speak with you. I'd like
20 to talk about the drug user fee relief for small
21 businesses.

22 I'm Perry Cole. I'm President and

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1 Executive Director of the Specialty Pharma
2 Association. We're a not-for-profit 501(c)(6)
3 industry association established in 2008. The
4 Specialty Pharma Association represents small- to
5 medium-sized pharmaceutical distributors and
6 contract manufacturers.

7 Our members include educational programs
8 via conferences, webinars, and newsletters. Our
9 member services include both federal and state
10 regulatory guidance, support, and representation.

11 The Specialty Pharma Association is the
12 only industry association that represents the
13 small- to medium-sized specialty pharma companies.

14 The U.S. Small Business Administration
15 establishes small business standards that
16 designate qualifications for small businesses.
17 The SBA Table of Small Businesses Standards
18 classifies small pharmaceutical companies as
19 pharmaceutical preparation, manufacturing, with an
20 NAICS Code of 325412.

21 Under this designation, the SBA size
22 standards for the number of employees is 750 or

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1 less, which would qualify nearly all SPA member
2 companies as small businesses.

3 The GDUFA fee schedule requires all
4 companies seeking ANDA approvals to pay the same
5 amount of fees regardless of the company size.

6 While we feel the GDUFA fees have been
7 advantageous in ANDA approvals, we believe the
8 current fee schedule is financially unfair to
9 small businesses seeking approvals.

10 Requiring the small companies to pay the
11 same fees as large companies limits the small
12 company's ability to file for approvals.

13 Limiting a small company's ability to
14 file for approval creates an unfair disadvantage
15 for small companies to compete fairly.

16 In an effort to provide a fair and
17 reasonable alternative to the current GDUFA fee
18 schedule, the SPA proposes consideration of the
19 following three suggestions.

20 Number one, the FDA recognize small
21 companies qualifying as SBA-designated small
22 businesses under the guidelines for pharmaceutical

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1 preparation manufacturers. This designation would
2 include pharma companies with 750 or less
3 employees seeking ANDA product approvals.

4 Number two, the FDA allow a waiver of
5 GDUFA Fees for the first product approved by a
6 company qualifying as a small business. This
7 waiver is consistent with the current PDUFA fee
8 schedule.

9 Number three, the FDA waive the
10 establishment fees for qualifying small companies
11 until such time the product is approved by the
12 FDA. With an average ANDA approval time of 42
13 months, requiring small companies to pay this fee
14 prior to approval and marketing creates an unfair
15 hardship for small companies.

16 We understand changes to the GDUFA fee
17 schedule -- or fee guidelines require new
18 legislation, and the SPA is seeking some
19 Congressional support for the drug user fee relief
20 for small businesses.

21 On behalf of the Specialty Pharma
22 Association and all small pharmaceutical

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1 companies, I want to thank you for this
2 opportunity to present our request for GDUFA fee
3 relief for small businesses.

4 MR. SHERWOOD: Have you seen any
5 trending on the small business companies in
6 meeting that definition in terms of, you know,
7 dropping out of the marketplace or possibly the
8 reverse because of the GDUFA I legislation?

9 MR. COLE: I have -- several companies
10 have dropped out. When the products had to come
11 off the market because they needed -- required
12 approval, some of the old DESI products, many
13 companies that I know of went out of business
14 because they couldn't afford the fees to have
15 their products approved.

16 MS. CLARKE: I have a few follow-up
17 questions. One is do you have a sense of what the
18 percentage of the current generic drug
19 manufacturing industry members would fit this
20 definition? Because I think it might be actually
21 quite large if just the number of employees would
22 be used.

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1 MR. COLE: IT could be quite large. I
2 don't have a number.

3 MS. CLARKE: Okay. Have you ever
4 considered any other definitions for consideration
5 for defining small business, other than the number
6 of employees? I know -- I'm very familiar that
7 that's SBA's, but there could be other ways of
8 characterizing the business?

9 MR. COLE: Well, we understand under
10 PDUFA it's 20 million or less, I believe, in
11 annual revenues. We decided to go the small
12 business route because we felt like that was out
13 of the Small Business Administration guidelines,
14 and, for whatever reason, they chose to use
15 employees instead of revenues. So that's where
16 we're coming from.

17 MS. NGUYEN: Okay. Thank you. Other
18 questions?

19 MR. SHIMER: Yeah. Based on your
20 definition, do you have any idea or estimate of
21 the number of applications submitted on a yearly
22 basis that this would impact?

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1 MR. COLE: Well, what you would be
2 talking about is the number of applications that
3 are not submitted because of the cost, so --

4 MR. SHIMER: I'm saying if we were to
5 grant this on this definition, how many ANDAs on
6 an estimate on a yearly basis could potentially
7 qualify for this type of waiver?

8 MR. COLE: Okay. Sir, I can't -- I
9 can't answer that. I don't know.

10 MS. CLARKE: Thank you for your comments
11 and your proposal.

12 MR. COLE: Thank you.

13 DR. POLLI: Good afternoon. I'm pleased
14 to be with you here today. My name is Jim Polli.
15 I'm a faculty member at the University of
16 Maryland. And I'd just like to provide some
17 examples of FDA-supported research.

18 The five examples that I'll talk about
19 are lamotrigine bioequivalence in generic-brittle
20 patients; BCS Class III biowaivers, excipient
21 considerations; looking at some prescription data
22 with regard to switches and switchbacks; a cage

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1 model for in vivo release of long-acting release
2 microspheres; and development of USP 4 assay for
3 doxorubicin liposomes.

4 So these are just examples that I happen
5 to be familiar with. I can't say I've done any
6 analysis about the impact of all this type of
7 research. That's been supported by GDUFA.

8 Two generalizations I would like to
9 make, though. I think a lot of the researchers at
10 the -- at the academic institutions as well as
11 industry are making some really -- doing some
12 really great things. The other thing I'd like to
13 say is I think it's a very competitive process,
14 the way these grants are awarded, using the
15 grants.gov process.

16 Okay. With regard to this first topic
17 of bioequivalence of lamotrigine, this is work
18 that we've done at the University of Maryland,
19 and, as you may know, switching is a topic in the
20 epilepsy area that a lot of physicians and patient
21 groups do question. For example, here's an old --
22 it's been around for a while -- the position

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1 statement from the American Academy of Neurology.

2 AES also has a similar position statement.

3 And because of this, we were awarded an

4 FDA grant to look at bioequivalence in epilepsy

5 patients. So the question here is is

6 bioequivalence the same as generic -- is

7 bioequivalence the same in generic- brittle

8 patients who take the drug?

9 So, in particular, we were interested in

10 studying not only biology of this epilepsy

11 medication in epilepsy patients at home who are

12 taking the drug chronically, as opposed to -- as

13 opposed to single- dose studies, conventional

14 single-dose studies in healthy volunteers, but we

15 actually selected so-called generic brittle

16 patients. So it was really a bioequivalence

17 study, but, of course, we also looked at seizure

18 and adverse event-type information.

19 So here's a study design. It's a rather

20 unusual bioequivalence study design in that we're

21 using patients. They had to be taking the drug

22 already, because we wanted to sort of study the

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1 drug natively.

2 And what this is is -- it was also a
3 fully replicate design study. So, for example,
4 they received the brand on two occasions as well
5 as the generic on two occasions.

6 Okay. And here's the bioequivalence
7 results. I'd say these are very, very
8 bioequivalent. Those of you in the audience who
9 are very familiar with this, you'll see the
10 confidence intervals were very, very tight.

11 So it would seem as -- this would speak
12 very favorably in terms of the current FDA
13 standard in performing bioequivalence studies in
14 healthy volunteers, single dose. It translated
15 very well for epilepsy patients, real patients,
16 and, in fact, patients who have -- had some
17 problems in the past self-reporting in terms of
18 the issue of generics.

19 Here's just another example from this
20 particular study. This is Subject 026. Kind of
21 interesting. In red here, we see the number of
22 seizures this particular person had. They had

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1 focal motor seizures, so these are not
2 particularly very problematic seizures, but on the
3 brand, they had, actually, much fewer seizures
4 than on the generic arm. And this is very
5 interesting, given how similar their
6 pharmacokinetic profiles are.

7 And I guess the other thing I'd like to
8 add is, you know, the research that's going on is
9 actually inspiring other types of research that
10 are not necessarily supported at all by FDA. So
11 we're actually re-challenging this subject, just
12 to see what happens.

13 Here, this is very interesting that
14 there was a difference -- in this one subject, of
15 course, there's a case study in that regard --
16 there's a difference in terms of seizures, even
17 though there's, you know -- the pharmacokinetic
18 profiles are virtually identical, I think is fair
19 to say. Okay. So some conclusions from this
20 first study is, you know, that the current BE
21 standard seems to be working well when translated
22 in the patients.

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1 On the topic of BCS Class III
2 biowaivers, here's some data from a few years ago
3 with regard to frequency of approvals in terms of
4 BCS Class I, II, III, and there's very few for IV.
5 So Class III drugs are drugs that have high
6 solubility, but low permeability. And just
7 recently FDA updated its BCS guidance to allow
8 biowaivers for such immediate- release products
9 that are very rapidly dissolving.

10 And some research that was done, again,
11 at the University of Maryland, was to study how
12 much excipient can one have and have no effect on
13 the issue of bioequivalence of these so-called
14 Class III drugs?

15 So here's just my own personal
16 interpretations of the data to date. And we
17 studied the most -- 14 most common excipients in
18 immediate- release dosage forms of ANDAs.

19 And on the right side are the common
20 levels that one sees of these excipients in
21 immediate-release tablets and capsules. And then
22 in the middle is the amount that we studied. And,

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1 you know, there's a very -- we studied -- we
2 purposely studied very large amounts of common
3 excipients, and, for many of these excipients,
4 we're seeing -- we would conclude that they can be
5 used at very large quantities without impacting
6 drug absorption from so-called Class III drugs.

7 Some other folks at the University of
8 Maryland are also doing -- looking at Medicare
9 Part D data with regard to switches and
10 switchbacks and this sort of thing. Here, we're
11 trying to look at -- I forget what drug this is
12 looking at. I forget. I'm sorry.

13 But, anyway, just -- this is not my
14 particular area, but just to give you a notion
15 that because Medicaid Part D data is available,
16 efforts are underway to look at whether, you know
17 -- whether that data could be used as signals for
18 quality. Are there quality problems?

19 And, of course, one big issue right now
20 is actually developing methodologies to be able to
21 look at this sort of data and trying to develop
22 reliable measures for trying to use prescription-

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1 type data.

2 Okay. Another example here, this comes
3 from the University of Michigan, Steve
4 Schwendeman's lab. He's developing a so-called
5 cage model for in vivo mechanistic studies of
6 long-acting release products. So this looks at
7 micro-particles. There's a lot of drugs which are
8 complex drugs, and what the Schwendeman Lab is
9 looking at here, implanting a so-called cage on
10 the back of a mouse, and in the cage they put
11 these particles, and then they test to see how
12 fast the particles release the drug.

13 And, you know, it's quite amazing what's
14 really not well -- not well-known with regard to
15 some of these types of complex products. You can
16 see the cumulative release here for both in this
17 blue -- I think that's in vivo, and then the black
18 is in vitro. You see there's a big difference
19 between the laboratory studies to show how the
20 product is performing versus what's happening in
21 vivo.

22 So in some ways, some of the research

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1 that's going on is a little bit more basic than
2 others, just to develop methodologies that might
3 be able to predict performance of complex
4 formulations.

5 Along the same line, this is from Anna
6 Schwendeman from the University of Michigan.
7 She's developing a USP-4 release assay for
8 doxorubicin liposome, again, an example of a
9 complex product.

10 Here, we see an illustration of the drug
11 in a liposome formulation. And, again, it's an
12 example of a complex formulation where there --
13 it's -- there's really not a lot of great
14 understanding of putting tools in place, such as
15 release testing, to anticipate quality. Thank you
16 very much.

17 MS. CLARKE: Thank you for your
18 presentation. I doubt most of us are well-
19 equipped to ask you questions.

20 MALE SPEAKER: Okay.

21 MS. NGUYEN: Thank you to our
22 presenters. Next we'll move to the open comment

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1 period. We have one presenter for this time. And
2 I ask that you stay at the podium after your
3 remarks to give the panel an opportunity to ask
4 you questions.

5 DR. YAKATAN: Okay, fine.

6 MS. NGUYEN: I'm sorry. Just -- and
7 after the Q&A, Mary Beth Clarke will conclude the
8 meeting with her remarks. Thank you.

9 DR. YAKATAN: Good afternoon. My name's
10 Gerry Yakatan. I'm the Founder and CEO of IriSys,
11 spelled incorrectly up there, but that's because
12 they couldn't read my handwriting, I think.

13 We're a San Diego-based CDMO, and that's
14 contract development manufacturing organization.
15 A lot of our work -- and we're in a very
16 entrepreneurial area in San Diego, so a lot of our
17 work's involved with novel drug delivery, work
18 with Phase I, Phase II, helping companies get into
19 early-stage stuff.

20 But as we've been involved in CGMP
21 manufacturing of clinical trials materials, we've
22 wanted to increase our reach and increase our

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1 equipment and get into some commercial
2 manufacturing.

3 So I want to be that -- some of you guys
4 have asked about, you know, who's being affected
5 by this -- the GDUFA's fees and stuff like that?
6 I'm a living example of someone who is affected by
7 the situation. And I'm going to try to give you
8 just some practical experiences of what would
9 happen.

10 We're a contract manufacturing
11 organization. Somebody comes to us and says, you
12 know, "We'd" -- a small company. "We'd like to
13 have you manufacture a generic product for us."
14 And I'd say, "Fine. We're -- that's our business.
15 That's what we want to do. We want to -- we want
16 to expand our manufacturing, want to be in
17 commercial manufacturing. We'll be happy to do
18 one."

19 But the problem is that we're going to
20 have to pay \$250,000 fee, and we're -- and we'll
21 never have profit enough to make that up, even for
22 one year, probably, from a small generic product,

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1 because, again, we're into small-volume products.

2 We're a relatively small organization.

3 So that's exactly where you have all the
4 shortage problems. There's a reason there are
5 shortages of these things. They're small volumes
6 and pricing was lousy, so people got out of it.
7 So you end up with a shortage.

8 I see that as an opportunity and
9 something I'd like to get into, but who in their
10 right mind who's responsible for 45 or 50 people's
11 families earning a living would go into a business
12 where automatically you're going to lose money
13 with the first product that you get involved with?

14 You could not make a small generic
15 product and give up 250,000, even if it were just
16 one year, but what about that second year or third
17 year that you might have to sit out there before
18 the approval?

19 The other thing I've never understood,
20 and haven't been involved with generics for a long
21 time, and also with PDUFA, why the manufacturer is
22 bearing the major portion of this when the person

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1 making the money is the ANDA holder? That's the
2 person selling the product. That's the person
3 that's raising those prices.

4 So if you want to -- and I don't think
5 it's FDA's position to get involved in pricing of
6 pharmaceuticals, but the marketplace could take
7 care of that. But what the FDA shouldn't be doing
8 is suppressing competition by this I hope
9 inadvertent situation that came about because of
10 the GDUFA user fees.

11 So there are people like me who want to
12 get into generic manufacturing, and you guys are
13 going to be the only ones who could help with that
14 pricing issue, because it's obviously not in the
15 best interest of GPhA or, I don't know, PBOA, who
16 -- if you look at who's on those lists of their
17 members, they're large organizations. If
18 somebody's making a hundred generics in their
19 plant, then they're paying one-one hundredth of
20 the fee that has to be allocated to each product.

21 If I make one or two or even three, I've
22 got to divide that \$250,000 across that product.

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1 Why should somebody come to me to make a generic
2 when they could make it -- they don't have to bear
3 that cost of the user fee because it's divided --
4 in a company that makes a lot of them, it's
5 divided across the total number of generics that
6 they're making? It just makes no sense at all,
7 and that's something that needs to be changed in
8 the new -- in GDUFA II. Thanks.

9 MR. FLANAGAN: Did you fly all the way
10 out from San Diego?

11 DR. YAKATAN: Pardon me?

12 MR. FLANAGAN: You flew all the way out
13 from San Diego?

14 DR. YAKATAN: I flew all the way out
15 from San Diego, yes.

16 MR. FLANAGAN: Thank you. So, in your
17 experience, how -- what's kind of the floor for
18 how big a small company has to be -- I don't know
19 whether it's in terms of capitalization or number
20 of employees or investment, but how big must a
21 small company be to comply with GMPs and be a
22 manufacturer? Because, you know, you can't -- you

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1 can't be a guy in his garage. You have to have a
2 certain amount of scale.

3 DR. YAKATAN: Well, we, right now -- we
4 did GMP manufacturing for Phase I and Phase II
5 products even when we were only five or six
6 people. We're now 47 people in our company, and
7 we're quite capable -- we've had a number of FDA
8 inspections and stuff like that.

9 We're quite capable of following GMP.
10 We're not asking -- and I don't think other people
11 that are like us would ask for any waiver of
12 anything, of complying with GMP or anything like
13 that. We're not looking for that. We're just
14 looking for a chance to compete because I see some
15 of these generics out there, and, yes, some people
16 are raising prices. Hey, to me, that looks like a
17 real good opportunity.

18 And my margins, or the total dollar
19 number that I'd want to make out of things, are a
20 lot less. I'm not going to compete with a Lipitor
21 generic. I mean, the volumes are too large, and
22 there's a lot of people out there. But there are

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1 a lot of smaller products where the prices don't
2 have to rise so much if there are enough
3 competitors.

4 MS. CLARKE: Thank you for your
5 comments.

6 DR. YAKATAN: Thanks.

7 MS. CLARKE: I thought at first I had
8 the enviable position of getting to go last, but
9 following so many really good presentations and
10 such a rich presentation of information, I'm now
11 not feeling quite so good, except that since we're
12 ahead of schedule, I think this means we'll finish
13 early, so I think everybody will be happy about
14 that.

15 So I'm going to touch on just a few
16 themes. I'm not going to at all attempt to rebut
17 or repeat everything that we've heard today
18 because it was quite a lot of information, and if
19 I don't touch on your specific issue, please do
20 not take that as a sign that it was not important
21 or relevant for our discussion, because we
22 appreciate all of the comments and all of the

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1 participation from everyone who has spoken today.
2 And that's why we have so many people here taking
3 notes, and we'll have a transcript for you.

4 So, again, I do want to thank all of you
5 all, to all of our participants for today's
6 meeting, both speakers and those of you who have
7 been thoughtful listeners, which includes my
8 colleagues here at FDA.

9 We've had a robust day in which we've
10 heard from stakeholders, our public health
11 partners, those responsible for healthcare
12 delivery, both providers of care and those
13 administering large healthcare programs.

14 You've also heard from the partners of
15 the first Generic Drug User Fee Agreement, which
16 is a little past its halfway point; the industry
17 that approves the important generic drug products
18 for the American public; and the program officials
19 here at FDA.

20 It's a broad coalition, interested in
21 and benefiting from this program and its continued
22 growth, and that should not come as a great

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1 surprise to anyone.

2 Generic drugs really are the foundation
3 of drug therapy in the United States. They're not
4 just our oldest drugs. They're the most tried-
5 and-true drugs and the ones that touch the most
6 American lives. They're depended upon by both
7 healthcare providers and patients and handle a
8 majority or a large bulk of our healthcare needs.

9 So to some of the themes that we've
10 heard today, the imperatives that drove the first
11 Generic Drug User Fee Agreement in 2012, many of
12 which are still with us today -- also not a
13 surprise since it really hasn't been that far --
14 we have a complex and I think rapidly evolving
15 industry that has many partners, and we appreciate
16 greatly hearing from so many different parts of
17 the industry here today.

18 And they're located also across the
19 globe. This poses challenges for FDA in ensuring a
20 safe and high-quality and reliable supply of
21 products, and I think we heard quite a bit from
22 the provider community about the problem with drug

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1 shortages, and we take that under serious
2 advisement. It is an issue that receives a great
3 deal of attention here at the Agency and is one
4 that we understand, while not explicitly embedded
5 into GDUFA, it is certainly something that GDUFA
6 touches.

7 Some of the other imperatives that are
8 still with us is a large and growing number of
9 generic drug applications submitted to the Agency.
10 And we hope and find that these are for
11 increasingly more complex products because that's
12 where new drug development is, in fact, moving.

13 This poses scientific challenges for how
14 we ensure the equivalence and also, without the
15 funds of GDUFA, make review much more different.
16 So the advances in science that we hope to produce
17 under GDUFA will also be translated into faster
18 review.

19 The goals of GDUFA I, access, safety,
20 and transparency, are still with us today and are
21 the ones that we are -- we'll build out in the
22 remaining years of this program and are being

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1 realized in the modern regulatory program that's
2 well underway in how we're building it out here in
3 FDA. And I think you heard a lot about that this
4 morning.

5 A few things, though, that have changed
6 during the course of the time, just since we
7 launched the program, which really is the funding
8 model which is so vitally important and the whole
9 reason for this program and the generic drug
10 program here at FDA itself.

11 With the resources from this program,
12 we've been able to fund important infrastructure,
13 building what we hope is a more complete and
14 accurate inventory of the industry. I'm going to
15 say that now because I think our speakers raised
16 important considerations about definitional
17 changes that need to be considered.

18 And we're well on our way to developing
19 new processes and new systems for a modern program
20 that will affect not only review, but also our
21 inspections processes, a huge human capital
22 investment, which, for those of you all who are

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1 familiar with hiring in the federal workplace,
2 know that that is a considerable undertaking, not
3 only hiring a whole cadre of people who are here
4 to review applications, to do inspections, and to
5 build and support this program, but getting them
6 trained. Many of these employees only showed up
7 in 2014, still more in 2015, and they are still
8 undergoing that training process.

9 Also, the research projects -- and I
10 appreciate the highlight of that at the end of
11 today's comments, because the research program for
12 this -- for this user fee program was sort of
13 landmark. It is not part of the PDUFA program,
14 but, in fact, science, and not having the science
15 that we needed to expand the number of generic
16 drug products in different therapeutic categories
17 was seen as a specific weakness that GDUFA needed
18 to address.

19 So all of those things have been going
20 on here at the Agency since 2012 and even a little
21 bit before, I will tell you, as we began the
22 planning, hoping for the -- for the passage of

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1 this program and for its launch.

2 For those of you all who may not know or
3 may not remember, the legislation for this program
4 was passed on July 12th of 2012, and we went live
5 with this program on October 1 of 2012. That is a
6 very short time frame to get up a program and to
7 have the number of systems up and running just to
8 do the bare bones basics that had to be done on
9 day one of the program.

10 So where we stand now at this point from
11 FDA's standpoint is that we have met our
12 commitments to date for the program and we feel
13 that we're on track to meet the commitments of the
14 third year and towards the end of the first phase
15 of this program.

16 But you've also heard comments from
17 several people in industry, and I want you to know
18 that we have heard those, both today and even
19 before today. So some of the things that we've
20 heard are the impact on small business.

21 We've heard quite a bit about the fact
22 that there is no small business waiver, and I

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1 think most of you all know that there is really no
2 legal authority for us to have one under GDUFA I.

3 We hear those concerns, and I will also
4 add as a note that, as we asked questions of some
5 of you all, we were not indicating a lack of
6 willingness to consider that. If anything, some
7 of our pointed questions are because we too are
8 trying to ascertain some of the very specific
9 business intelligence data and have been doing so
10 for some time. So we hope that you will join us
11 in trying to complete that profile of the
12 industry.

13 Some of the other things that we heard
14 from industry is a -- fewer communications that
15 have happened. David Gaugh mentioned the fact
16 that he thought neither FDA nor the industry had
17 anticipated what has been perceived as
18 communication silence for the first two years in
19 the program.

20 FDA knew when they negotiated the first
21 agreement that the hiring and the training of new
22 staff as well as the building of all of the new

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1 programs was going to take considerable energy and
2 time during the first two years, and we too may
3 have thought -- forgotten a little bit about the
4 level of communication needed that is -- that was
5 needed by the industry.

6 We have taken steps now to address that,
7 and we believe that the industry will be pleased
8 over the next few months with the progress that is
9 made there.

10 We also pledge to strive, to the extent
11 possible, to maintain that pre-program
12 productivity. And I would like to say that that is
13 a considerable undertaking with the work -- with
14 the increased workload, which you've heard about.
15 But we don't want to make excuses because, at the
16 end of the day, we too serve the goal of trying to
17 have more generic drugs accessible to the public.
18 And so we continue to work on both the back -- the
19 official GDUFA backlog as well as the increased
20 workload that came in in Year 1 and Year 2.

21 So what to conclude, for those of you
22 all who have been sitting in the audience, you may

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1 feel that you're hearing a program -- a tale of
2 two different programs, the FDA saying that they
3 have succeeded and the industry saying that they
4 have concerns.

5 I think both stories have some validity,
6 and what I would like to say to you by way of
7 context is this. Here at FDA, we have over 20
8 years of experience in negotiating and
9 implementing user fee agreements and then the
10 programs that flow from them.

11 It is pretty much common wisdom and our
12 experience that the IIs are very challenging.
13 This is the point in time in which the big initial
14 investments must be made, programs begin to be
15 transformed, payers cannot see all the advantages
16 of what they are paying in, and it seems like the
17 new program and its benefits are but a dream.

18 There's also on both sides, when any
19 agreement is first negotiated, some assumptions
20 that are made that sometimes prove not to be true,
21 and there are also unforeseen consequences that
22 were not planned for.

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1 All of those things are customary in the
2 course of launching a new program, but are things
3 that we do take seriously, and we have, as Keith
4 mentioned earlier in the -- in the day -- we have
5 been keeping track of those, we have been trying
6 to make adjustments for those, and we will
7 continue to do so.

8 I think they inform an important part of
9 the dialogue, both for the success of the first
10 round of GDUFA and its program implementation, but
11 also lay the groundwork for what we hope to have
12 as a successful negotiation for GDUFA II, because
13 the program can only be successful if it really
14 serves the twin goals of both industry and FDA,
15 which I do believe at the heart, while you may
16 hear two different sides of the story, really are
17 the same. Both sides want very much to serve the
18 American public with a steady supply of high-
19 quality generic drugs.

20 And so I'm going to conclude with just a
21 few more things to say, which are mainly about
22 next steps for you.

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1 So the negotiations process themselves,
2 which is between FDA staff and the regulated
3 industry, is due to begin sometime in the fall.
4 That is not an entirely open process in terms of
5 watching the negotiation, probably not an
6 advisable thing. However, there is a great deal of
7 transparency in terms of the notes that are
8 produced.

9 However, for those of you all that are
10 not in the regulated industry, there's also a
11 process for interested stakeholders. And right
12 now there's a Federal Register Notice that is out
13 that outlines steps of how you can register to be
14 a part of that process. And we would welcome your
15 input.

16 So as a last thought, again, let me
17 thank you for your interest, your time, and your
18 thoughtful engagement, which we appreciate. On
19 behalf of both the FDA and the entire generics
20 drug program, please note that we've listened to
21 your comments. We'll consider what we've heard
22 today as we move forward with the program and with

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1 the negotiations for a new user fee agreement.

2 And we really do look forward to continued

3 dialogue with all of you on these issues. Thank

4 you.

5 (Whereupon, at 2:34 p.m., the meeting

6 was adjourned.)

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1 CERTIFICATE OF NOTARY PUBLIC

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

15

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MICHAEL FARKAS
Notary Public in and for
the State of Maryland

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2 I, MARY E. YOUNG, do hereby certify that this
3 transcript was prepared from audio to the best of
4 my ability.

5 I am neither counsel for, related to, nor
6 employed by any of the parties to this action, nor
7 financially or otherwise interested in the outcome
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9

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MARY E. YOUNG

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