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Part 15 Public Hearing 09-17-2014

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FOOD AND DRUG ADMINISTRATION (FDA)
OFFICE OF THE COMMISSIONER

GENERIC DRUG USER FEE AMENDMENTS OF 2012
PUBLIC HEARING ON POLICY DEVELOPMENT --
REQUEST FOR COMMENTS
PART 15 PUBLIC HEARING

Wednesday, September 17, 2014

College Park Marriott Hotel and Conference Center
3501 University Boulevard, East
Hyattsville, MD 20783

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1 P A R T I C I P A N T S
2 (Continued)

3 FDA Participants (Continued):

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11 Carole Ben-Maimon, MD
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13 Ken Cappel, RPh
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16 Amneal Pharmaceuticals

17 John Diloroto
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1 P A R T I C I P A N T S
2 (Continued)

3 Public Participants (Continued):

4 Leonard Lawrence
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5 Satish Pejaver
InnoPharma

6 Steven Pressman
7 Executive Vice President
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8 Gill Roth
9 Pharma and BioPharma Outsourcing Association

10 Rob Vincent
Teva Pharmaceuticals USA

11 Priscilla Zawislak
12 Global Regulatory Affairs Manager
International Pharmaceutical Excipients
13 Council (IPEC)

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

2 MR. FLANAGAN: So apologies. We don't
3 have a podium up here facing you, so I'm going to
4 stay seated as I make opening remarks. Apologies
5 for the discourtesy.

6 Good morning. Welcome. And thank you
7 very much for coming. The agenda says that I have
8 10 minutes of remarks, but I really don't. There
9 is only one thing I want to talk about.

10 My name is Keith Flanagan. I am the
11 Transition Lead for Policy in CDER's Office of
12 Generic Drugs. There is a lot we would like to
13 talk about, but the purpose of today's hearing is
14 for us to listen and to learn from you. We have
15 tried to be very conscientious and very meticulous
16 about GDUFA implementation, but FDA isn't always
17 100 percent perfect about everything all the time.
18 You have information, insights, and ideas that we
19 need to do the best job that we can.

20 GDUFA creates a once-in-a-program-
21 lifetime opportunity to build some policy
22 infrastructure, and we want to make sure that we

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1 do a great job, and we need your help to do that.

2 So with that in mind, again thanks for
3 investing the time in preparing remarks. Thanks
4 for coming all the way out here, and we earnestly
5 welcome your comments. Thank you.

6 MS. NGUYEN: Good morning, everyone. My
7 name is Martha Nguyen, and I am a Senior Policy
8 Advisor in the Office of Generic Drug Policy. I
9 am the presiding officer for the first panel
10 today, and I would like to welcome you to this
11 Part 15 hearing on policy development related to
12 GDUFA implementation.

13 Before we begin, I would like to go over
14 some logistics. First, please turn off any mobile
15 devices because they might interfere with the
16 audio in this room, but I am going to now give you
17 conflicting information because I am also going to
18 give you the Wi-Fi password for this hotel space,
19 but you can write that down and use it during the
20 breaks. The network is "Guest Net," and the user
21 name and password are both "FDA," and those are
22 case sensitive, so uppercase "FDA" for username

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1 and password.

2 Also, we ask that all attendees sign in
3 at the registration desk so that we can track the
4 number of attendees and follow up with you
5 afterwards if there is anything else we think
6 would be useful to share by e-mail.

7 The agenda includes two 15-minute breaks
8 and a 1-hour lunch break. We'll try to end the
9 hearing at 5:00, and if we finish before that,
10 we'll end before.

11 For any media present, the press officer
12 for today is Jordana O'Grady (ph). She is waving
13 her hand in the back there. She will be the
14 contact for any media in the room today.

15 So here are a few rules and procedures
16 to keep the hearing moving as efficiently as
17 possible. Each registered speaker will have 15
18 minutes to present. There are timekeeping lights
19 on the podium that will let you know when your 15
20 minutes are up, but please also be mindful of your
21 time allotment.

22 There is a little remote on the podium,

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1 and once the slides are on the screen, you will
2 advance your own slides by pressing the right
3 arrow.

4 After each presentation, the panel
5 members will have 10 minutes to ask questions
6 about the presentation.

7 No participant may interrupt the
8 presentation of any other participant, and only
9 FDA panel members may ask questions during or
10 after the presentation.

11 If a speaker's presentation takes less
12 than 15 minutes, we will move right into the
13 questions from the panel members and then on to
14 the next presentation.

15 If presentations from the registered
16 speakers wrap up ahead of schedule, we will allow
17 additional commenters to speak for up to 5 minutes
18 each in open comment sessions after the first and
19 second panels.

20 If you signed up to speak at the
21 registration desk this morning, please look for
22 your name on the list of commenters, which we will

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1 project onto the screen at the start of the open
2 comment sessions.

3 Please approach the microphone in the
4 order shown on the list. We will allow as many
5 commenters as time permits. And a recording of
6 this meeting will be transcribed, so please
7 remember to use the microphone when speaking. The
8 transcript will be accessible through
9 Regulations.gov and on FDA's GDUFA website in
10 about 30 days.

11 I think there was some miscommunication
12 about whether this hearing would be webcast, and
13 it's my understanding that FDA is not webcasting
14 the hearing today.

15 So, as Keith mentioned, the purpose of
16 today's public hearing is to seek input on GDUFA
17 implementation from a broad range of stakeholders.

18 In the first panel, we are seeking
19 comments on the five draft guidance documents that
20 we have issued to date to facilitate
21 implementation of GDUFA. We would especially like
22 to hear if there are GDUFA implementation issues

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1 related to the draft guidances that have not been
2 addressed; if there are other GDUFA implementation
3 topics that need development of guidance; and,
4 finally, if there are any generic drug development
5 issues unrelated to GDUFA implementation that need
6 the development of guidance. We will consider all
7 information from this public hearing, including
8 the public docket, when developing our future
9 policy priorities. So any comments that aren't
10 presented today can be submitted through
11 Regulations.gov using the docket number for this
12 hearing, which is FDA-2014-N-1168.

13 We have two distinguished panels of FDA
14 experts to listen to the presentations today.

15 Kathleen (Cook) Uhl, Acting Director of
16 the Office of Generic Drugs, will preside over the
17 second panel, and we'll ask her to introduce
18 herself when she arrives, but before the first
19 panel members introduce themselves, I want to
20 thank them, our presenters, and all of you in the
21 audience for participating in this hearing today.
22 We value your input, are grateful for your active

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1 engagement, and look forward to a very productive
2 rest of the day.

3 Thank you.

4 Keith? Just introduce yourself.

5 MR. FLANAGAN: Again, I'm Keith
6 Flanagan. I'm the Transition Lead for Policy in
7 CDER's Office of Generic Drugs.

8 MS. KIM: I'm Nam Kim. I'm the Director
9 of the Division of Regulatory Policy III in the
10 Office of Regulatory Policy in CDER.

11 MR. YOUNG: I'm Johnny Young. I am the
12 Acting Division Director for the Division of
13 Filing Review in the Operations Office.

14 MS. GIAQUINTO: And I'm Elizabeth
15 Giaquinto. I'm a Regulatory Counsel in the Office
16 of Generic Drug Policy, Division of Policy
17 Development.

18 MS. NGUYEN: So we'll now have our first
19 presenter.

20 Priscilla?

21 MS. ZAWISLAK: Thank you, and thanks to
22 FDA for allowing us to speak today. I'm here on

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1 behalf of the International Pharmaceutical
2 Excipients Council, IPEC-Americas.

3 And the scope of what we would like to
4 comment on today are some critical issues related
5 to two of the draft guidances where active
6 ingredients are included. One of them is the ANDA
7 submissions refuse to receive standards, and the
8 other is on the content and format of the ANDAs.

9 With respect to just general comments,
10 there is confusion in the industry on FDA's policy
11 on inactive ingredients, which needs to be
12 clarified and communicated consistently in
13 publications and guidance documents. The draft
14 guidances that we've seen do not reflect
15 historical practices both in industry and FDA in
16 reviewing inactive ingredients, and the failure to
17 clarify inactive ingredient issues prior to
18 finalizing guidance documents is going to impact
19 the GDUFA primary tenets of predictability and
20 timeliness in the review process.

21 Further, FDA's increased emphasis on
22 using the controlled correspondence prior to

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1 filing is resulting in increased delays in filing,
2 and in the generics pharmaceutical industry
3 they're not able to make high quality submissions
4 and reduce the number of review cycles unless
5 these inactive ingredient issues are adequately
6 addressed.

7 With respect to the Refuse-to-receive
8 Standards draft guidance, one of the biggest
9 concerns that IPEC has had is on the acceptance of
10 the family approach, and by that, we mean that
11 materials that are compositionally similar and
12 expected to have some toxicity, the same toxicity,
13 profile, are considered excipient families. For
14 example, they might differ in physical attributes,
15 such as viscosity, but they are the same chemical
16 entity, so the tox profile is similar.

17 Further, toxicology studies are
18 typically conducted on representative material
19 based on similarity across an entire family, not
20 every grade within the family. There may be 10,
21 20, 50 grades within a product family, and these
22 all have the same tox profile. This approach has

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1 been used for decades in the food and chemical
2 industry. FDA CFSAN has typically used this
3 approach for food additives, and the excipients
4 are generally made in many cases in the same
5 plants, the same process, as food additives. FDA
6 CDER and OGD has also used this approach in the
7 past until about 2011. So it's unclear to IPEC
8 why OGD now thinks that this approach is not
9 acceptable because this approach has been used for
10 a very long time.

11 Also, with respect to the acceptance of
12 the family approach, most of the inactive
13 ingredients that are in drugs today have been
14 safely used for over 50 years in a variety of
15 uses, not just in pharmaceuticals but also as food
16 additives and cosmetic ingredients. The
17 expectation that data will be generated on each
18 grade of the excipient is just not realistic. A
19 lot of the data has been generated over the years,
20 and to do new studies would be a major issue for a
21 lot of companies.

22 There is also no evidence that using the

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1 family approach creates any significant patient
2 safety risk. This also contradicts the IPEC-
3 Americas work with FDA's OGD excipients working
4 group on justifying the level of inactive
5 ingredients by citing the level for a related
6 excipient within the same family.

7 And then, finally, on the content format
8 of the ANDA's draft guidance, this guidance refers
9 to information included in the RTR to ensure
10 submission of high quality ANDAs, but there are
11 many issues in the RTR that should be clarified
12 and resolved in regard to the inactive
13 ingredients. This guidance also reiterates that
14 information in the RTR should be followed without
15 addressing the significant issues raised by IPEC
16 and others. So due to our concerns over the
17 comments previously provided which have not been
18 acted on, IPEC-Americas will also be submitting
19 more further detailed comments in writing after
20 the hearing.

21 Thank you.

22 MS. NGUYEN: Thank you.

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1 Questions from the panel?

2 MR. FLANAGAN: So I understand policy
3 concerns you raised concerning IID issues?

4 MS. ZAWISLAK: Mm-hmm.

5 MR. FLANAGAN: What has the experience
6 of your members been with respect to the inactive
7 ingredients database, and how could the
8 functionality of that be improved to be more
9 useful to you?

10 MS. ZAWISLAK: We've had an IPEC FDA OGD
11 working group now for a couple of years, and we
12 had provided some background information on some
13 of the issues that caused our industry. I
14 think we've made a lot of good progress. We have
15 a draft question and answer document that is now
16 going through I believe the Office of Policy to be
17 issued that will address some of the more basic
18 questions with a Phase II document, hopefully to
19 follow that. But especially since the RTR draft
20 guidance was published last year for comment, the
21 number of issues that we, as excipient
22 seller/manufacturers, are getting from our

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1 customers who are filing ANDAs has increased
2 exponentially because there is so much confusion
3 and the conflicting information that we're getting
4 with regards to policy has been a lot of questions
5 around that, and even some of the things that our
6 working group has tentatively agreed on as to what
7 we can communicate to industry, we're still now
8 getting a lot of questions particularly after
9 yesterday's publication, the final guidance, and
10 we anticipate even more. So the policy issues
11 have been a major impact on our organization.

12 MS. NGUYEN: Other questions from the
13 panel?

14 (No audible response.)

15 MS. NGUYEN: Thank you.

16 Up next we have Steven Pressman.

17 MR. PRESSMAN: Thank you very much for
18 having me here today. I appreciate the
19 opportunity to speak. The area that I want to
20 address today are the GDUFA fees, facility fees,
21 associated with small business where the areas of
22 certain businesses, I don't know that it was

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1 considered in a detailed matter of the impact that
2 the fees have on small business. As far as the
3 dollar volumes that these business do, the amount
4 of ANDA business or generic drug business that
5 these companies do, and in the area of companies
6 that are just getting into the business and don't
7 have any products on the market at such time, and
8 without any negative references, but really at the
9 mercy of whenever they get approval, they're just
10 going to keep paying these annual fees.

11 So again in my discussions that I've had
12 with the FDA over the past year or year and a half
13 or so in regards to these fees were that there was
14 representation from the industry when they came up
15 with the guidance or when the guidance was thought
16 of and created and that it has been put into law
17 and therefore it cannot be changed. However, we
18 just were notified in the past couple of weeks
19 that the fees are now being increased. So it's
20 quite surprising that the fees can be increased
21 without any impact on the law, but there is no way
22 to decrease them or to look at them to see about

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1 reduction or reasserting how they need to be
2 assessed against the different businesses.

3 Now, these fees may be a minor impact to
4 some of the multibillion dollar businesses out
5 there, but to a small business that's, let's say,
6 under the \$100 million range, it's a big impact,
7 especially on some of these drugs we're waiting 2
8 to 3 years to get approvals. The dollars, the
9 annual fees, add up when there are no other drugs
10 in the marketplace that are currently being
11 marketed.

12 And what this is doing, based on my
13 discussions with other companies in the industry,
14 it's discouraging competition and creating a
15 barrier to entry, which I know the FDA is not
16 looking to create a barrier to entry, but this is
17 the impact that it's having. Perhaps one way to
18 look at it would be if a company is under a
19 certain threshold in generic drug volume out
20 there, maybe the fees don't kick in until they hit
21 a certain number of annual revenue.

22 So what's happening now are the major

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1 companies just keep gaining market share and
2 eliminating any competition from coming in, and
3 it's increasing prices in the market place to the
4 American public.

5 Also the issue of drug shortage comes
6 into play with this type of situation, and again,
7 as I said, drug price inflation.

8 So we now have 2 years of data on hand
9 to see how the fees have been applied and the
10 impact it's had on the Agency.

11 Sorry. I was thinking someone else was
12 doing this, that's my mistake. So we can go back.

13 So, again, so as I said, the fees have
14 been increased since their implementation. The
15 impact to these larger companies out there is
16 minor or no impact at all. And no offense to
17 anyone in this room, but if I was a multibillion
18 dollar company, I might want the fees to be \$10
19 million a year so I will never have any
20 competition coming against me.

21 And, again, as said, discouraging
22 competition due to barrier of entry, creating an

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1 oligopoly, innovation is being hampered,
2 elimination of consumer generic drug choices,
3 there are drug shortages, and the inflation of
4 drug prices because the competition is being
5 eliminated, and I know that that was not the
6 purpose of implementing these fees, it was to get
7 things through the process more quickly.

8 So the fees need to be looked at in more
9 detail now that we have 2 years of data on hand.
10 Company size should be a consideration. There are
11 many other government agencies that use the size
12 or dollar revenue of businesses to determine how
13 the fees are going to be collected and how they
14 are going to be utilized, and that will create a
15 level playing field in the marketplace, and again,
16 the ultimate recipient of this is going to be the
17 American consumers who are paying for the drugs.

18 So, again, financial strength needs to
19 be taken into consideration, and that seems to be
20 the main theme here, and again what also needs to
21 be looked at is, does a company have any ANDAs
22 that have been approved with drugs in the market?

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1 Because there is a big difference if it's going to
2 take 3 years to get a drug approved and you're
3 going to pay \$750,000 in GDUFA fees, which may not
4 have been even considered before the drug
5 development process started versus just paying on
6 an annual basis going forward.

7 And again the area that we referenced in
8 the Federal Register.

9 Any questions?

10 MR. FLANAGAN: Yes. Thank you very
11 much. The last slide proposes that if there were
12 changes made in this space, that the financial
13 strength of the company should be taken into
14 consideration. Did you have any thoughts
15 regarding how to do that? Would small companies
16 self-certify as to their financial strength?

17 MR. PRESSMAN: Well, if, for an example
18 -- and I'll just throw out round numbers for
19 easiness sake -- let's say a company is only doing
20 -- has no approvals per se. I don't think there
21 should be any facility fee until they receive an
22 approval because we're at the mercy, for lack of a

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1 better term, of the FDA of whenever the FDA gives
2 the approval, if they ever give the approval. So
3 what is the purpose of paying an annual facility
4 fee if we're not producing any drugs out of that
5 facility and selling them to the public?

6 And as far as again any thoughts on how
7 to certify, we all file tax returns. That's
8 probably the simplest way of looking at it. There
9 has to be some honor and integrity in the business
10 world, and if, let's say, are you doing more than
11 \$10 million a year in generic drug business? No?
12 Okay, maybe that needs to be the number. If
13 you're doing less than \$10 million, maybe you
14 don't pay a facility fee, maybe you only pay one-
15 tenth of a facility fee. Perhaps if you're doing
16 a billion dollars of business and this could
17 result in more income for the GDUFA program versus
18 less income, if there was a sliding scale, maybe a
19 company doing a billion dollars a year in generic
20 drug business needs to be paying \$2 million a year
21 in fees versus only \$250,000 in fees.

22 So it needs to be sat down obviously and

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1 the discussion needs to take place in a more
2 detailed manner than just in a 15-minute
3 conversation, but I've gone and met with
4 Congressman Waxman about this. He was actually
5 shocked when I explained these things to him. I
6 said, did anyone even think for one second to take
7 into consideration how this is going to impact
8 small business and again ultimately the American
9 public that all you're doing is pushing out
10 companies, you're not encouraging competition,
11 you're stifling it? And he immediately said
12 you're 100 percent right. It's now been into law,
13 we don't know how to change it, but again if the
14 fees are able to be changed upward, I know the
15 fees can be changed downward.

16 So, again, I'm open to come out and meet
17 with anybody at the FDA and have discussions. We
18 just got a letter recently where -- and this was
19 an argument that I had, we had ANDAs on file at
20 our company before the fees were put into place,
21 and we were told, oh, you're stopped right now.
22 The process is stopped for you at the FDA until

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1 you pay these fees. We said, well, they didn't
2 exist before we made our submissions. We just got
3 a letter now that we paid the fees, the clock was
4 now rolled back for us to when we originally did
5 the submissions, which is how it should have been.
6 In other words, we should not have been told, "Oh,
7 you haven't paid your fees." Well, the fees didn't
8 exist when we submitted. I see a puzzled look on
9 your face, so that's why I'm explaining. The fees
10 weren't in place when we made the submissions, so
11 why would we be now delayed a year when it was a
12 policy that didn't exist before? And it's not a
13 crime, but my analogy was, well, you can't be
14 convicted of a crime that wasn't a crime when you
15 did it and now you made it a law and, oh, by the
16 way, you did this a year ago.

17 MR. FLANAGAN: Thank you. Thanks for
18 clarifying it. Thanks for traveling all the way
19 out here.

20 MR. PRESSMAN: My pleasure. Thank you.

21 MS. NGUYEN: Up next we have David
22 Gaugh.

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1 MR. GAUGH: Thank you. And thanks to
2 the FDA and the panel for holding this open public
3 hearing. We greatly appreciate it, and this is a
4 very important topic for the generic drug
5 industry.

6 So let me just give a little bit of
7 background. So GPhA represents the manufacturers
8 and distributors of generic pharmaceutical
9 products; manufacturers and distributors of the
10 bulk active chemical industry; and suppliers of
11 other goods and services for the industry. Our
12 manufacturers produce 90 percent of all
13 pharmaceuticals dispensed in the United States,
14 and their products are used in more than 3 billion
15 prescriptions every year. And the generic
16 products represent greater than -- and this slide
17 says 84 percent, but we just have some new data
18 out that that number has now jumped up to 86
19 percent of all prescriptions dispensed in the
20 United States.

21 I show this slide just to show a
22 representation of who we are and how much we

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1 affect from a different company's standpoint. And
2 GPhA has two different member organizations or
3 categories I should say, not different
4 organizations. One is a member, full member,
5 which is this representation. These are 29 of
6 these member companies. We also have 42 associate
7 member companies that we represent. So upwards of
8 70 companies.

9 And I would also like to point out that
10 this is an important enough issue to us today that
11 we have 21 of those companies here in
12 representation and 52 members of those companies.
13 So very important topics for us and you'll have
14 several later today at the open mic session
15 providing some input and some clarity to some of
16 this information that you provided us.

17 So first off, I do want you to know that
18 GPhA and its member companies are very committed
19 to GDUFA. We were at the table when GDUFA was
20 negotiated, and, no, not everything got negotiated
21 perfectly necessarily in GDUFA1, but there will be
22 a GDUFA2 we would anticipate, and so we'll have

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1 some clarity from some of the speakers we hear
2 today and that we've heard at other times on what
3 we can do to get to GDUFA2, but it is very
4 important to us. It helps speed the process and
5 enhancement of the approvals, and so we must equip
6 the FDA to be able to do that. We know that and
7 that's why the industry stepped up to \$300 million
8 a year roughly, or 1.5 billion over the course of
9 the 5 years to provide those resources for the FDA
10 to be able to do the things that they need to do
11 to get to our ANDA and ANDA approvals in a more
12 efficient and timely manner. But with that said,
13 we do need to be working together to ensure that
14 the millions of Americans and patients around the
15 world continue to receive the timely access to
16 safe, effective, and affordable drugs.

17 And I would like to point out just as a
18 reminder that GDUFA has three key public health
19 aims:

20 safety, access, and transparency. So I
21 think those are words that we all know very well,
22 but I don't want us to forget that those are three

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1 very important tenets of GDUFA.

2 And as I go through some of these
3 slides, they are going to be pretty high level
4 slides, and the reason for that is that we're
5 going to be providing much more granular detail as
6 we get to comments into the open docket over the
7 next several weeks, so we're pulling those
8 together with our member companies.

9 As part of this slide deck -- and I'm
10 not going to go through all of it because I only
11 have 15 minutes, but it is a 25-slide deck, and
12 there is some significant detail in what we're
13 calling the appendix to the deck, so I'll refer to
14 that a little bit. I'm not going to go through it
15 now, but I do put that out for you to be able to
16 reference as you go through this meeting and then
17 also as you go through the open comments period in
18 the coming days and weeks as you go through that
19 process.

20 So the five guidances that you asked
21 that we address and then any other guidance, I
22 want to go through those rather quickly if we can

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1 right now and address them.

2 So the first one is the ANDA submission
3 content and format. And some points we wanted to
4 bring to light is while each application is
5 responsible for the best possible submission,
6 there have been several historic barriers to fully
7 address all explanations, especially for more
8 complex products.

9 So as we move forward, and I know the
10 FDA and OGD and the Policy Department within OGD
11 are working rapidly to get policies in place to be
12 able to address all this, we want to make sure
13 that we're looking broadly across all activities
14 and all areas from the ANDA submission standpoint.

15 Interactions and advice from FDA
16 regarding specific ANDA issues typically have been
17 too limited. Lack of pre-ANDA consultations, for
18 example. Limited transparency has reduced
19 predictability of applicants, and in many cases it
20 is a one-way communication process we think that
21 needs to be changed to definitely be a two-way
22 communication process.

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1 Inconsistencies among reviewers is
2 another issue that we identify, so having a robust
3 and a quality submission we absolutely agree and
4 support. We also have to have robust processes on
5 the FDA end where there is consistency among
6 reviewers that are reviewing these robust quality
7 submissions.

8 Retrospective applications of new
9 criteria that have come into place since the date
10 of the original submission, in some cases years
11 afterwards, are taken into consideration while the
12 ANDA has been sitting at the FDA for a number of
13 months and even years before it's actually picked
14 up, and so that needs to be taken into
15 consideration as well.

16 Since the implementation of GDUFA, all
17 informal contact between reviewers and applicants
18 has ceased and has not been replaced with any
19 meaningful alternative, results in major reduction
20 in transparency, and so we would ask the FDA to
21 review comments that we have provided before that
22 was on August 11th for the content and format.

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1 There is significant information in there that
2 addresses many of the points and beyond of what
3 I've just addressed.

4 And, finally, we would recommend that
5 the Agency and GPhA collaborate to develop a
6 guidance to address common quality issues related
7 to submissions and reviewer consistency.

8 Next is controlled correspondence
9 related to the generic drug development. GPhA has
10 significant concerns regarding certain aspects of
11 this draft guidance. To meet our shared aims of
12 reducing the review cycles, FDA should encourage
13 early engagement and feedback in advance of
14 submissions in order to minimize FDA review
15 timeframes and expedite patient access to
16 generics.

17 What is the Agency's plan for reviewing
18 and providing a response to controlled
19 correspondence pending an Agency's response prior
20 to Fiscal Year 2015?

21 Next is ANDA submissions, amendments,
22 and easily correctable deficiencies. GPhA

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1 believes a significant portion of the issues
2 identified during the technical reviews can be
3 classified as Easily Correctable Deficiencies, or
4 ECDs, and communicated to applicants during the
5 review process. Industry is able to respond to
6 ECDs in a very short timeframe, on average 5
7 working days, upon receipt of the ECD, which can
8 facilitate the review process and enhance
9 efficiencies for both the Agency and for industry.

10 In the spirit of the goals letter, we
11 request more opportunity to resolve questions via
12 phone and mail, which is a more efficient process
13 for both the Agency and industry resources to
14 ensure timely transparency access to medications.
15 And again I would point the FDA and the panel to
16 the comments that GPhA provided on September 9th
17 regarding this draft guidance.

18 Next is prior approval supplements under
19 GDUFA. The draft guidance helps outline the
20 Agency's implementation of GDUFA allowing greater
21 predictability for industry and more timely review
22 of supplements, clarification requested on changes

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1 in GDUFA metrics when additions to amendments on
2 PASs is requested, and providing valuable
3 clarification on GMP inspection cycles, and risk-
4 based approach. And again we ask that you refer
5 to the GPhA full comments that were provided on
6 September 9th of this year.

7 And then the fifth guidance that was
8 provided in the docket to be addressed in this
9 meeting we're not able to address at this point in
10 time because that draft guidance just came out
11 yesterday, so we're in the process of reading and
12 reviewing rapidly, but we'll save that comment for
13 our follow-up comments to the docket.

14 Some additional comments to guidance
15 that we would like to make in addition to the five
16 that were there, and one has already been
17 addressed, but we would like to address it again
18 because it's very important to the entire
19 industry. The Inactive Ingredient Database, or
20 IID, is an important area of need for us. The IID
21 is a critical tool for the generic industry at
22 large. The IID supports ANDAs and should be

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1 complete, accurate, and transparent. The industry
2 should have access to the MDI for all routes of
3 administration. And again we ask that you refer
4 to the GPhA member comments that were provided
5 during the regulatory priorities open session that
6 was in the May timeframe. And as a final note, we
7 believe that providing further investment by the
8 Agency to the IIDs should greatly reduce the
9 number of control correspondences that you are
10 getting currently and are somewhat being addressed
11 in the new draft guidance.

12 Other additional policies. As stated in
13 my opening comments, access is key to public
14 health and an aim of GDUFA. Therefore
15 communications and communications with applicants
16 is important and should be provided, and
17 priorities based on public health needs, target
18 action dates, which have been introduced, and
19 other related actions for ANDAs are not included
20 in the cohort metrics, and we think that they
21 should be.

22 A realistic plan based upon dedicated

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1 resources to address the enormous backlog of ANDAs
2 and prior approval supplements should be reviewed
3 and addressed.

4 Continued meaningful interactions with
5 industry while planning new guidances before
6 enforcing those draft guidances would be greatly
7 appreciated, and we think that would help both the
8 Agency and the industry as we move forward.

9 Pre-ANDA consultation meetings and
10 communications we believe is an important and a
11 key component to moving forward with GDUFA.

12 Central repository or bulletin board
13 announcements to industry to post-current thinking
14 on ANDA data requirements, webinars, et cetera, so
15 that there are no surprises on either side would
16 be greatly appreciated.

17 Provide specific timeframes, for
18 example, 60 days or similar, of controlled
19 correspondence to answer suitability petitions.
20 And more details, as I said before, will be
21 provided in the open docket in the periods coming
22 up in the next few weeks.

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1 And then what other GDUFA implementation
2 topics are needed for the guidance. Guidance
3 clarifying QBD, QOS, requirements and expectations
4 we think is an important guidance to review and
5 consider. Industry needs a consistent approach of
6 predictability.

7 To date, guidance documents have focused
8 on processes rather than on what is quality for an
9 ANDA submission for an agency. So as we've talked
10 at different meetings and different time points,
11 we talk about quality submissions, and we
12 absolutely support that premise, but we want to
13 know what is out there to help us define what is a
14 quality submission, we don't think it's there. So
15 again -- and I've said this before, but I think
16 it's worth repeating, GPhA would like to recommend
17 that the FDA collaborate with the industry to
18 develop a guidance to address common quality
19 issues on ANDA submissions.

20 Thank you.

21 MS. NGUYEN: Thank you.

22 (Beginning to clap.)

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1 MS. NGUYEN: Questions from the panel?

2 MR. FLANAGAN: Someone started to clap.

3 (Laughter.)

4 MR. GAUGH: Just flies, I think they
5 were trying to --

6 (Laughter.)

7 MR. FLANAGAN: So, Mr. Gaugh, thanks for
8 all the detail, it's very helpful. Lots of
9 potential areas of improvement you identified.

10 MR. GAUGH: Yes.

11 MR. FLANAGAN: When we're thinking
12 through what the most urgent priorities should be
13 and the next tranche of policy improvements that
14 we make, how important is communications
15 transparency? And I have a follow-up question.

16 MR. GAUGH: That would be number one.

17 MR. FLANAGAN: So some of the things
18 that we've contemplated doing to improve
19 communications transparency, sort of a transition
20 management tool as we get into goal dates, are
21 target action dates for pre-Year 3 submissions
22 when we pick one up for review, assigning a target

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1 action date, and notifying the applicant with
2 caveats of when we hope to take action on that
3 submission so that folks know when something is
4 under review.

5 In the ECD space, having more real time
6 communications potentially working on pre-CR
7 majors, and for the most commercially significant
8 and most important from a public health
9 perspective, first generics, which we'll discuss
10 in much greater detail this afternoon, possibly
11 offering some sort of -- providing some sort of
12 mid-review status update, would all those things
13 be helpful or any of them not a good idea?

14 MR. GAUGH: So I would answer with a
15 caveat. Absolutely all of those would be helpful,
16 and we do applaud that the FDA is moving in that
17 direction, and there has been a lot of
18 conversation back and forth over many months
19 between GPhA and the FDA about getting to some of
20 these points, and so we greatly appreciate that.

21 I think the thing that concerns us and
22 my colleague who was up here just before talking

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1 about inspections and fees, that's completely
2 understandable where he's coming from, but
3 additionally to that and on the finish-fill dosage
4 side, our companies -- and I hate to say it quite
5 this way, but I'm going to, live and die by when
6 they are going to get their ANDAs approved, and
7 the decisions that they have to make to prepare
8 for that, and that preparation is a bit of a
9 runway. So you can't get approval today and
10 launch tomorrow if you don't know that today is
11 your approval date. So there needs to be some
12 further clarity, and you're providing some of that
13 through what you discussed but with a backlog of
14 over 3,000, probably pushing more towards 3,200,
15 3,300, that's a significant number of products
16 that are very important to the industry as well as
17 to the American public and the health care system.
18 And I know you have a priority review process in
19 mind. We just know that there are products that
20 are going to fall at the bottom end of that
21 priority, and those companies still need clarity
22 on where they are and what they can plan for the

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1 future. So we want to make sure that you're
2 thinking about that and taking that into
3 consideration.

4 Thank you.

5 MR. FLANAGAN: Thank you.

6 MS. NGUYEN: I have a question.

7 MR. GAUGH: Yes.

8 MS. NGUYEN: How much time do you need
9 to prepare for product launch?

10 MR. GAUGH: So that's a great
11 question and kind of a what if, I guess, but in
12 the realm of 4 to 6 months at a minimum, and
13 sometimes it's a full year. So depending upon the
14 product that we're talking about, some products
15 have API, for example, sources if there is only
16 one source for that API, and that API is very
17 expensive, for example, so it's not something
18 that's, quote, held in inventory by either the
19 finished dose company or by the API manufacturer.
20 So giving them some lead time to produce their
21 API, getting that API into the finished dosage
22 manufacturing process, getting into the

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1 manufacturing process, all takes considerable
2 time. So I would say expedited in best case
3 scenario, everything sitting in inventory,
4 probably 4 months, but it could take upwards of 12
5 or longer months depending upon the circumstances.

6 MS. NGUYEN: So in the case where you
7 need a year to prepare for launch, and we provide
8 you with a target action date of 4 months, that's
9 not enough time.

10 MR. GAUGH: No, but it's clarity --

11 MS. NGUYEN: It's better than nothing.

12 MR. GAUGH: It's better than nothing,
13 yes. And it's clarity that we have. And again
14 we're making business decisions off of what we
15 know. It's very hard to make business decisions
16 off of what we don't know. So that's why we're
17 looking for any type of information and a target
18 action date of only 4 months, no, is not enough
19 time, but some of the information that we provided
20 for consideration for options for other
21 communication time points would add to that
22 timeframe.

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1 MS. NGUYEN: And this vein of
2 discussion, this is more focused on backlog and
3 your one year to application since as we enter
4 Year 3, you will have the clarity that you seek.

5 MR. GAUGH: Absolutely. That's in the
6 metrics, yes. So this is absolutely backlog Year
7 1, Year 2, that we're talking about specifically.

8 MR. FLANAGAN: So actually I have a
9 follow- up question which it may be hard for you
10 to generalize. There may not be a tidy answer.
11 But given the volume of the submissions -- right?
12 -- and our obligation to move the freight along,
13 it's probably not feasible in the immediate short
14 term for each RPM to consult in depth with each
15 applicant concerning the status of each
16 submission, and like discern the best regulatory
17 path forward. It's very resource intensive and
18 requires a lot of experience and sophistication.
19 Right? Are there individual data points that are
20 more helpful than others when your member
21 companies are trying to do the calculus on whether
22 to launch a product? For example, anecdotally

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1 we've heard from a lot of people that if the
2 submission is doing well in chemistry, that they
3 feel like that's disproportionately important, and
4 I know it's hard to generalize, but to the extent
5 that you can, could you please?

6 MR. GAUGH: Yes. And so you're right,
7 it is hard to generalize, and I think probably the
8 best option is to say that we have provided some
9 comments to the FDA on communications and on
10 various different example time points that could
11 be used, and we'll add those comments to this
12 docket as well, and we would refer you back to
13 those.

14 MR. FLANAGAN: Very well. Thank you.

15 MR. GAUGH: Thank you.

16 MS. NGUYEN: Thank you.

17 It looks like next we have a 15-minute
18 break. So I have let's reconvene at 10:05. I
19 have 9:49. And as a reminder, the Wi-Fi network
20 is "Guest Net," and the user name and password are
21 "FDA," all caps.

22 (Break.)

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1 MS. NGUYEN: I think we're going to get
2 started in a minute, so if you could please find
3 your seats.

4 Okay, thanks, everyone. During the
5 break, the Acting Director of the Office of
6 Generic Drugs arrived, Cook Uhl. Could you please
7 introduce yourself?

8 DR. UHL: Am I on?

9 MS. NGUYEN: Yep.

10 DR. UHL: There's no color here to tell
11 me I'm on or not.

12 MS. NGUYEN: You're always on.

13 DR. UHL: All right. Good morning.
14 Kathleen Uhl, Acting Director of OGD. Thank you.

15 MS. NGUYEN: Thank you. So we'll just
16 go right into the next set of presentations. Up
17 next is Robert Vincent. Please when you start
18 your presentation state your name and your
19 affiliation.

20 MR. FLANAGAN: Is Marcie next?

21 MS. NGUYEN: Marcie is not going in the
22 morning.

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1 MR. VINCENT: Okay. Good morning.

2 Thank you. I'm Rob Vincent, with Teva

3 Pharmaceuticals USA. And I thank you for the

4 opportunity to speak this morning and provide

5 comments with regard to the GDUFA implementations.

6 The first thing I thought was important

7 was we should note that there certainly have been

8 already some benefits seen from the movement taken

9 toward GDUFA for the industry. First off, the

10 implementation of the complete response letter or

11 concept has certainly been an improvement. It

12 gives industry a concept of where each of the

13 disciplines is at with regard to their review, how

14 significant the issues may be within each of the

15 disciplines as opposed to getting discipline-

16 specific letters. The chemistry could be further

17 along in biopharmaceutics or compliance or another

18 area further behind depending on the given file,

19 so this gives us a better picture of the overall

20 application review.

21 The issuance of the multiple guidances

22 that have come out regarding providing greater

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1 clarity on what the Agency expectation is for the
2 original ANDAs and prior approval supplements
3 certainly is a benefit. Any guidance is better
4 than being left to shoot for a target that we
5 can't see.

6 We also have seen more timely response
7 on new post-approval submissions that are being
8 sent to the Agency as well as the backlog
9 submissions has certainly been getting addressed.

10 And also the early complete assessment
11 reviews of DMFs certainly helped in terms of
12 knowing that our DMFs are acceptable for review.
13 The issues there have been taken care of, or at
14 least are acceptable for -- excuse me, not taking
15 care of -- they're essentially complete to allow
16 full review, and we are certainly in anticipation
17 of the 3-year metrics at greater clarity to review
18 timing allows us to, as was said earlier, make
19 better business plans with regard to our business
20 of providing drugs to the consumer.

21 The challenges that we have had to date.
22 For one, the timing of the guidances has been a

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1 little close to the start of Cohort 3, so there
2 hasn't been a whole lot of time to comment or to
3 prepare comments, although I also understand that
4 this is not a small feat that we're attempting,
5 there is a lot of work to be done, so it's not
6 unexpected, but it's a little difficult to deal
7 with multiple issuance of guidance one on top of
8 the other.

9 And while the spirit of GDUFA was
10 intended to increase transparency and
11 predictability in the review process and timing,
12 there have been a few little snags in there.
13 Currently the communications from the PMs
14 regarding applications has been less informative
15 than it was even in the pre-GDUFA days. When you
16 call for a status, any meaningful information is
17 not provided, it's usually something more along
18 the lines of, "It's in review. Call back in 3
19 months." A little difficult to like again make
20 any business decisions based on the limited bit of
21 information on that.

22 Another example is the controlled

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1 correspondence guidance expressly states you're
2 not to check on status. Now, I understand when we
3 get to the metric where you're expecting a
4 response in 2 months, you don't want to take up
5 that time in the 2-month period responding to
6 various industries' requests on status, but when
7 it gets beyond the metric date, technically there
8 is nothing in the guidance that would allow you to
9 call in to check status. It could effectively
10 hang out in limbo.

11 And also pre-ANDA meeting requests.

12 This is something that requires a very
13 timely feedback from the Agency, and yet they're
14 being excluded from the controlled correspondence
15 metric, which again is not encouraging or it's not
16 helping with regard to the predictability and the
17 review process or timing.

18 And then, of course, again just the
19 controlled correspondence guidance, having
20 excluded so many things from consideration under
21 that guidance is causing concern because they were
22 items that would have been considered controlled

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1 correspondence previously.

2 Now, my intent here really was not to
3 provide specific comment on the guidances that
4 have been issued so far but more so the questions
5 that were raised by OGD to try to address some of
6 those. So specific comments to the guidances
7 we'll be issuing in writing to the docket.

8 But as far as, are there GDUFA
9 implementation issues related to the five
10 guidances that have not been addressed? And again
11 I say that submissions that don't fall into the
12 metric, and I'm of course now drawing a blank for
13 the actual numbers, but say it's, what, 60 percent
14 in the first year, I realize you're targeting as
15 many as you can. Your goal is at least 60. Those
16 that don't make it into the metric, though, there
17 is no time limitation given. And I realize some of
18 them are going to be complicated and take more
19 time, but at some point they can't be allowed to
20 fall into yet another backlog situation or
21 recreate the backlog situation.

22 We're also looking for ideas to when the

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1 GDUFA guidances themselves are targeted to become
2 official. The hope is that once they are
3 official, they'll become more consistently applied
4 and enforced across all of the application reviews
5 and again gives us a better gauge as to how to
6 predict issues with the Agency.

7 And again I'll stress that just the
8 controlled correspondence guidance just seems to
9 have removed far too many of the topics. The more
10 complicated issues are the ones that really are
11 the ones that we need Agency feedback on and your
12 input, and those seem to be the ones that have
13 been expressly removed from the controlled
14 correspondence guidance.

15 Other GDUFA implementation topics that
16 are in need of guidance, defining again -- and I'm
17 going to hit on the controlled correspondence
18 because that seems to be the one that we've had
19 the biggest issue with, is defining a process and
20 timing for those topics that have been excluded
21 from controlled correspondence. If they are going
22 to remain excluded from the controlled

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1 correspondence, then there needs to be a process
2 by which we can handle these more complex issues,
3 or those may require multiple discipline reviews.
4 Just because they're difficult doesn't mean they
5 should be allowed to be set aside.

6 And then, let's see, are there topics or
7 issues related to generic drug development not
8 directly affected or as a result of GDUFA that
9 need development of guidance? And this one seems
10 to keep coming up, the inactive ingredient
11 database. The accuracy and completeness of the
12 current database is lacking. There have been
13 instances where we believe that ingredients had
14 originally been in the database, had been removed
15 either because the application reference had been
16 withdrawn, but no indication as to whether it was
17 withdrawn for reasons of safety. If it wasn't
18 withdrawn from safety, could it or should it stay
19 within the database? By addressing the issues
20 with the inactive ingredient database, we believe
21 it will actually decrease the number of controlled
22 correspondences coming to the Agency, which will

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1 help you meet any of the metrics going forward and
2 will allow you to better utilize your resources.

3 There also needs to be clarity with
4 regard to single dose versus maximum daily dose
5 issues with regard to inactive ingredients. We've
6 heard tell that the bar to get an application
7 accepted is, is your formulation acceptable from
8 an inactive ingredients on a single unit that your
9 max daily is a review issue? If your application
10 gets issued -- or excuse me, accepted but then can
11 ultimately become approvable, it kind of defeats
12 the purpose. So not having that information at
13 the time of filing certainly creates an issue for
14 industry, and the addition of that information
15 into the database I think would ease the process
16 on both sides of the -- both for the Agency as
17 well as for industry as well as dosage form
18 interchangeability.

19 Can an ingredient that was used in a
20 buckle formulation be used to justify a sublingual
21 or a transmucosal, likely a topical in a
22 transdermal, can they be interchangeable?

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1 Other topics will be, of course, complex
2 drug products, LARs, rings, combination products
3 where a drug and device are closely related or the
4 device is regulating the actual delivery of the
5 drug, not just quantity, but duration, abuse-
6 deterrents, which I know there have been recent
7 discussions with the agency concerning that
8 particular topic.

9 And finally, one which I know is based
10 in law, but Section 1113 of FDASIA was originally
11 aimed to extend the Paragraph 4 applicants period
12 to obtain a timely tentative approval without
13 forfeiting the eligibility for exclusivity, but
14 due to the language of the law, there is an
15 ambiguity as to regarding what this length of
16 period is. Is it 30, 36, or 40 months?

17 So whether it be some sort of guidance
18 with regard to where that particular
19 interpretation may be would certainly be helpful
20 for the industry in determining -- in helping us
21 to determine, are we still eligible? Have we
22 forfeited? And it affects our business decisions

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1 in preparation for launch.

2 So that's the end of my presentation.

3 So thank you.

4 MS. NGUYEN: Thank you.

5 Questions?

6 MR. FLANAGAN: Thank you very much for
7 the specificity. This is not a passive-aggressive
8 request, I'm just really seeking clarity. On the
9 complex drug product and combination drug product
10 issues, have you all submitted comments to the
11 science side of OGD as they formulate their
12 regulatory science agenda? To what extent is this
13 a science issue versus a policy issue? Can you
14 comment on the interplay between science and
15 policy on that bucket of tough issues?

16 MR. VINCENT: Oh, boy. That would be
17 tough to do. You're right. With some of these
18 topics, the complex, the device oriented, there is
19 a very much of an intertwining of both the policy
20 and the science. It's very difficult to separate
21 the two issues.

22 With regard to have there been comments

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1 or questions or communications with the science
2 staff within OGD, I believe there have been
3 members, at least within my organization, that
4 have reached out to have some of those
5 discussions. Some of them have been favorable and
6 productive, and others not as much as we would
7 have liked. Certainly, again, any communication
8 is better than radio silence, so we certainly
9 welcome the communication and the opportunity.

10 As far as policy goes, on that one I'm
11 going to have to defer, on that I'm not as
12 familiar with where the company has taken a
13 stance.

14 DR. UHL: Yeah. So can I just expand a
15 little bit on what Keith is saying, and maybe I'll
16 put words in your mouth. I apologize, Keith.
17 It's usually the other way around, that the lawyer
18 puts the words in somebody's mouth, but no worries
19 here.

20 There is a process for regulatory
21 science with GDUFA, there is a regulatory science
22 program with money and grants and research, and

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1 there is -- I respect your opinion of that they're
2 close and they're intertwined, however, if you
3 don't have the scientific basis, it's hard to
4 create the policy in certain circumstances, and it
5 would be helpful for us for you to tease that out
6 in the comments that you submit to the docket
7 because what are the scientific gaps drives the
8 GDUFA research program. What are the policy gaps?
9 So are there particular guidances that you would
10 like some clarity on or would like to see? That's
11 fine. If there's a scientific gap, that's kind of
12 a separate issue. So it's helpful for us to have
13 them nuanced and teased out to assist us because
14 this is multiple components moving forward in the
15 entire program.

16 So to the extent that you could, Teva,
17 or other companies could in their comments to the
18 docket, it would help us tremendously.

19 MR. FLANAGAN: Because we already know
20 that complex drug products are a regulatory
21 challenge for us.

22 DR. UHL: Right.

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1 MR. FLANAGAN: The issue is which
2 subissues and which types of products should we
3 focus our regulatory -- your regulatory resources
4 on.

5 DR. UHL: Right. Right. It will help
6 us in a prioritization scheme because there are
7 limitless numbers -- well, maybe not limitless
8 numbers, but we do know there are a number of
9 products for which there are no generics. There
10 is a finite amount of resources that we have to
11 create either the science base or the policy base
12 for those. So it would be helpful to get that
13 kind of input.

14 So can I follow up with a second type of
15 question? Thank you.

16 Controlled correspondence, you used a
17 considerable amount of your time talking about
18 that. Could you expand, and if you don't feel
19 comfortable now, but if you could in the docket,
20 on what specific areas you feel were removed that
21 should be added back in, and in addition, the
22 aspect of a process to handle more complex issues.

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1 Can you expand on what that process could be,
2 should be? What would that look like?

3 MR. VINCENT: I'll take the second part.
4 Actually the second part may actually be a little
5 easier only because it's proposals or ideas of
6 ways you could potentially approach that topic.

7 The complex issues, complex products, or
8 combination products, require more in-depth
9 knowledge of the product and the process,
10 something that you've got a handful of people in
11 the industry perhaps that know of that technology.
12 Some may or may not reside within the Agency. The
13 only way to get that information is to have more
14 open dialogue between industry and the Agency,
15 perhaps as -- well, actually you've already
16 started doing some of it with the abuse-deterrents
17 recently, there have been some communications
18 there. There are networks on the branded side,
19 possibly a little easier than it does on the
20 generic side. It's a little difficult for us to
21 get together in a room with all of our -- you
22 know, all of the generic industry and start

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1 talking about areas of science because some of it
2 gets into what's proprietary and what's our
3 business edge. So it's a little difficult to be
4 forthcoming in a more public environment. There
5 are perhaps an opportunity for more one-on-one
6 meetings between select members of the industry
7 and members of OGD. It would be helpful and it
8 would allow that exchange of science information
9 that wouldn't be as accessible in a public forum.
10 I realize that's a little more resource intensive
11 for the Agency, having to meet individually, but
12 otherwise I don't know that you would be able to
13 get that free flow of ideas on the science.

14 MS. NGUYEN: Does that answer all the
15 questions?

16 (No audible response.)

17 MS. NGUYEN: Could you comment on why
18 the flow of information challenges exist more in
19 the generic sector than in the brand sector?

20 MR. VINCENT: Well, that's my
21 assumption. I've never worked in the branded side,
22 I'll say that right off the bat, but from my

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1 perspective, you've got multiple generic companies
2 potentially targeting a specific branded product.
3 And we're all trying to find ways of developing a
4 product that is the same but depending on given
5 development requirements, it may have to be just a
6 little different for legal purposes. So we're all
7 finding different ways of making it that little
8 different, and we're certainly not wanting to
9 share that information with our direct
10 competitors.

11 MS. NGUYEN: That's helpful. thank you.
12 I had another question. You had mentioned that
13 status checks are not permitted. You talked about
14 this in the context of the controlled
15 correspondence guidance and suggested that status
16 checks after a metric had passed might be
17 appropriate.

18 MR. VINCENT: Right.

19 MS. NGUYEN: Was that comment intended
20 for just the controls metrics or all metrics?

21 MR. VINCENT: Certainly it would be nice
22 for all metrics. I understand that it would be

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1 better if the Agency's resources were spent
2 reviewing instead of answering calls from
3 industry, but whether it be an application, a
4 controlled correspondence, a prior approval
5 supplement, you've exceeded your goal date and
6 you've not gotten your letter, so you're not going
7 to be one of the applications or the supplements
8 that make it within the GDUFA metric date.

9 Granted, industry has not been
10 prohibited from getting a status check, but like I
11 said earlier, the status checks that we've been
12 getting haven't been exactly meaningful in helping
13 us have any kind of business intelligence with
14 regard to the review of those submissions. So if
15 those applications or those supplements or those
16 controlled correspondences that have not met the
17 metric or the action date, if we could get a more
18 meaningful correspondence on that, that might be a
19 middle ground to work with. It's certainly one
20 idea.

21 MS. NGUYEN: And by status check, you
22 mean when we'll get you the answer, or what more

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1 information would you like?

2 MR. VINCENT: Timing would be helpful
3 certainly. If there is any indication as to --
4 well, I'll go back several years when, you know,
5 you might be able to get the comment that
6 chemistry review is just wrapping up, we should
7 have those -- we're hoping to have those questions
8 issued within the next 2 weeks. Bioreview is
9 done, they found it acceptable. That's something I
10 didn't know before. So that gives me a better
11 gauge as to how far my application is in the
12 review process.

13 So it can be timing. It can be somewhat
14 -- I realize you can't necessarily give the
15 content of the comments, but even if there is a
16 gauge as to whether it's major or minor ECD would
17 certainly be helpful.

18 MS. NGUYEN: So at the start of your
19 presentation, you were highlighting the benefit of
20 receiving complete response letters --

21 MR. VINCENT: Right.

22 MS. NGUYEN: -- that gave you

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1 information on the different disciplines and the
2 application status with respect to those reviews.

3 Could you, following on your comments, tell us
4 about the benefit, if any, of having information
5 about pre-CR majors? Which would be not a
6 complete response.

7 MR. VINCENT: Right. Uh --

8 MS. NGUYEN: Is this something you want
9 us to work on?

10 MR. VINCENT: Right. Having information
11 pre-CR majors. Good question. That one requires
12 some thought.

13 MR. FLANAGAN: Is the answer that you
14 get significant deficiencies more rapidly so you
15 can start to attack them and move your submission
16 forward more rapidly than you otherwise would have
17 if you had to wait for the CR?

18 MR. VINCENT: Wait for the response,
19 right.

20 MR. FLANAGAN: Can I ask a related --
21 we're over time, but --

22 MS. NGUYEN: May we have more time,

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1 Larry?

2 MR. FLANAGAN: It's an easy question.

3 Don't worry.

4 UNIDENTIFIED MALE SPEAKER: Okay. Whew.

5 (Laughter.)

6 MR. FLANAGAN: So one of the challenges
7 we have is the commitment letter only gives us
8 credit towards a GDUFA action if it's a complete
9 response; right? So that means the commitment
10 letter calls for us to have all the reviews
11 completed and to have inspections done and
12 compliance status determination and everything you
13 would want to know wrapped up in one package, and
14 there's the benefit of getting a complete
15 response, which you highlight. However, the
16 downside is it involves delay as you wait for all
17 the pieces to come together. Right?

18 MR. VINCENT: Right.

19 MR. FLANAGAN: We are thinking, as I had
20 an exchange with Mr. Gaugh, we're thinking about
21 ways that we can show some flexibility because of
22 the downside of that commitment letter

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1 requirement. If we were doing things like issuing
2 pre-CR majors and on occasion if the scientific
3 and technical review is complete and we didn't
4 have the inspection, how supportive do you think
5 industry would be about giving us wiggle room on
6 that because every time that we do something to
7 try to be helpful, like I just described, it hurts
8 us from a GDUFA perspective. We cannot take
9 credit for that action.

10 What are your thoughts on that?

11 MS. NGUYEN: That was not a short
12 question.

13 MR. FLANAGAN: It was pretty easy. It
14 was like a softball question that you're supposed
15 to say --

16 (Laughter.)

17 MR. VINCENT: Okay. To that, I'll ask
18 the first part of the question: Would getting
19 that forewarning of some of those major issues
20 ahead of the CR major be helpful? Absolutely.
21 And depending -- I'm sure there are certain
22 circumstances where if the issue is major enough,

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1 a company could decide, you know what? I almost
2 have to go back and redevelop the product to
3 potentially do new studies. I don't have the
4 resources to do that, and they could withdraw the
5 application at that point, thereby not consuming
6 your resources, continuing on in the reviews.

7 So when issues are major enough, I would
8 support -- I would think that would certainly give
9 industry a leg up, it gives us more time to
10 respond, we'll be able to respond to the major
11 when it comes in, in a more timely manner, and
12 keep the whole review process going much better.
13 So to that, I don't know that anyone would argue
14 with getting information early, especially if it's
15 major to the development.

16 The other one -- the other part of the
17 question actually, I don't know, it's somewhat of
18 the softball part of the question in that, how do
19 you do it in such a way that you can relay that
20 information and still get some sort of credit?
21 Because it leads into the ultimate -- your credit
22 only comes in at the complete response. Should

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1 there be consideration for that? Absolutely,
2 especially when it runs into a situation where the
3 application may eventually get withdrawn. There
4 will be no issuance of a major letter, yet you've
5 consumed some of your resources in identifying
6 some of these issues. So my guess is you're going
7 to have to go back in and look at the policy and
8 potentially within GDUFA2 structure something in
9 there that would allow for that communication
10 during that initial review period, but it's
11 something I think overall industry would certainly
12 welcome.

13 MS. NGUYEN: Thank you. Any other
14 comments from the panel?

15 (No audible response.)

16 MS. NGUYEN: So this is a general
17 comment. You know, we've asked a couple of
18 questions of you and of the room. If folks have
19 comments, please submit them to the docket. The
20 docket number for today is FDA-2014-N-1168. You
21 may know that we had a regulatory science public
22 hearing earlier this year. If your comments are

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1 more appropriate to be submitted to that docket,
2 please do so or submit comments to both dockets.
3 That way, we and the right folks can consider them
4 as we develop our priorities for the coming year.

5 Thank you.

6 Next up is Marcie McClintic Coates, from
7 Mylan.

8 MR. FLANAGAN: No.

9 MS. NGUYEN: No.

10 MR. FLANAGAN: It's Good Keith.

11 MS. NGUYEN: Good Keith. Oh, I'm sorry.
12 I'm out of order. Did I just say "Good Keith" on
13 the microphone?

14 (Laughter.)

15 MS. NGUYEN: Keith Webber. I'm sorry, I
16 don't have my correct papers in front of me. So
17 could you please state your affiliation?

18 DR. WEBBER: Yes. Keith Webber. I am
19 affiliated with the generics industry in general,
20 with Perrigo Company specifically. And I first
21 want to start out with thanking the FDA for
22 providing this venue for us to provide comments

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1 regarding recent GDUFA guidance documents as well
2 as other topics which could use guidance.

3 And I want to start out, let's see, with
4 figuring out how to use this. There we go.

5 I need to start out with some
6 disclaimers. Number one, my comments at this
7 public hearing are not meant to be a specific
8 benefit to my company, Perrigo, but they are
9 really intended to improve the general
10 collaborative effort between the generic drug
11 industry and the FDA to accelerate the development
12 and approval of generic alternatives to brand name
13 pharmaceuticals. And finally, I haven't received
14 any specific compensation for this presentation.

15 Next on the agenda, I would like to say
16 thanks to the FDA for the GDUFA invitation
17 activities that you've gone through so far.
18 Quarterly meetings with industry, representatives
19 through GPhA, and other venues at the FDA we have
20 greatly appreciated. Our publication of the FDA
21 processes and procedures in your maps online is
22 very helpful for us to understand how the FDA

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1 addresses issues and deals with applications. The
2 publication of guidance for industry that we're
3 talking about today I think has been very helpful
4 to the industry.

5 The meeting with industry via the small
6 business and industry assistance process I think
7 has been appreciated by many as well. And then
8 you've also held webinars to provide information
9 to the Agency with regard to GDUFA implementation
10 and other topics.

11 Today you presented us in a Federal
12 Register Notice with two basic areas, one is on
13 the draft guidances and other GDUFA issues that
14 are related to the draft guidances, and then other
15 topics that need guidance addressed. That's the
16 main area I'm going to speak about. I have one
17 slide which covers the afternoon on 180-day
18 exclusivity. I'll probably throw that in this
19 morning if I can, but will not speak this
20 afternoon on that topic since it's really not the
21 main thrust of my presentation.

22 Let me start out to say many of the

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1 comments I have in my presentation are much more
2 specific than you've heard so far, and I hope
3 that's appreciated. We will be submitting comments
4 to the docket as well, but I thought that to hit
5 on some really focused concepts with regard to or
6 focused areas within the guidance document would
7 be helpful.

8 Thumbs-up mean good, we like it. In the
9 controlled correspondence related to generic drug
10 development guidance document, the citizens
11 petition is being preempted by controlled
12 correspondence -- or preempting controlled
13 correspondence, I said it wrong -- is understood.
14 I mean, there are different requirements,
15 different regulatory issues there.

16 I think generally the out-of-scope
17 topics and out-of-scope entities that are
18 described in that guidance document are presented
19 with sufficient clarity, although there are some
20 questions that we have in that regard. Number
21 one, CC questions requiring policy development
22 will not be answered. I can understand the

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1 complexity of policy development. I think we do
2 have some concerns about how broadly that might be
3 applied, not to have it be sort of a pat answer,
4 "Oh, this is policy development, we're going to
5 get out, we won't answer that."

6 So what falls under policy development,
7 further guidance in that would be helpful. And
8 requests that will not be considered controlled
9 correspondence, bioequivalent study design
10 requests, clinical protocol design requests. I
11 understand those are fairly complicated or can be.
12 But as was brought up by another speaker, what is
13 the alternative there? If we can get meetings with
14 OGD to discuss those issues in a timely manner,
15 that I think would be sufficient and perhaps
16 preferable to a controlled correspondence, but
17 that depends on being able to get those meetings.

18 Let's see. Next, Number 3, inactive
19 ingredients can be addressed in one controlled
20 correspondence. Given the timelines, I can
21 understand that. To some extent, however, it's
22 likely to increase the number of controlled

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1 correspondence you receive. There is no reason
2 that a manufacturer can't submit two controlled
3 correspondence, one with three, one with one, if
4 they have four questions. So it's not really
5 going to do I think much in terms of workload
6 other than increase it in terms of tracking those
7 documents, getting responses sent out on those, et
8 cetera. So that might be something to consider
9 changing.

10 The FDA does not review proposed
11 formulations that are not required to be Q1/Q2
12 equivalent. I know this has been a policy before.
13 It does create some difficulties for the industry
14 in that if a biowaiver is needed or dependent upon
15 a Q1/Q2 formulation, then we really should be able
16 to get an answer on those because that could
17 result in a Refuse- to-receive, and a Q1/Q2 may
18 not be required for approval, but if it's required
19 for getting in the door, then we need to know
20 that.

21 The FDA will not respond to status
22 requests regarding pending controlled

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1 correspondences. I think if the GDUFA guideline
2 deadline has passed, then we should be able to
3 request a status update on that controlled
4 correspondence because oftentimes things that are
5 submitted in controlled correspondence are
6 critical to decision in terms of product
7 development.

8 This slide here addresses the RTR
9 guidance which was actually just finalized
10 yesterday, so I won't go into much more detail in
11 this other than to say my first comment there
12 regarding the five-day response time for filing
13 deficiencies we felt was too short, but we do
14 notice that that was up to 7 days, not quite the
15 10 we hoped for, but that's a good move in the
16 right direction.

17 Now I'll move on to the ANDA content and
18 format guidance. This is a thumbs-up. It's a
19 very valuable and appreciated guidance document by
20 industry. It provides a lot of good information.
21 There are some very specific comments related to
22 that document. First off, in Module 1,

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1 information is asked to demonstrate sameness to
2 the RLD for inactive ingredients and that they
3 don't impact safety and efficacy. It seems like
4 in Module 1 it's asking for depth in detail of
5 information that really I think would be better
6 put into Module 2 and 3. So if that's not your
7 intent, maybe further guidance in that area would
8 be helpful.

9 In Module 2, the CTD summaries, thumbs-
10 up. Question-based review I think is something
11 that's been very successful and helpful.

12 Let's see. Now moving on to Module 3,
13 drug substance section. Information on drug
14 substance manufacturers ask for three different
15 numbers, a Central File Number, the Facility
16 Identifier Number, and the Data Universal
17 Numbering System number. It seems like there are
18 an awful lot of numbers there. Probably the FEI
19 number and a DUNS number would be sufficient. We
20 would request or suggest that some of the GDUFA IT
21 funds be funneled toward developing electronic
22 cross-referencing system that would eliminate some

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1 of the redundant facility identifiers.

2 In the section on reference standards,
3 it says that reference to DMF alone is inadequate.
4 I think we need more clarity there because
5 oftentimes API manufacturers will have
6 noncommercial reference standards that we don't
7 know about as a finished dosage form manufacturer,
8 and so it would be good to know where we can
9 reference the DMF and where we can't.

10 Now, in regard to drug product in Module
11 3, the description for drug product, Section P1,
12 states that manufacturers of colors and flavors
13 can provide information directly to the reviewer.
14 It would be good to know more specifically how
15 that can be done within the ANDA submission. And
16 information about the manufacturing of the drug
17 product asks for complete testing description of
18 the facilities performing their testing. We're
19 not totally averse to redundancy in the
20 application, but this information is also asked
21 for in S4.2 and P5.2. So if it's possible to
22 avoid redundancy, that would be helpful.

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1 P3.4 asks about controls of critical
2 steps, and they ask for acceptance criteria and
3 test results for exhibit batches. Does this
4 include the same release testing that's requested
5 in P5.1? We're saying it's sort of redundant for
6 a potentially duplicative area.

7 The process validation information
8 that's asked for in P3.5, our experience has been
9 the process validation has historically been done
10 post-approval and so we question, is this a change
11 in policy asking for process validation pre-
12 approval? So that's something we could use some
13 more information on.

14 Some sections on Nodule 3 with regard to
15 the regional information. Again, any information
16 on components. It asks for certificates of
17 analysis for drug substance lots and active
18 ingredient lots, packaging component lots. And
19 again this seems redundant with the information
20 that's asked in other areas of the CTD, so that
21 might be something else to look at in terms of
22 revising the guidance.

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1 Moving on to the guidance on ANDA
2 amendments and ECDs, Easily Correctable
3 Deficiencies. This was one of the major comments
4 we had, was regarding major amendments. It says
5 that a request by the Agency for full-term
6 stability data would be a major amendment. We find
7 this to be problematic in that if full-term
8 stability is needed, it may in and of itself
9 require a 12-plus-month delay in getting that
10 response to the Agency if that data has to be
11 generated, which it would have to be generated.
12 So adding 10 months to the review rather than a
13 standard 3 months doesn't seem to be really
14 justified by the length of time it takes to review
15 stability data, it doesn't take that much extra
16 time, and so it's an additional burden of up to 22
17 months to the Agency -- to the industry.

18 Moving to the guidance on prior approval
19 supplements, we appreciate the documentation.
20 CGMP inspection cycle for the different types of
21 facilities. That's very good. And the acceptance
22 of comparability protocols in lieu of multiple

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1 prior approval supplements is very much
2 appreciated and is something we would like to see
3 more of in the industry.

4 We could use more clarity on what types
5 of changes can be bundled into a single prior
6 approval supplement and which cannot. For
7 example, if you're adding multiple API sources, is
8 that okay? So we would like to know.

9 Other GDUFA implementation topics that
10 need guidances. With regard to the post-complete
11 response letter teleconferences that are part of
12 the GDUFA goals letter, our experience has shown
13 that interactive T-cons are usually not scheduled.
14 Generally, written responses are issued to the
15 industry. We do appreciate that we get clear
16 timelines of when those responses will come,
17 that's very helpful, however, the clarity of
18 direct conversation is really lost in that
19 process, and the written responses don't
20 necessarily address the breadth and depth of the
21 applicants' questions.

22 Finally, responding to a T-con request

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1 with written responses doesn't, we think, meet the
2 GDUFA goal of interacting with the applicant, as
3 we agreed to in the GDUFA goals letter.

4 Some other topics, very specific ones.
5 Setting specifications, how that's done, we see
6 variability there. Sampling plans are another
7 area where we could use additional guidance, and
8 safety of inactive ingredients. So specifically
9 with setting specifications, we get comments, the
10 specs are too wide, set them to the RLD data. If
11 we set specs to the RLD, we go to (inaudible),
12 test it, tighten it to match the process results.
13 We matched ICH. Maybe we are asked to tighten to
14 match the process. I think there is some focus on
15 developing specifications that are clinically
16 meaningful, and so this is an area where I think
17 we really need to get better guidance.

18 Sampling plans, we've gotten variable
19 questions from the Agency with regard to sampling
20 plans, 3 samples per batch, 10 samples per batch,
21 5 samples per batch. There doesn't seem to be a
22 clear policy there in terms of sampling plans.

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1 And then finally the safety of inactive
2 ingredients. We would recommend that you consider
3 a FDA approach and accept food standards for
4 inactive ingredients in drugs. We've gotten
5 comments that a component which is safe in foods
6 at quite high levels is not acceptable in a drug,
7 and that just doesn't quite make sense to the
8 industry in general from a safety perspective.
9 And as was said before, revising the IID to give
10 maximum daily intake by route of administration
11 would be very helpful. I won't go into any more
12 details there.

13 With regard to this afternoon's session,
14 I'll just say very quickly I'm sure the FDA will
15 consider -- consideration of eligibility for 180-
16 day exclusivity for specific products be published
17 process. We think the process works well now,
18 don't recommend any changes there. Disclosure of
19 which companies are vying for exclusivity could
20 well put companies at severe commercial
21 disadvantage. That's one comment we have.

22 And again with what legal or regulatory

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1 mechanisms could facilitate resolving of 180-day
2 exclusivities. The current criteria for
3 identifying first generics seem to be sufficient,
4 so we're okay with those. That's for my afternoon
5 session.

6 And I thank you again very much for
7 providing this venue and I'll take any questions
8 you have.

9 MS. NGUYEN: Thank you, Keith.
10 Questions.

11 MR. YOUNG: Keith, I have several
12 questions focused on what seems to be the topic of
13 the morning, the IID. So one of the points that
14 you cover in your presentation, I don't recall if
15 you verbalized it or not, but it is on a slide,
16 has to do with the suggestion that because the IID
17 is in need of repair, that essentially levels of
18 inactive ingredients not be considered for filing
19 purposes. Is there an alternative suggestion that
20 would be used in lieu of that?

21 DR. WEBBER: I think that in lieu of
22 that, it would be valuable to move that into a

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1 review issue and look at what documentation the
2 company provides to justify the level of the
3 inactive ingredient in their product and also to
4 go back, as part of the review process, and ensure
5 that the levels that are in the generic product
6 are actually not in compliance with the levels
7 that are currently in either foods, I would say,
8 or in other drugs, because the IID, it's not
9 always up to speed, and it also gives you numbers
10 in percentages, which are hard to convert into
11 maximum daily doses.

12 MR. YOUNG: And as a follow-up to that,
13 with respect to -- and I've heard it mentioned
14 several other times this morning, again with
15 regard to the IID, it seems that having the MDI as
16 a listing would be helpful. Are there other types
17 of categories of information that industry feel
18 would be useful to be incorporated into the IID
19 where possible?

20 DR. WEBBER: If possible, I think it
21 might be valuable to have, in addition to the
22 maximum daily dosage, some information with regard

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1 to a differential between single dose or short-
2 term acute treatment drugs versus chronic
3 administered drugs that might be given for a
4 lifetime.

5 MR. YOUNG: And my final question. When
6 it's suggested that food levels or a food level
7 statement could be used in lieu of a particular ID
8 level for justification purposes, is there
9 consideration being given to whether or not the
10 length of administration is playing into that sort
11 of suggestion; in other words, acute versus
12 chronic use?

13 DR. WEBBER: Well, most foods are
14 administered chronically.

15 (Laughter.)

16 DR. WEBBER: So I've really given a lot
17 of thought to that, whereas drugs are generally
18 given for less time, usually until the issue
19 resolves or the illness resolves, and so I think
20 using the food safety standards for food additives
21 would be a worst case scenario compared to drugs.

22 MR. YOUNG: Thank you.

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1 DR. WEBBER: Thank you.

2 MS. NGUYEN: Go ahead.

3 MS. GIAQUINTO: I believe you gave QBR a
4 thumbs-up in your presentation. Is there anything
5 we can be doing to improve how widely used QBR is
6 in applications currently submitted? Are there
7 other examples we should be putting up on our
8 website or QOS model summaries?

9 DR. WEBBER: I'm not really sure about
10 that. I think that the Agency has done a fairly
11 good job of providing guidance on use of QBR. I
12 know there is a revised list of questions that are
13 out for consideration, not for implementation as
14 yet. I think that it's not clear, I think, to
15 many in the industry how much the QOS is actually
16 used as part of the review process, so that might
17 be something that would be worth perhaps open
18 public discussion as well.

19 MS. GIAQUINTO: Thank you.

20 DR. UHL: Thanks, Keith. I wonder if
21 you could just give a little bit more
22 clarification on the issue related to the Q1/Q2

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1 and biowaivers.

2 DR. WEBBER: Sure.

3 DR. UHL: So is it that industry wants
4 to be able to submit those as controls, so they
5 basically get a response that blesses the
6 application for filing, or what exactly is the
7 ask?

8 DR. WEBBER: Yes. I think the ask is
9 that if Q1/Q2 is required to get a biowaiver for a
10 particular product, then we have the confidence
11 and assurance that if we submit an application
12 that is Q1/Q2 and we submit a biowaiver, that we
13 would not be refused to file because we hadn't
14 done a biostudy.

15 DR. UHL: Okay. Thanks.

16 MS. NGUYEN: I have a few detailed
17 questions. You had mentioned in the ANDA content
18 and format guidance that there were a couple of
19 areas of possible redundancy.

20 DR. WEBBER: Mm-hmm.

21 MS. NGUYEN: Did you have for the three
22 -- or for the two that you flagged, did you have a

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1 recommendation as to whether the information on
2 drug product manufacturers should go in 32P3 or
3 32P52?

4 DR. WEBBER: Let's see, let me go back
5 to that one real quick if I can. Is this a slide?

6 MS. NGUYEN: No. It starts with
7 "Specific Comments Continued." That one.

8 DR. WEBBER: This one.

9 MS. NGUYEN: No. I'm sorry. It's the
10 next one right after that.

11 DR. WEBBER: Okay. Testing description.
12 I think that -- I haven't really given a lot of
13 thought to where it should go. I would suggest
14 that it perhaps go in the earlier section, which
15 is P3 and then -- because that's focused more on
16 the description of the facilities that are
17 performing new tests and put the actual tests and
18 description of tests themselves into the other
19 sections, just off the top of my head, that's what
20 I would do.

21 MS. NGUYEN: Okay. Thank you. On the
22 next slide, information on components.

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1 DR. WEBBER: Mm-hmm.

2 MS. NGUYEN: Should that go into P2 or
3 S404 or any of the other ones? It looks like P2
4 might capture in one place information that is
5 asked for in several other sections, so the CTD.

6 DR. WEBBER: Yes. And I would say that
7 the certificates of analysis should probably go
8 not in the P2 section, that's my own belief, that
9 the P2 is more of an overview summary of the
10 product development, not really delving into as
11 much detail and specifics as perhaps a certificate
12 of analysis would.

13 MS. NGUYEN: Okay. Thank you. And I
14 had a clarifying question. It's actually three
15 slides from that one, my slide 14, but on the
16 post-CR letter teleconference.

17 DR. WEBBER: Mm-hmm.

18 MS. NGUYEN: So right now we give you
19 the opportunity to request a teleconference.
20 Could you tell me what happens so that it ends up
21 that we don't have one getting scheduled?

22 DR. WEBBER: Well, generally we follow

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1 out a procedure of submitting a request for a
2 post-complete response teleconference and provide
3 the information that we are looking for answers
4 to. It's a learning experience for all in
5 industry of how to do this. So in some cases we
6 provide a very abbreviated description of what we
7 need information on, and without going into huge
8 detail, if we get a response back that, well,
9 we're not going to have a meeting, but we will
10 send you written responses, then the written
11 responses may only address superficially what we
12 were requesting information about without really
13 delving into the information that we would provide
14 in a meeting and a discussion that would occur in
15 a meeting. Then we get a response back from the
16 Agency that says we're going to send written
17 responses and we're going to do it by this date,
18 which is, like I said, very nice to get a specific
19 date for those. And then usually we get the
20 responses by that date and we move forward from
21 there with our best guess of what we should do
22 based on that information.

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1 MS. NGUYEN: But you would like more
2 often to have a conversation about the
3 deficiencies, not just the questions that you
4 identify as needing clarity.

5 DR. WEBBER: No, well, not generally
6 about the deficiencies, but we would like to delve
7 more deeply into the reasoning and thought
8 processes that the Agency had with asking that
9 question and then be able to discuss with the
10 Agency our reasoning for why this may be -- how it
11 should be addressed, for instance, what
12 information we might have that would address it in
13 a particular way and not just generally to meet
14 and discuss about the overall deficiencies, but we
15 still continue to be very specific.

16 The result of that I think is going to
17 be that there will be -- if we continue to not get
18 meetings, the meeting requests are going to get
19 much, much more detailed, asking very, very
20 specific questions, get very long and become
21 actually a review document in and of themselves.

22 MR. FLANAGAN: So it's just the

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1 substantive issues, you would also seek or
2 recommend additional clarity regarding the process
3 there; right?

4 DR. WEBBER: You mean in this particular
5 venue or in --

6 MR. FLANAGAN: Well, on how the process
7 will unfold post-CR.

8 DR. WEBBER: What I really am looking
9 for is that we would have -- more often than not,
10 we would have a meeting with the Agency to discuss
11 the post -- teleconference with the Agency to
12 discuss the post-CRL questions rather than getting
13 written responses.

14 MR. FLANAGAN: Okay.

15 DR. UHL: And, Keith, to clarify on that
16 because it sounds to me like what you're saying is
17 you really want to have an in-depth discussion and
18 conversation. So can you expand on that or
19 elaborate on that given the context of the
20 commitment letter that refers to these post-CR
21 meetings as 30-minute teleconferences?

22 DR. WEBBER: I think that we still

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1 believe they could be 30-minute teleconferences,
2 but I think that the face-to-face interaction, not
3 face-to-face, but telephone-to-telephone
4 interaction, with the Agency is much more
5 productive to talk with the scientists directly
6 than it is to just throw something in terms of
7 questions to the Agency, they throw back answers,
8 and we move on from there.

9 DR. UHL: Okay. Thanks.

10 MS. NGUYEN: I don't know if you can
11 give a general answer to this question, but in
12 this teleconference, do you find that there are
13 times when FDA has misunderstood the content of
14 the information provided in the application and
15 you would like to use the teleconference as an
16 opportunity to clarify as opposed to seek more
17 information on how to respond to the deficiency?

18 DR. WEBBER: Well --

19 MS. NGUYEN: Are you seeking to change
20 our mind?

21 (Laughter.)

22 DR. WEBBER: In some cases, yes. In

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1 some cases, yes. There have been instances where
2 we have questioned a CR comment and the Agency has
3 gone back, looked at it, and said, "You're right,
4 we're going to take that out of the letter." And
5 so sometimes we're successful at changing the
6 mind. Sometimes it is just a matter of
7 determining or finding out how we should address
8 that question. If there is a particular issue
9 related to a tox study, let's say, we could
10 provide within our request a description of the
11 tox study we plan to do. We could have a 30-
12 minute teleconference that says, okay, the Agency
13 says, yeah, we like this, we like that, we don't
14 like this, and getting that type of response,
15 which requires really an interaction in a single
16 response from the Agency really isn't sufficient
17 to efficiently and quickly resolve the issue and
18 move us toward product on the market.

19 MS. NGUYEN: Thank you. Are there other
20 questions from the panel?

21 DR. UHL: So just for my clarification
22 on this then. So essentially these post-CR

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1 meetings are you looking for something that's
2 more than just a teleconference to discuss the
3 content of the CR letter.

4 DR. WEBBER: We're looking for a
5 teleconference to discuss specific questions that
6 are in the CR letter and get clear direction and
7 understanding of how to move forward with our
8 responses.

9 DR. UHL: Okay. Thank you.

10 MS. NGUYEN: Thank you. Other
11 questions?

12 (No audible response.)

13 MS. NGUYEN: Okay. Thank you.

14 DR. WEBBER: Thank you very much.

15 MS. NGUYEN: I think that concludes the
16 morning presentations, so we will now move into
17 the open comment session. I think, is it just
18 three? We have three presenters, so I think there
19 is time to allow each commenter to speak for 10
20 minutes.

21 Our first commenter is Candis Edwards.

22 MS. EDWARDS: Good morning. Candis

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1 Edwards from Amneal Pharmaceuticals. I didn't
2 know I had 10 minutes, so I can slow down a little
3 bit, I won't talk as fast.

4 MS. NGUYEN: Or we can ask you more
5 questions.

6 MS. EDWARDS: Yeah. Absolutely.

7 So I wanted to address a couple of
8 issues since I had a short period of time. We
9 will provide more detailed comments to the docket,
10 but I wanted to address controlled correspondences
11 specifically. The recent practices in OGD's
12 modernization of the controlled correspondence
13 system has resulted in controlled correspondences
14 being closed at the Agency's discretion without
15 providing an answer to the questions posed since
16 the ANDA itself was already submitted, and what
17 was happening was that the CC was pending in the
18 queue for an extended period of time which
19 actually surpassed the development of the ANDA
20 from the firm's perspective, so the ANDA was
21 filed. And this results in an at-risk filing for
22 the ANDA holder because we don't have the answer.

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1 We really feel that the CC should still
2 be addressed by the Agency rather than close out
3 so that the sponsor has an opportunity to withdraw
4 the ANDA if appropriate, thereby you would
5 actually avoid unnecessary expenditure of OGD
6 review resources. So we would ask that you
7 continue or at least have a discussion before
8 they're arbitrarily closed out.

9 Also, with regard to controlled
10 correspondence, it's recommended that the Agency
11 issue a guidance for OGD/sponsor meetings to
12 address ANDA development issues. And I'll compare
13 it to the type A, B, and C meetings under PDUFA,
14 understanding that the differences are for
15 generics there are many companies going after one
16 product, and on the PDUFA side you have one
17 company, usually one product, but there might be
18 something that we can gain from that process.

19 The meetings I believe would minimize
20 the need for controlled correspondence because the
21 controlled correspondence issue addresses one --
22 excuse me, the controlled correspondence program

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1 addresses one issue at a time, and sometimes the
2 answers are taken out of context of the entire
3 development program, and so it results in the
4 inability of the ANDA sponsor to proceed in a
5 timely manner with product development. So what
6 am I saying? I've got multiple controlled
7 correspondences on one product where if I had an
8 opportunity to have a predevelopment meeting, I
9 would get answers to all of the questions that I
10 need, so I'm very much in favor of more meetings
11 in order to address these issues.

12 With regard to the Easily Correctible
13 Deficiency guidance, I have two comments. OGD's
14 current practice involves attempting to identify a
15 non-exhaustive list of examples of ECDs, and it
16 sort of reminds me of when we were back in the
17 SUPAC days and we were trying to figure out what
18 goes here and what doesn't as opposed to looking
19 at the principle of true risk assessment and
20 actually being able to categorize the risks
21 associated with a certain change, and using that
22 information then to make the decision as to what

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1 the appropriate filing mechanism was. So it seems
2 that we're sort of taking that same approach with
3 ECDs. And Amneal recommends that there also be a
4 possibility that OGD can base a classification of
5 a deficiency as an ECD on a sponsor's ability to
6 respond to the deficiency with some predetermined
7 time period, for example, 10 days, because I think
8 the key, the real key, is once you identified a
9 deficiency, how long is it going to take for the
10 sponsor to get information back to you as opposed
11 to which actual category it falls in. So that
12 would be a recommendation, to include that.

13 I also would recommend that OGD adapt
14 practices which are utilized during NDA review
15 whereby a project manager is authorized to engage
16 in a telephone discussion with a sponsor in order
17 to obtain rapid clarification on uncomplicated
18 review questions, which if resolved, are then
19 usually followed up by some formal correspondence
20 to that, and the file within some agreed upon
21 timeframe. That might also move the process along
22 a little quicker.

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1 My last comment, it deals with a
2 definition of first generics. I know that this is
3 a topic that will be addressed in the afternoon,
4 but I'll still take this opportunity, unless you
5 prefer me to hold this till the afternoon because
6 I didn't realize they were separated out.

7 MS. NGUYEN: If you could hold it till
8 the afternoon, we'll have a different panel --

9 MS. EDWARDS: Okay. Just sign up and
10 then I'll come back up again.

11 MS. NGUYEN: Please. We'll have a
12 separate panel that will --

13 MS. EDWARDS: Okay. So I'll hold off on
14 the last comment.

15 MS. NGUYEN: Thank you.

16 MR. FLANAGAN: You wanted to leave,
17 didn't you?

18 MS. EDWARDS: Pardon me?

19 MR. FLANAGAN: You wanted to leave us.

20 (Laughter.)

21 MS. EDWARDS: No, I'm here for the day.
22 This is my lifeblood. So those are the two

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1 comments I wanted to give.

2 MS. NGUYEN: Thank you, Candis.

3 MS. EDWARDS: Okay.

4 MS. NGUYEN: Questions?

5 DR. UHL: Thanks, Candis for those
6 comments. Could you clarify a little bit on your
7 first issue about closing out a control when an
8 application is submitted? That's on a company-
9 specific basis?

10 MS. EDWARDS: Mm-hmm.

11 DR. UHL: So the company submitted the
12 control, the same company decided to submit the
13 application --

14 MS. EDWARDS: Before getting it.

15 DR. UHL: Before the control was closed.

16 MS. EDWARDS: Right.

17 DR. UHL: So help me understand why you
18 would still want that control answered while the
19 application is in-house under review.

20 MS. EDWARDS: Because for the company
21 it's an at-risk file in, there was a question that
22 I had to understand how to proceed. So since I

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1 didn't get an answer in a time that was in line
2 with the product development, I went ahead and
3 used my best judgment and did what I thought
4 hopefully I would get an answer of yes to.

5 DR. UHL: Right.

6 MS. EDWARDS: And that's included in the
7 file. So either you're going to look at it right
8 then when you have it in front of you or you're
9 going to put it down and you're going to come back
10 to it when you do either acceptance to file or
11 review of the ANDA. It's still going to have to
12 be addressed. So I think since it's already made
13 its way up in the queue, it's beneficial, since
14 you've utilized that time, to just go ahead and
15 address the issue. I may withdraw it and the
16 application may go away, thereby saving review
17 time subsequently.

18 MR. FLANAGAN: But doesn't the answer to
19 the outstanding question come in the CR?

20 MS. EDWARDS: Yes, it does, but I could
21 have withdrawn it. Do you understand what I'm
22 saying? You might have said -- and I don't want

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1 to use examples, it's hard to do this without
2 examples, but the answer might have been your
3 proposal is not acceptable. Well, if I knew that
4 was the answer, I would not have proceeded in that
5 direction in my development, and I would not have
6 filed the ANDA, then I would have taken an
7 alternative approach that would have been
8 acceptable. So it's the value -- I think the
9 whole concept here is the value of getting the
10 answers up front. The more that we can get
11 clarification and get our answers up front to our
12 issues, the less resources are going to be
13 utilized by OGD, and these applications are going
14 to start to sail through the system, and I think
15 that's really what I'm going to.

16 DR. UHL: So you would say that if you
17 had a control that wasn't answered and you took
18 the risk essentially -- right?

19 MS. EDWARDS: Right.

20 DR. UHL: -- of submitting an
21 application, and somewhere during that -- so we're
22 assuming you would submit after October 1, and

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1 there would be GDUFA goal dates, so sometime in
2 there you would get a response to that control.

3 MS. EDWARDS: Mm-hmm.

4 DR. UHL: The applicant would make a
5 decision potentially to withdraw that application.

6 MS. EDWARDS: Right, potentially.

7 DR. UHL: So I would posit the argument,
8 though, that once the application comes in, we're
9 investing resources, the whole time to be moving
10 that through the GDUFA chain.

11 MS. EDWARDS: Right.

12 DR. UHL: We would answer the control in
13 the context of the filing review, the scientific
14 review, et cetera. You're -- I'm just getting --

15 MS. EDWARDS: Right.

16 DR. UHL: You don't want it then.

17 MS. EDWARDS: The only thing is that the
18 resources that you're going to use in the review
19 process are much more intensive than the resources
20 you're going to use in the controlled
21 correspondence. And I think that once we start to
22 approach goal dates for responses to control

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1 correspondence, I think these situations will go
2 away because the company won't have to wait 9
3 months or a year for an answer. So really what
4 we're probably having this (inaudible) situation,
5 because of the backlog, because of backlog in
6 applications, as well as backlog in controlled
7 correspondences, so that is also contributing.

8 So I guess what I'm saying is at least
9 that there would be a dialogue before it was
10 arbitrarily closed out to speak with the sponsors
11 and say, "Hey, would it be beneficial to answer
12 this? I know you filed." You know, there is
13 another situation where the ANDA may be open-
14 ended, maybe a controlled correspondence in
15 response to a complete response. So there are a
16 couple of situations, but again it's just been
17 arbitrarily closed with no interaction or
18 discussion. I think that's the main point.

19 DR. UHL: So I'm just trying to seek
20 clarification because in my mind I'm hearing
21 mixed, this is kind of pre-GDUFA without goal
22 dates, which was past practice, this is --

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1 MS. EDWARDS: Yeah. Right.

2 DR. UHL: So you're still making the
3 recommendation that effective October 1, when
4 controls come in with goal dates and there are
5 applications, your recommendation is all those
6 controls get closed out with a response
7 irrespective of whether or not an application has
8 been submitted related to that issue.

9 MS. EDWARDS: Yes. You're talking post-
10 goal date. I think the question is --

11 DR. UHL: We're only 14 days to goal
12 date --

13 MS. EDWARDS: I know.

14 (Laughter.)

15 DR. UHL: -- so unless you're submitting
16 a whole bunch today --

17 MS. EDWARDS: No.

18 DR. UHL: -- we're really darn close to
19 that.

20 MS. EDWARDS: What I'm saying is you're
21 asking me to draw this line in the sand. It's
22 probably hard now because I think the situation

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1 I'm describing is relevant because there are a lot
2 of controlled correspondences in the queue that
3 have been there for a long time. It will improve.
4 This is only the first year that you're going to
5 have to face your metrics and achieve your goals.
6 As you progress, it will improve, and this
7 situation will probably not exist.

8 DR. UHL: Okay. Thanks for that
9 clarity.

10 MS. EDWARDS: Okay.

11 MS. NGUYEN: I just have a quick
12 question. Could you -- you had mentioned that we -
13 - in the current amendments guidance, we have
14 provided a list of examples of Easily Correctible
15 Deficiencies, and you suggest that we classify
16 those based on the time it would take for a
17 company to respond to those deficiencies. I think
18 we heard in other presentations today that there
19 is significant variation in financial resources
20 among companies. Could you pose a timeframe that
21 would be equitable for small companies and large?

22 MS. EDWARDS: Okay. I'm not going to do

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1 that here, but I will do that in my written
2 comments.

3 MS. NGUYEN: Thank you.

4 MS. EDWARDS: That's a good point and
5 it's something that I did think about, so since I
6 only had 5 minutes, I will do it myself.

7 MS. NGUYEN: Thank you very much.

8 MS. EDWARDS: Okay.

9 MS. NGUYEN: Other questions? I think
10 we're over time.

11 MS. EDWARDS: Okay. Thank you.

12 MS. NGUYEN: Thank you, Candis.

13 Next up we have Satish.

14 MR. PEJAVER: My questions are related
15 more --

16 MS. NGUYEN: I'm sorry. Could you state
17 your name and affiliation?

18 MR. PEJAVER: Yes. Satish Pejaver, from
19 InnoPharma.

20 MS. NGUYEN: Thank you.

21 MR. PEJAVER: Again, my questions are
22 related more towards timelines in terms of how we

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1 get feedback from FDA. And I just want to take
2 some specific examples. These are based on our
3 experiences at InnoPharma. The first one I want
4 to talk about is like CBE-30. So CBE-30, you
5 know, there is a timeline defined by the
6 nomenclature itself that you need to get some kind
7 of feedback from FDA possibly within 30 days. So
8 there have been instances where we have one
9 instance where we filed a CBE-30 and we didn't get
10 a response within the 30 days, but we met all the
11 CBE-30 requirements, but then after 9 months we
12 got rejection of the CBE-30 and the conversion of
13 a CBE-30 to a PAS. So I think from a business
14 perspective, I mean, that can be disastrous
15 because you're following the guidelines and it
16 says CBE-30, and then if you don't get a response
17 in 30 days, you say go ahead and market the
18 product.

19 So I think that's something that again
20 is just a comment. I don't know how it needs to
21 be addressed, but definitely if there is an issue
22 with a CBE-30 submission, then we should get

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1 feedback, "Hold," or, "We are reviewing it," or,
2 "It's fine." So some kind of feedback. I think
3 that puts us in jeopardy in terms of how we
4 operate as a company.

5 The other timely aspect -- and I think
6 many people in this room will have the same
7 comment -- is about acceptance of the ANDA. I
8 mean, before the GDUFA, we had some sense on when
9 we would get an acceptance, and it's typically in
10 a 2-month timeframe. Now it varies all over the
11 place. I mean, I do understand we're going
12 through a transition scenario, but the timelines
13 are very -- I mean, it can vary. We have one
14 which is we haven't gotten a response for 18
15 months. So it's very difficult again from a
16 business perspective, and we find quality and we
17 don't get a response for 18 months, and there is
18 no open communication in terms of what's
19 happening.

20 So I think, again, my question or
21 comment is, is there metrics for acceptance of
22 ANDAs? And I think there should be. And it's

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1 something that we are battling with right now. I
2 would like to get some feedback on that if
3 possible today.

4 The other thing is on controlled
5 correspondence right now, post-October 1st, we
6 have 70-percent response within 4 months. So I
7 think the clarification there that we're looking
8 for is, what is a 70-percent comprised of? Like
9 how is 70-percent defined? Is there some kind of
10 Tier 1/Tier 2 criteria which would fall under the
11 70 percent? And I think some of the simpler
12 things, again, with, let's say, Q1/Q2, people have
13 raised that question before. So Q1/Q2, I think it
14 can be easy to respond before the timeline.
15 Before the pre-GDUFA days it was 6 months, not 6
16 months, actually 2 months, and now I don't get a
17 feel for when we'll get a response on that. It
18 again varies. It's never within 2 months, but it
19 varies quite a bit. So some kind of clarification
20 on that, as particularly Q1/Q2, because that
21 defines how we are going through our development
22 process and how we need to develop the product

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1 there, so it's very, very important criteria from
2 a business perspective as well.

3 So the other question on controlled
4 correspondence also in the pending controlled
5 correspondence is, how are they going to be
6 handled post-October 1st? So anything that's
7 submitted October 1st falls into the 70-percent
8 metrics and the 4-month metrics, but what about
9 the pending controlled correspondence? Is there
10 some clarification, some guidance, on how that's
11 going to be handled?

12 A couple of other comments that I have,
13 new controlled correspondence guidance conflicts
14 with the commitment letter from FDA. Just one
15 example would be --

16 MR. FLANAGAN: Conflicts with what?

17 MR. PEJAVER: With the commitment
18 letter. So, for example, the commitment for
19 clinical division feedback said you require one
20 additional month for that feedback to come in. As
21 for the new controlled correspondence guidance,
22 anything enrolled in clinical does not fall into

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1 the metrics. So that actually doesn't jive.

2 The other comment I have is on stability
3 guidelines and the Q1A-E document, which is final.

4 There are some clarifications that are required,
5 you know, especially for sterile injection,
6 injectables, secondary packaging of injectables,
7 powder fills. So again some clarification on
8 these pieces of information we can definitely put
9 into the docket. How is that typically handled by
10 FDA?

11 So this is a list of comments that I
12 had, and I guess if you need any more
13 clarification, I can definitely provide that.

14 MR. FLANAGAN: Thank you very much for
15 all those comments. My colleagues are going to
16 remind me that I'm not really supposed to answer
17 questions. Right? You raised a laundry list of
18 comments. Please do submit all of those to the
19 docket because I was writing furiously, but you
20 had a significant volume of them.

21 MR. PEJAVER: Sure.

22 MR. FLANAGAN: I do have a couple

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1 comments, although my colleagues may join me. The
2 first thing you raised was CBE-30s and the delayed
3 response. I was a co-presenter yesterday at an
4 FDA PQRI conference with Lawrence Yu, who is the
5 Acting Director of OPS, and Susan Rosencrance, who
6 is a senior leader in the CMC organization, and
7 they presented a lot of data concerning CMC's
8 aggressive attack on the supplement backlog, which
9 I think actually Dr. Webber mentioned as well. So
10 we're aware of the significant volume of work we
11 have in that space and are making good progress
12 attacking it. I would also note that only PASS
13 have metric goals pursuant to GDUFA, but we still
14 want to attack the CBEs.

15 MR. PEJAVER: Mm-hmm.

16 MR. FLANAGAN: On the filing issues --
17 and Johnny may wish to supplement or correct my
18 remarks -- but we're aware of those issues as
19 well. Pursuant to GDUFA, the clock starts to tick
20 at submission, not when we figure out what we want
21 to do with the submission, and we issued the
22 finalized RTR guidance yesterday and concurrently

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1 issued a draft guidance concerning RTR for
2 basically failure to explain, failure to how --

3 MS. NGUYEN: Provide information on
4 purities.

5 MR. FLANAGAN: Thank you. And that's
6 going to be the -- that's maybe the first in a
7 series of draft guidances because there are
8 recurring discipline-specific filing rather than
9 review issues that we should RTR for when people
10 send us stuff that we shouldn't accept that
11 penalizes everyone else who is sending in a
12 quality submission, and we should be making
13 improvements to RTR over time, it's just that we
14 want to do it in a manner consistent with our
15 procedural obligations and in a way that it's
16 transparent and gives industry an opportunity to
17 comment.

18 And the last thing that I would touch on
19 is a common question. You asked, okay, so assume
20 that the metric for Year 3 for controls is 70
21 percent within 4 months. How do you decide which
22 goes in the 70 percent and which goes in the 30

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1 percent? We don't have like a clever master plan
2 to divide them into buckets we're going to try and
3 hit and buckets we're on purpose going to miss.
4 We're going to try to get 100 percent.

5 MR. PEJAVER: Sure.

6 MR. FLANAGAN: So that's the answer.

7 DR. UHL: So I appreciate your request
8 of us that you get feedback today and leave here.
9 I want to kind of jump in where Keith was because
10 I'm thinking that Part 15 hearings are not
11 something that the generic industry is necessarily
12 very familiar with or something that they engage
13 the Agency with frequently, and so the purpose of
14 a Part 15 hearing is for us to hear, to listen,
15 and to ask stakeholders for clarification on
16 particular issues. And we've had several of these
17 and we will continue to have public hearings and
18 Part 15 hearings to allow us to get feedback from
19 our stakeholders to clarify what we are doing
20 internally. Okay. So I understand your need. I
21 just want to set your expectations that that's not
22 the purpose of today. And I'm sure you got some

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1 clarity from Keith.

2 I would like a bit of clarification on
3 one of the things that you mentioned, was the
4 acceptance criteria. You're talking about a
5 filing decision or an approval decision?

6 MR. PEJAVER: A filing decision.

7 DR. UHL: A filing decision.

8 MR. PEJAVER: Yeah.

9 DR. UHL: Thank you. I just wanted to
10 be clear that that's what you were meaning. Thank
11 you.

12 MR. PEJAVER: Just one last comment
13 again on ANDAs that have been submitted and have
14 not been accepted yet, and some clarification on
15 how those ANDAs are going to be handled because
16 they don't fall under the GDUFA metrics. That's
17 what I understand. So some clarification on that
18 would be great as well.

19 Thank you very much.

20 MS. NGUYEN: I have a question for you.
21 Thank you for your comments. You had mentioned --
22 you started your comments with the discussion

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1 about the CBE-30s that were denied to a prior
2 approval supplement 9 months later. Do you have
3 the clarity that you need to know whether to
4 submit a prior approval supplement or a CBE-30?

5 MR. PEJAVER: There are guidelines for
6 CBE-30. In some cases, there are some grey areas,
7 but when it's somewhat clear-cut as for the
8 guidelines, we assume that if FDA does not come
9 back in 30 days, that it meets the requirements.
10 It would be great to get feedback within the 30
11 days no matter what because in some cases there
12 are some grey areas where FDA may decide to be
13 more conservative or they understand the position
14 of the industry and they grant the CBE-30, but
15 without any dialogue, it's very difficult.

16 In this particular case, we followed the
17 guidelines. So I think the haziness on the
18 submission was somewhat limited, was pretty clear-
19 cut, so it was a surprise to get the feedback 9
20 months later.

21 MS. NGUYEN: I would like, if you're
22 able to submit comments to the docket, more

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1 information on some of those gray areas. We would
2 like fewer gray areas over time so that there was
3 more clarity as to how you should proceed with
4 change.

5 MR. PEJAVER: Okay.

6 MS. NGUYEN: Thank you.

7 MR. PEJAVER: Okay. Thank you.

8 MS. NGUYEN: Anything else from the
9 panel members?

10 (No audible response.)

11 MS. NGUYEN: And our last commenter for
12 this morning?

13 MR. ROTH: Hi. I'm Gil Roth, the
14 President of the Pharma and BioPharma Outsourcing
15 Association. I want to thank you for the
16 opportunity to speak today. I founded the
17 association earlier this year to help organize and
18 represent contract manufacturers and contract
19 development manufacturing organizations, we'll
20 call them CMOs for the sake of this comment
21 session. This came after 14 years of covering the
22 industry as the editor of Contract Pharma

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1 Magazine.

2 And our main area of interest at this
3 hearing is facility fees for final dosage for
4 manufacturers. I was gratified to hear Mr.
5 Pressman's presentation earlier about the small
6 business issues related to those fees, and we're
7 coming from somewhat different directions, but I
8 think we have some of the same goals. Several of
9 our members are interested in a small business
10 exemption under GDUFA as well as perhaps a tiered
11 structure for CMOs as opposed to companies that
12 are manufacturing generics for themselves. It's a
13 very different business being a contract
14 manufacturer than being a pharma company or a
15 generic company operating under much different
16 margins.

17 Within the field, we have some companies
18 that might have a single generic client that they
19 do one week of work for per year, and yet they
20 face the same facility fee that a major, major
21 generic facility is going to pay. Not all
22 contracts are made to accommodate that sort of fee

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1 being transferred, and it's a very anecdotal
2 industry, but I have anecdotes of companies that
3 have told me they're essentially looking to get
4 out of manufacturing generics because these fees
5 make it unprofitable for them as well as for the
6 client company they're working with.

7 Now, one of our members has helped --
8 well, a congressman, Representative Robert Hurt,
9 Republican in Virginia, he and Phil Roe in
10 Tennessee have introduced HR-3631, a Small
11 Manufacturer Protection Act, which empowers the
12 Secretary at FDA to issue small business
13 exemptions when GDUFA might create barriers to
14 entry. I believe the threshold for that is
15 companies that are \$20 million and smaller, and
16 that bill is currently sitting in the Health
17 Committee.

18 I'm here because this is our coming out
19 party in a sense. This is the first public
20 appearance the association has made.

21 MS. NGUYEN: Congratulations.

22 MR. ROTH: Thank you very much. We're

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1 interested in reaching out to FDA in helping to
2 inform them a bit more about how the CMO industry
3 differs from the branded pharma industry, from the
4 generics industry. Like I said, they operate on
5 very different margins. Some of them are carved
6 out of existing pharma companies. In this case,
7 some of them have generic products of their own
8 through other businesses. I should note that the
9 interest in GDUFA does not reflect the entirety of
10 the membership of the PBOA. Some of these
11 companies don't handle generics at all, some are
12 biologics focused, but still they're contract
13 manufacturers and they don't seem to be
14 represented in the way GDUFA was structured in its
15 initial incarnation. We're hoping going forward
16 with the renewal that we can have some effect and
17 help negotiate some way of differentiating CMOs
18 from pure generic companies under the facility
19 fees going forward, particularly for final dosage
20 form.

21 And that is essentially all I have to
22 say. We are planning on submitting comments to the

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1 docket in the weeks ahead to again try and pave
2 the road here, but if you have any questions, I
3 would love to start a conversation.

4 MS. NGUYEN: Thank you.

5 MR. FLANAGAN: Welcome to the excitement
6 of GDUFA.

7 MR. ROTH: Thank you very much.

8 (Laughter.)

9 MS. NGUYEN: It's always a party.

10 MR. ROTH: Well, this all began because
11 I was reporting on GDUFA for Contract Pharma
12 Magazine, where I was the editor, and the number
13 of contract manufacturers who said to me, "We
14 don't know what we're doing under this. We can't
15 pass these fees along to our clients," they were,
16 I don't want to say blindsided, we knew fees were
17 coming. I don't think they knew exactly how it
18 would be structured and how they would be
19 implemented. We want to be part of the party, I
20 guess.

21 MS. NGUYEN: Do you have -- can you give
22 me a ballpark estimate on how many players would

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1 fit into the under \$20 million exemption?

2 MR. ROTH: Not entirely. It's an
3 industry that's dominated by a few very, very
4 large companies and a very large number of small
5 companies, and some of those come and go. If
6 anything, when I was building the membership list
7 for this, I looked over the self-identified
8 facilities list under GDUFA to see which companies
9 I knew which companies didn't appear to be generic
10 firms of their own, and start figuring out who was
11 a small CMO, who I don't want to say get caught in
12 the net, but showed up as a self-identified
13 manufacturer of generics.

14 MS. NGUYEN: So was it a lot?

15 MR. ROTH: There's a bunch. I will try
16 and get that information for you.

17 MS. NGUYEN: Yeah. I just want a feel
18 for what would happen if we were to work on an
19 exemption. I think a presenter earlier had talked
20 about a sliding scale fee structure. You're
21 talking about an exemption which would be
22 something different. I don't know if you would

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1 also -- if you like what we currently do in PDUFA
2 and whether that would be acceptable.

3 MR. ROTH: And that's what I was
4 wondering. Under PDUFA, there is both a small
5 business exemption and facility fees are applied
6 directly to the drug filers, not to the individual
7 manufacturing sites. Both of those did not carry
8 through to GDUFA. So we want to see about how
9 that can be implemented.

10 One of the ideas we had was simply a
11 checkbox of sorts under the self-identified
12 facilities list to ask companies, do you or any of
13 your subsidiaries own any NDAs of your own? If
14 they don't, it's a contract manufacturer, it's not
15 a generic company, and that might be a good way of
16 splitting the pie to separate final dosage form
17 into companies making them for themselves versus
18 ones that are making them for clients.

19 MS. NGUYEN: Thank you.

20 Other questions from the panel?

21 DR. UHL: I was just wondering if you
22 could elaborate on your choice of the \$20 million.

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1 MR. ROTH: Oh, that's not my choice.

2 That's in the small business -- that's in HR-3631.

3 DR. UHL: Okay. Even that, how was that
4 put? I mean, do you have any knowledge of that,
5 that selection?

6 MR. ROTH: I don't know how that number
7 was settled on, but it might be something that's
8 come up in small business waivers in the past, but
9 I'm afraid I don't know how they settled on the
10 number.

11 DR. UHL: Okay. Thank you.

12 MS. NGUYEN: Other questions?

13 (No audible response.)

14 MS. NGUYEN: We'll look forward to
15 seeing your comments in the docket.

16 MR. ROTH: Thank you very much.

17 MS. NGUYEN: So that concludes the
18 morning session. We are at 11:47. Let's
19 reconvene at 1:05. So we'll follow the agenda and
20 just meet back here in an hour and 15. Thank you.

21 (Lunch.)

22 MS. TOUFANIAN: Good afternoon. We'll

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1 go ahead and get started. My name is Maryll
2 Toufanian. I am an Acting Division Director within
3 the Office of Generic Drug Policy. First, we
4 would like to thank everybody for their
5 participation this morning. We thought it was a
6 really informative and helpful discussion.

7 This afternoon we'll be shifting gears a
8 bit. I'll relay that the process is similar to
9 this morning in that we have two speakers who have
10 prepared remarks, and then we'll give an
11 opportunity for folks who would like to comment on
12 the issues that we'll be discussing, some of whom
13 I believe have registered earlier today whose
14 names will be projected on the list, and then if
15 we have any additional time, we'll go ahead and
16 permit additional comments.

17 This afternoon's policy discussion
18 concerns two topics of GDUFA implementation that
19 are informed by the unique incentives for generic
20 drug manufacturers embedded into the Hatch-Waxman
21 amendments. All of us are familiar with the 180-
22 day exclusivity, so I won't get into the nuances

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1 of that, but before we discuss our criteria -- or,
2 excuse me, our topics of discussion today, I would
3 like to give the new panel -- you'll see some
4 fresh faces up here -- an opportunity to introduce
5 themselves. These are folks that are on the front
6 line of considering the issues we'll be discussing
7 today, many of whom will be familiar to the folks
8 in the room.

9 MR. FLANAGAN: I'm Keith Flanagan. I'm
10 the Transition Lead for Policy in OGD.

11 MR. REED: Dave Reed, Regulatory Counsel
12 in OGD.

13 MS. DETTELBAACH: I'm Kim Dettelbach.
14 I'm Senior Counsel in the Office of Chief Counsel.

15 MR. SHIMER: Martin Shimer. I'm the
16 Deputy Director of the Division working with
17 Maryll.

18 DR. UHL: And good afternoon. I'm
19 Kathleen Uhl, the Acting Director of the Office of
20 Generic Drugs at CDER.

21 MS. TOUFANIAN: Thank you. So as I
22 indicated, we have identified two topics on which

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1 we really look forward to getting comments from
2 stakeholders involved in GDUFA implementation.

3 The first concerns, what is actually a
4 criterion for Agency prioritization set forth in
5 the commitment letter, the notion of a category of
6 a first generic who will be receiving priority
7 review, and what we have discovered based on
8 informal comments is that description and
9 categorization set forth in the commitment letter
10 is not as clear as we would like, or it's not as
11 easily defined as we thought. We have received
12 differing definitions. Is a first generic a first
13 ANDA that is submitted for a particular RLD? Is
14 it a first-to-file ANDA that contains a Paragraph
15 4 challenging patents with a brand drug? Is it
16 the first generic that's approved, that is
17 approvable, the first generic that is marketed or
18 marketable, and/or is it the most important number
19 one priority for a specific company?

20 Having received these informal and
21 somewhat differing or diverging understandings of
22 what a first generic is, we thought it was

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1 essential to invite stakeholder comment on what is
2 the appropriate definition of a first generic for
3 the purposes of agency prioritization of ANDA
4 review.

5 And the second topic we'll be receiving
6 comments on is the Agency's consideration of 180-
7 day exclusivity. I think everyone is well aware
8 of what that is and that the Agency's
9 consideration in decisions with respect to 180-day
10 exclusivity are complex, fact-specific, ever
11 shifting, almost always occurring prior to
12 approval and almost always involving confidential
13 commercial information, and that being said, we
14 have received again a number of informal comments
15 from a variety of stakeholders asking whether
16 there is a way to make that process more
17 transparent and potentially open to public
18 participation.

19 As I indicated, many of these decisions
20 are fact specific, but they deal with issues that
21 recur for a variety of applications and for a
22 variety of products. So we are soliciting

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1 comments on if there are mechanisms mindful of the
2 confidential nature of some of these
3 determinations, are there mechanisms to make part
4 or all of those considerations public?

5 The folks in the room are the folks that
6 deal with these issues on a daily basis, and we
7 thought it would be very helpful to get comments
8 on those as well.

9 In addition, we're welcoming comments on
10 other elements with respect to the sort of non --
11 I don't want to say non-scientific, but the more
12 policy or legal elements of GDUFA implementation
13 where additional guidance or additional clarity
14 from the Agency would be beneficial.

15 So with that, we'll go ahead and start.
16 I believe Robert is -- no? You're all set?

17 MR. VINCENT: I'm (off mike).

18 MS. TOUFANIAN: Okay. I'm sorry. Then,
19 Marcie, if you would like to go ahead and join us.
20 Please go ahead and just introduce yourself and
21 identify your affiliation.

22 MS. McCLINTIC COATES: Sure. Well, good

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1 afternoon and thank you. My name is Marcie
2 McClintic Coates, and I serve as Mylan's Vice
3 President and Head of Global Regulatory Affairs
4 and also as a former member of the GPhA GDUFA
5 Negotiating Team.

6 Mylan has a 53-year history of working
7 closely with FDA, and we appreciate the
8 opportunity to provide comments today,
9 particularly given a lot of involvement in the
10 development on negotiating of the GDUFA program
11 along with our industry colleagues.

12 We look forward to supplementing the
13 docket today with additional detail regarding all
14 of the questions that have been published in the
15 Federal Register Notice, and we thank the Agency
16 for creating this forum today. I think it's well
17 served and a continuation of having these goes a
18 long way for both industry and FDA, so thank you.

19 For today, I will share some general but
20 important considerations that really should shape
21 our thinking as we implement GDUFA to ensure that
22 the true intent of the program is operationalized

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1 in a way that's consistent with the key aims that
2 we sought for in the negotiations of the three
3 public health aims of improved safety, access, and
4 transparency, and certainly consistent with the
5 key underpinnings that make our industry so
6 unique, the Hatch-Waxman system that we have.

7 GDUFA was one of the most significant
8 pieces of legislation impacting the generic drug
9 industry since the Drug Price Competition and
10 Patent Term Restoration Act of 1984, commonly
11 known as Hatch- Waxman, which essentially created
12 the generic drug industry as we know it today and
13 interestingly next week will celebrate its 30-year
14 anniversary.

15 Since the passage of this act, generics
16 have played an increasingly vital role in the
17 nation's public health, as FDA has approved more
18 than 8,000 generic equivalents to brand name
19 drugs, resulting in 85 percent generic utilization
20 in the U.S. and saving the country over a trillion
21 and a half dollars in just the last decade.

22 Now, much of that success has come

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1 directly from the very unique Hatch-Waxman
2 framework that Congress put in place to expedite
3 generic competition to give patients faster access
4 to more affordable medicine on the very earliest
5 possible date that no legal barrier approval
6 exists.

7 Now, exactly 4 years ago today on
8 September 10, 2010, FDA had a very similar public
9 forum as this welcoming dialogue on what a generic
10 user fee program ought to look like, and what did
11 industry think about? So I went back and
12 revisited our comments then and comments that many
13 of our colleagues have put forth as we started to
14 really look at the need for a program, and one of
15 the comments that we shared, Mylan's CEO shared,
16 at the time that I think is still relevant is
17 while it's widely recognized that Hatch-Waxman has
18 successfully delivered significant savings to
19 consumers, no one could have predicted in 1984
20 that that framework would over time tax the FDA
21 system due to the complexity of the global
22 marketplace. Today's reality means we must

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1 address the issue through a holistic user fee
2 approach, one that supports the mission and true
3 intent of Hatch-Waxman at the same time generating
4 much needed funding for the FDA and assurance for
5 product safety amidst the globalizing industry
6 that the Agency regulates.

7 Now, over the time period leading up to
8 GDUFA, median review times had hit 31 months, they
9 had doubled over the last decade, and, quite
10 frankly, as we all know, the Agency's resources
11 had just not kept up with that demand nor the
12 ability to inspect facilities located in the U.S.
13 and outside the U.S. at the same frequency and
14 occurrence and thus contributing to these delays
15 because a recent inspection history is, of course,
16 needed before you can get approval.

17 Now, what was happening prior to then,
18 as we know, we were inadvertently forfeiting
19 exclusivity as an industry. As you know, the
20 generic drug industry has 180-day exclusivity,
21 it's the sole exclusivity that exists for
22 generics, and in 2003, the Medicare Modernization

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1 Act updated those Hatch-Waxman amendments and
2 provided forfeiture provisions finding that if a
3 company fails to get a tentative approval within
4 30 months, you will lose your 180, and as that
5 number -- in 2003, when that was created, it took
6 16 months median review time to get a tentative
7 approval at FDA. And now that we're at 30, 31
8 months prior to the start of GDUFA, companies were
9 inadvertently forfeiting through no fault of their
10 own and thus threatening this important
11 exclusivity that Congress had put in place to
12 incentivize companies to take on the expensive --
13 the extensive legal risk involved to challenge
14 patents and at the end of the day get products
15 into the hands of consumers faster.

16 So it was with all those pieces in mind,
17 with Hatch-Waxman being at that point a century
18 old, that industry came up with, with FDA a
19 comprehensive user fee program that was focused on
20 three public health stated aims of GDUFA:
21 improved access by expediting the availability of
22 low cost medicine by bringing greater

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1 predictability, increasing timeliness in the
2 review, improved transparency by improving FDA
3 communications and feedback within industry in
4 order to expedite product access, and improved
5 safety by ensuring that both foreign and domestic
6 industry participants in the U.S. are held to
7 consistent high quality standards and inspected
8 biannually using a risk-based approach.

9 Now, as FDA is now operationalizing
10 GDUFA and coming up with new policy development
11 activities training within the Agency, these three
12 overarching stated purposes of improved safety,
13 access, and transparency should really serve as
14 the guiding principles on all of the
15 implementation efforts, and these are complemented
16 by two longstanding and bedrock principles that
17 have historically made the U.S. generic drug system
18 the most successful in the world. Number one, FDA's
19 relentless passion and commitment, sense of urgency,
20 to carry out the unique Hatch-Waxman framework
21 of getting drugs approved and into the hands of
22 patients on the very earliest date that no legal

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1 barrier exists as well as, two, FDA's strong
2 reliance on good science to continuously improve
3 and evolve Agency thinking.

4 So thus GDUFA was intended to provide
5 FDA with additional resources to essentially
6 achieve the ultimate purpose of Hatch-Waxman that
7 had become really strained with the growth of the
8 industry and the number of facilities and players
9 involved and the lack of resources at the Agency
10 for generic drugs. And both Congress and the
11 courts have found that Hatch-Waxman's central
12 purpose is to implement the policy objective of
13 getting safe and effective generics into the
14 market as quickly as possible after patent
15 expiration or earlier where companies are able to
16 do so by challenging patents.

17 Now, the GDUFA goals letter identifies
18 improved access as a key public health aim of
19 GDUFA, and leading up to GDUFA, as we mentioned,
20 the generic approval had increased to 31 months in
21 2011. Now, a significant amount of progress has
22 been made to date implementing GDUFA, and we will

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1 outline more of those as well because they are
2 worth noting and they're important, toward the
3 inspection disparities, many of them, and we were
4 having conversations at lunch with several
5 colleagues about the improvements that have
6 occurred, but one area that we both continue to
7 struggle in is on the median approval times on
8 that purpose of access. So while much has been
9 made to hire and train and set up the
10 infrastructure to get the generic review system a
11 more predictable footing from the start of GDUFA,
12 the median time for generic approval has increased
13 to 36 months in 2013, and it's projected to be at
14 around 43 months in 2014, although not all full
15 data is out yet, but from the sampling that we
16 have been able to see. And in the last year, the
17 U.S. health care system has lost an estimated --
18 over a billion dollars in savings due to delays in
19 first generic approvals missing getting approval
20 in that earliest stage that no legal barrier exists
21 for approval. And we, as an industry, continue to
22 have inadvertent forfeitures for failing to get

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1 that timely approval. On top of that, of course,
2 the Agency has received a record number of
3 applications just in June alone, so the workload
4 has not gone away either.

5 We are encouraged by the new
6 Prioritization Map that has come out with FDA to
7 try to address these challenges and to make sure
8 that we're not losing sight of those critical
9 products, applications that are opening the market
10 and getting more affordable access to patients.
11 We would urge FDA to ensure that the key
12 principles are carried out through the
13 prioritization of both the application submitted
14 before October 1, 2014, as well as those that come
15 after this date. And this is a very important
16 point as we look at this framework and we have as
17 a sister model to look at, is PDUFA, but I think
18 this is really helpful to underscore this
19 distinction.

20 While much of GDUFA is modeled after
21 PDUFA, GDUFA is particularly distinguishable from
22 PDUFA because GDUFA's goal of decreasing the time

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1 for approval is tied to the Hatch-Waxman
2 amendments, which link the patent dispute process
3 with the generic drug approval process and
4 requires FDA to make approval determinations on
5 applications within 180 days. And in proposing
6 and negotiating that framework, much time was
7 spent identifying the unique Hatch-Waxman
8 framework that differentiates our program from
9 following a rubber stamp, mirror image of PDUFA.
10 And as shared during several previous public
11 meetings as we talked through this, if the generic
12 drug user fee program is tied solely to the
13 certainty of an artificial timeframe alone without
14 regard to the Hatch-Waxman framework, that
15 encourages the earliest entry of generic
16 competition, this would be flawed because not all
17 applications can or should be treated equally.
18 FDA should not simply create a cookie-cutter
19 approach that treats all applications alike and
20 fails to recognize the legal distinctions between
21 each application, such as first-to-file ANDAs,
22 subsequent ANDAs, and/or significance of a

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1 particular product, like one that treats an unmet
2 medical need or otherwise a first generic or an
3 orphan drug or some other significant public
4 health impacting application.

5 Mylan recommends that FDA clarify its
6 recent Prioritization Map with associated target
7 action dates to prioritize those applications that
8 have the most significant impact on the public
9 health so that more timely approvals can be
10 achieved. These include the availability of new
11 first generic medicines, medicines that lack
12 significant generic competition, including second-
13 to-file as well as any other applications that
14 particularly play an important role in the public
15 health in addition to PEPFAR and drug shortage
16 applications.

17 First generics should include those
18 applications for which no other generic version of
19 the same reference listed drug has yet been
20 brought to the market under an approved ANDA.
21 Consistent with the purposes of Hatch-Waxman, FDA
22 should aim to approve applications immediately

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1 upon patent expiration, exclusivity expiration,
2 expiration of a 30-month stay, commencement of a
3 patent license date, or the earliest date that no
4 other legal barrier to approval exists; for
5 example, for a late statement or a forfeiture by
6 the first applicant. FDA should prioritize any
7 other application for which the applicants can
8 sufficiently demonstrate a significant and
9 compelling public health need taking into
10 consideration factors such as whether the product
11 will fulfill an unmet medical need or satisfy an
12 undue economic hardship.

13 As the Agency assigns appropriate action
14 dates and time to allow for a final and tentative
15 approval, that should be aligned with the relevant
16 Hatch-Waxman dates, and once that has been
17 identified, these dates should have the ability to
18 change to an earlier date just given the
19 constantly changing dynamic nature of the Hatch-
20 Waxman framework if it's needed. If an
21 application has now entered into a settlement
22 agreement, then gives the opportunity for an

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1 application to be approved earlier, that target
2 action date should have that ability to respond to
3 that dynamic and nimble nature that Congress
4 intended to drive competition.

5 Additionally, all divisions within FDA
6 that can impact the approvability of an
7 application should be held accountable to that
8 date. So it's not just CMC and bioequivalence and
9 the traditional OGD review, but if something
10 entails a consult or a citizen petition review or
11 a review by Office of Chief Counsel, we would
12 suggest that all of those should be -- or of
13 wrapping up an inspection or closing out an
14 inspection -- included here.

15 And with respect to submissions that are
16 impending with FDA submitted anytime before
17 October 1st of 2014 when the Year 3 metrics kick
18 in, FDA should strive to maintain a level of
19 productivity at least similar to the pre-GDUFA
20 levels as provided in the goals letter, which says
21 FDA will aspire to maintain pre-GDUFA level
22 productivity as the Agency ramps up the program.

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1 Thus, FDA should aspire to meeting approval times
2 of no more than 30 months of applications
3 submitted before October 1, 2014, that are not
4 prioritized. So the backlog is moving through
5 toward approval.

6 In keeping with GDUFA's third core
7 purpose of improving transparency and feedback
8 with industry, we respectfully urge FDA to clarify
9 issues relating to determining the status of
10 pending ANDAs and approval timing so that
11 applicants are prepared to launch immediately upon
12 FDA approval to allow enough time to secure raw
13 materials, plan production schedules, manufacture
14 and coordinate distribution among many of the
15 other pre-launch activities necessary so that
16 industry can be prepared to provide more
17 affordable products on Day 1.

18 Industry cannot plan appropriately
19 without better predictability and potential
20 approval times and Agency action dates. When too
21 much is made or there are significant delays in
22 launch, expired drug must be disposed, resulting

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1 in unnecessary waste. Additionally, when there
2 isn't enough visibility to know when to expect
3 approval, production delays are incurred counter
4 to the purposes of Hatch-Waxman of being there on
5 the earliest possible date.

6 We urge FDA to revise its internal
7 communication policy to align the purposes of
8 GDUFA and to improve communication and
9 transparency with industry with particular
10 emphasis on applications that are within at least
11 that 6-month time period for which no legal
12 barriers exist that would allow them to be
13 eligible for final or tentative approval.

14 In conclusion, we appreciate the
15 opportunity to share some of these general
16 comments and considerations that shape the
17 Agency's thinking around implementation as a
18 whole. It's these collective principles of
19 safety, access, and transparency, the Hatch-Waxman
20 program, and the strong focus on science that have
21 been the fundamental underpinning of the industry
22 for the last 30 years and have allowed us to get

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1 to the savings that we're able to offer to
2 patients, and we look forward to continuing to
3 partner with you to navigate through
4 implementation to ensure that GDUFA is implemented
5 as intended to get faster medication to patients.

6 So thank you.

7 MS. TOUFANIAN: Thank you very much.

8 Questions from the panel?

9 MR. FLANAGAN: Thank you for your
10 comments.

11 So I'm curious about the \$1 billion
12 number you cited.

13 MS. McCLINTIC COATES: Yeah.

14 MR. FLANAGAN: Are those submissions
15 where there are no scientific and technical review
16 issues outstanding inspection or compliance issues
17 outstanding, and no outstanding Hatch-Waxman
18 patent, legal, or related issues outstanding?

19 MS. McCLINTIC COATES: Yeah. It's a
20 good question. So of what was estimated in known
21 delays for first generics, it's a variety, and
22 candidly I would say that some of those, I

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1 couldn't tell you if they have those outstanding
2 because not the full visibility of the status of
3 the applications are available to know where delay
4 may sit, but the median review time for that
5 category is around 55 months of pending Agency
6 review.

7 MR. FLANAGAN: I'm sorry. So the answer
8 to my question is we don't know?

9 MS. McCLINTIC COATES: Well, as part of
10 the follow-up with the Agency, many of them vary.
11 Some of them do have -- are pending and you know
12 because the agencies recently ask you for a
13 comment. I don't have full visibility into all of
14 them because it was a blinded pulse check with
15 (inaudible), but some of them, we don't know if
16 things, where they're still -- some of them are
17 kind of languishing because you don't have that
18 full transparency about where the state may be.

19 MR. FLANAGAN: Well, the implication is
20 that -- or maybe I'm being hyperdefensive -- but
21 the implication of the number, which is large,
22 and, you know, arguably inflammatory, is that

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1 there is a billion dollars in lost cost savings
2 due to FDA dropping the ball, and my perspective
3 is that if the submission has quality challenges
4 and is not approvable or if there are outstanding
5 patent exclusivity or related Hatch-Waxman issues
6 that are out of our control, then how is it fair
7 to say that there's a billion dollars in lost cost
8 savings that could otherwise have been reaped if
9 the submission is not of high quality and there
10 are outstanding Hatch- Waxman issues?

11 MS. McCLINTIC COATES: Yeah, I can't
12 speak to these are not high quality from the ones
13 that you're referencing for the time period of
14 which they are at, and these are ones that the
15 date has passed by, a patent has expired or so
16 forth. So in terms of the straightforward pending
17 Hatch-Waxman pieces, it's not known to whether
18 those have those, but I think the broader point
19 that you're raising, and it's a big one, it is a
20 shared commitment between the Agency and the
21 industry to get there on Day 1. It is a
22 partnership between both of us dialoguing back and

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1 forth. In order for us to both get there on Day
2 1, we have to know where things stand, and the
3 Agency has its piece of review also. If we're
4 both going to get there on Day 1 and you send us
5 back comments and we then take an eternity to
6 respond to those back, then that also pushes out
7 Day 1.

8 So your point is the right one from a
9 standpoint of it's a share between Agency and
10 industry of where it is. It isn't necessarily
11 that all of that is on FDA, but it's on all of us
12 if we are missing the opportunity for Day 1s when
13 we can strive to get there, and that's why some of
14 the comments from this morning I think are very
15 helpful in terms of, what can we do up front to
16 make sure that some of the things that straggle on
17 down the road in your review, that you can try to
18 avoid them. So things like the controlled
19 correspondence guidance, clarification calls that
20 are maybe needed whenever guidances are coming
21 back, some presubmission meetings if it
22 necessarily warrants it, if you're dealing with a

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1 complex novel much like what Rob Lionberger
2 outlined at the GPhA Fall Tech meeting. All of
3 those sorts of things collectively go toward that.
4 So I'm not suggesting that it's as straightforward
5 as that, and this is a point, and no one should
6 interpret that. It's on both of us on both sides,
7 and it's a reality that as we look at this issue -
8 - and I'm pleased that the Agency is really
9 looking at it from that Hatch- Waxman lens right
10 now and the unique scenarios -- the reality is no
11 two applications are alike, and as we look at the
12 freight -- and there is over 3,000, or whatever
13 that number is -- that's the piece that we're
14 looking at, and what are the ones that we can take
15 off, and how do we move them forward quicker at
16 the end of the day, our same shared goal?

17 MR. FLANAGAN: And second question, you
18 said that GDUFA contains a productivity level
19 obligation for FDA. You did not qualify that
20 statement. My admittedly imprecise recollection
21 of the language exactly on point was that we had a
22 productivity maintenance of efforts obligation

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1 that was basically a best efforts provision given
2 a laundry list of other --

3 MS. McCLINTIC COATES: You're right,
4 it's an aspiration. And I'm sorry, I thought I
5 said FDA will aspire to maintain the languages,
6 that FDA will aspire to maintain pre-GDUFA levels
7 as FDA ramps up the program. So you're right,
8 it's an aspiration, it's not an obligation with
9 the program, but it's an aspiration that I suggest
10 that we should consider in terms of addressing
11 much of the comments and feedback from folks about
12 this backlog and how can we make sure that the
13 public health goals are continued to be met, that
14 those important medicines that are in there? Is
15 that something we can all push ourselves to strive
16 for, both us, and the timeliness and responses
17 with pieces, and on your end as well?

18 MR. REED: I have a question on
19 priorities. You gave quite a reasonable summary of
20 what might qualify as a first generic.

21 MS. McCLINTIC COATES: Yeah.

22 MR. REED: I think you mentioned first

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1 applicant to a particular RLD drug shortage and
2 other high priority health care needs, but you
3 also mentioned second generics, and that raises a
4 question I have, which is, how would you propose
5 that we prioritize within those products that have
6 been designated for priority? I would assume that
7 if you have a first-to-file and a second-to-file,
8 that the one -- they wouldn't be treated as
9 equals.

10 So my question is, within all of these
11 ANDAs that are designated as priority, do you have
12 a suggestion as to how we would prioritize within
13 them?

14 MS. McCLINTIC COATES: Sure. So with
15 respect -- and we can provide more comments
16 certainly to the docket because, of course, all
17 things in Hatch- Waxman are nuanced and fun, but
18 in terms of your question here, I would say that
19 the ultimate goal of Hatch-Waxman is to get there
20 on the earliest date that no legal barrier to
21 approval exists. So for that first-to-file, that
22 we're all doing -- it's in all of our interests to

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1 fight for the 180, do not have inadvertent
2 forfeitures, et cetera, to encourage that
3 important incentive. But with respect to 181
4 qualifying, so for those, the legal barrier to
5 approval, keeping with the purpose of Hatch-Waxman
6 to get there on the moment that that legal barrier
7 is lifted, that's going to be lifted on Day 181.
8 So in terms of moving that thing through the
9 process, that should be the striving goal in terms
10 of any compliance that needs to get wrapped up, et
11 cetera.

12 MR. REED: And there might be a dozen of
13 them. So do we strive to have all dozen ready on
14 181?

15 MS. McCLINTIC COATES: I think that it
16 is an important goal to strive toward. Every
17 application is different in terms of where it's at
18 in review, but in terms of the second and third
19 and fourth generics, the overarching purpose --
20 and that's more of what I'm speaking from because
21 a lot of these are fact-specific, but the
22 overarching purpose to drive competition, we know

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1 that when -- we know that from 30 years in the
2 industry that more players in the market are going
3 to drive down to more affordable pricing, and the
4 earlier entry that you can get there, how critical
5 that is.

6 So I just want to make sure I provide
7 that to make sure that those are not forgotten
8 about because there are a number of important ones
9 that are out there. And as the demand has
10 increased, it's difficult for one supplier perhaps
11 to absorb all of the U.S. demand for that, and so
12 for the purposes of shortages and availability and
13 scale and the medication that's involved, those
14 are still very important public health priorities,
15 that as we look at this that we want to make sure
16 are not forgotten.

17 MR. REED: Thanks.

18 MS. TOUFANIAN: Just a follow-up
19 question because I think it's easy for us to
20 identify that first date and it's easy for us to
21 identify that 181 date --

22 MS. McCLINTIC COATES: Yeah.

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1 MS. TOUFANIAN: -- but you referenced a
2 bucket of applications for which they become
3 available due to a settlement agreement sort of
4 off the calendar. And obviously that is a very
5 fluid situation and we may not be able to approve
6 a product the day after we receive notification of
7 a settlement.

8 MS. McCLINTIC COATES: Right.

9 MS. TOUFANIAN: Either today or I would
10 encourage in your comments to identify some
11 mechanisms that we could implement in our office
12 and together with industry to make sort of those
13 spot changes easier to administer if those are
14 going to be contained in that first generic
15 prioritization definition.

16 MS. McCLINTIC COATES: Yeah. Yeah.
17 It's a great point because many of them, to your
18 point, may be through a confidential settlement
19 discussion and sharing that information, and the
20 earlier that we can get that information to FDA
21 obviously, that's critical. So that's a good
22 topic I think for all of industry to consider with

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1 here, and I think we should add that to the docket
2 as well to be able to provide that information.

3 That's just the very fluid nature of the
4 Hatch-Waxman scheme, but our ability to pivot and
5 to be dynamic and move, and it's a balancing act
6 because FDA right now is putting forth any
7 processes and policies and procedures, so given
8 the volumes that we're dealing with, to make sure
9 we strike that same balance that Hatch-Waxman
10 struck to balance whenever that happens because
11 some things are going to get rattled and changed,
12 so how can we do that? I would urge my other
13 industry colleagues to submit comments around
14 exactly that point as the Agency struggles with
15 that and we struggle with you with that to make
16 sure that that happens.

17 DR. UHL: So in the spirit of clarity
18 here, because you and Keith are going back and
19 forth about language, I would just like to set the
20 record straight -- and we do have a recording for
21 this -- so since I carry my GDUFA commitment
22 letter with me everywhere I go, Page 3 of the

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1 commitment letter or the goals letter or whatever
2 it is you want to call it, so we're all talking
3 about the same document, Roman numeral Number VII,
4 "FDA will aspire to the extent possible to
5 maintain levels of productivity at least similar
6 to pre-GDUFA levels while hiring and training
7 incremental staff necessary to achieve the program
8 performance goals, building necessary systems, and
9 implementing outlined program changes in Years 1
10 and 2 of the program." So just so we're all clear
11 on language.

12 But I do have a couple questions for
13 you, Marcie, if you wouldn't mind.

14 MS. McCLINTIC COATES: Sure.

15 DR. UHL: You state that not all
16 applications should be treated alike. So in a
17 GDUFA system where there are goals, GDUFA goal
18 dates, attached to an application, how would you
19 propose that? And maybe you're not talking about
20 ones with goal dates and you're talking about
21 stuff that's in Years 1 and 2.

22 MS. McCLINTIC COATES: Yeah. No. I

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1 actually am referring to all of it. Just from a
2 standpoint of from an alike standpoint, it comes
3 back to public health. So the goal dates in the
4 CR letters and so forth were all vehicles to help
5 us get to that ultimate end of fulfilling that
6 public health piece. So from that standpoint and
7 appreciating that the applications that are
8 submitted regardless of what goal date they may
9 have to try to keep them moving through given the
10 mass volume that the Agency is working through, in
11 terms of treatment of appreciating that these all
12 may have different nuances, it's because of the
13 fact that, goal dates aside, the Hatch- Waxman
14 framework that links the patent resolution process
15 to the approval process, that linkage that exists
16 here and unlike anywhere else in the world, it
17 makes applications by their very nature different
18 and, additionally, so do the public health needs
19 of each of those applications. So, you know, an
20 application may be there to address a shortage, an
21 application may be there to cover an orphan
22 indication that hasn't had a more affordable

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1 generic, and we would urge that as we are
2 implementing this program aimed at giving FDA the
3 resources needed to continue to achieve the
4 purposes, that we not lose sight of those same
5 purposes of allowing for the public health ones,
6 most impacting public health ones, and the ones
7 that are linked to Hatch-Waxman, to move through
8 on their earliest date. The Hatch-Waxman statute
9 continues to provide that FDA should strive for
10 180 days, and that's still in the statute. These
11 goal dates are, though, intended to continue,
12 compared to where we have been, with the volumes
13 at 31 to get those pieces back and to help us move
14 to a place over time the first cycle approvals.

15 DR. UHL: So I think it would be helpful
16 for the Agency to hear in the docket what industry
17 thinks public health impact is because I think
18 that's a -- you've seen in the Prioritization Map
19 what we think are public health priorities, but I'm
20 hearing much broader than that from you, Marcie.

21 I would like another bit of
22 clarification because one of the comments you made

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1 was a first generic is when the product is brought
2 to market. So are you saying that a first generic
3 that's approved and not brought to market, because
4 that happens obviously in some of the settlements
5 that you guys have, where would you consider that
6 in the scope of first generic?

7 MS. McCLINTIC COATES: So what I
8 reference is that so first generics that include
9 applications which no other generic version of the
10 same reference has even yet brought to market. So
11 technically in that example, you may be your
12 traditional first-to- file qualifying for 180,
13 going to open up the marketplace, but there are
14 scenarios where that very first filer just decided
15 to withdraw and they never actually marketed the
16 product. So the American marketplace, patients
17 continued to not have access to a generic, and so
18 that would technically be a first generic that's
19 opening the door for that.

20 So they are not necessarily a P4
21 traditional first-to-file. There are those
22 scenarios. Does that help?

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1 DR. UHL: It does. Thank you.

2 MS. TOUFANIAN: Anybody else?

3 MR. FLANAGAN: I just want to express
4 gratitude and appreciation for the amount of time
5 you invested in preparing for this. You took it
6 really seriously and devoted a lot of thought to
7 it. So thank you.

8 MS. McCLINTIC COATES: Thank you for
9 your time. I appreciate the opportunity and look
10 forward to working with you more as we work to
11 tackle our shared challenge of getting access.
12 Thank you.

13 MS. TOUFANIAN: Thank you very much,
14 Marcie. Unfortunately, the agenda I have in my
15 book may be out of date, so are we moving to --

16 MR. FLANAGAN: Is that on? It's open?
17 Is it open?

18 UNIDENTIFIED MALE SPEAKER: No.

19 MR. FLANAGAN: It's open mic, though not
20 totally open.

21 MS. TOUFANIAN: I believe that certain
22 individuals did indicate a wish to speak. And

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1 we're having some technical difficulties.

2 (Pause.)

3 MS. TOUFANIAN: Terrific. It looks like
4 Ken Cappel. And I have to apologize in advance, I
5 am reading sideways, so I will obviously
6 mispronounce some of these names.

7 Ken, can you go ahead and introduce
8 yourself and indicate where you're from?

9 MR. CAPPEL: Sure. Good afternoon. My
10 name is Ken Cappel. I'm the Vice President of
11 Global Intellectual Property for Amneal
12 Pharmaceuticals. I would like you to know that
13 I'm a pharmacist as well. I take my
14 responsibilities to the patients very seriously.
15 And I'm also an attorney and take my
16 responsibilities to the client very seriously.

17 I gather I have a little extra time, so
18 I'm going to do my whole statement.

19 Amneal would like to thank you and the
20 Agency for holding this conference. We appreciate
21 the opportunity to assist the FDA in matters that
22 are important to the public health and the generic

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1 industry.

2 The Agency and our industry are aligned
3 in that together we seek to provide the U.S.
4 health care system with cost effective medicines
5 that are equally safe and effective when compared
6 with our brand counterparts. This is clearly our
7 common goal.

8 Our parents, grandparents, and children,
9 our neighbors and friends, and countless other
10 patients benefit from the availability of generic
11 medications. In fact, this very sentiment is
12 reflected in the following quote from Amneal's
13 website. "We at Amneal understand that every
14 product the company manufactures is destined for
15 someone's loved one. Quite simply, together we
16 have a responsibility to these individuals.
17 Hearings like this provide an opportunity to
18 facilitate dialogue and change. Ultimately we hope
19 to achieve our common goal."

20 As background, Amneal is a U.S. company
21 headquartered in New Jersey with additional key
22 sites in New York, Kentucky, and other locations

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1 outside the U.S. Amneal currently employs more
2 than 2,300 people globally. Over half of these
3 R&D, manufacturing operations, and other
4 professionals are employed within the United
5 States.

6 Our portfolio of approved products
7 includes about 100 solid, oral, topical, and
8 liquid finish dosage forms. We currently have
9 over 100 ANDAs pending at the FDA and several of
10 these filings are believed to be first-to-file
11 opportunities. Obviously these filings are
12 exceptionally important to Amneal.

13 Amneal has achieved exceptional growth
14 over the past 10 years. This growth has resulted
15 in the creation of over 1,000 U.S.-based jobs.
16 Amneal's expansion is supported by a strong
17 commitment to investing in R&D and growing its
18 infrastructure to support manufacturing in the
19 United States and abroad.

20 Amneal's ability to reinvest depends
21 heavily on the revenues generated by sales of
22 products which, without timely FDA approval, will

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1 almost certainly fall short of the expected return
2 on investment needed to sustain growth. Amneal
3 fully recognizes that this is a two-way street,
4 improving transparency in the approval process
5 specifically regarding first-to-file products will
6 help to achieve our common goal.

7 GDUFA was supposed to improve many
8 aspects of the ANDA approval pathway. Notably,
9 Amneal expected that GDUFA fees would improve
10 communication and feedback from the FDA, which in
11 turn would lead to higher quality ANDA filings and
12 decreased approval times. Unfortunately, this has
13 not yet been realized.

14 Amneal would like to address GDUFA and
15 180- day exclusivity. Specifically, we are deeply
16 concerned with the lack of communication
17 surrounding first-to-file opportunities and the
18 need to obtain tentative approval within the 30
19 months of ANDA filing.

20 As you know, to be eligible for 180 days
21 of marketing exclusivity, a generic filer must be
22 the first applicant to file a substantially

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1 complete ANDA containing a paragraph for
2 certification. Congress enacted numerous
3 amendments to the Hatch-Waxman Act under the 2003
4 Medicare Modernization Act, and under the amended
5 statute, the first applicant could be deemed to
6 forfeit its eligibility if it failed to receive
7 tentative approval 30 months from the date the
8 ANDA was accepted by the FDA unless that failure
9 to obtain tentative approval was caused by a
10 change to the requirements for approval of the
11 application imposed after the date on which the
12 application was filed.

13 There is a lack of communication from
14 the FDA on these first-to-file applications, which
15 creates uncertainty for the applicant and the
16 other ANDA filers. This unpredictability actually
17 creates additional work for the Agency because the
18 industry that's really seeking feedback -- excuse
19 me -- that's really seeking feedback from clarity
20 typically undertakes letter writing campaigns in
21 an effort to ascertain the status of the
22 application as the critical 30-month date rapidly

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1 approaches. Unpredictability also hinders launch
2 planning and can result in a delay of generic
3 products reaching the public as early as possible
4 as well as potentially costing first filers
5 significant revenues generated during the
6 exclusivity period.

7 We also understand that the Agency is
8 navigating relatively new issues regarding risk
9 evaluation and mitigation strategies and abuse-
10 deterrent dosage forms. Dealing with these issues
11 may significantly delay FDA approval, which poses
12 a risk to the 180-day exclusivity. The industry
13 needs transparency regarding FDA's expectations
14 and concerns in these areas. This will allow the
15 industry to have some measure of predictability
16 while the FDA attempts to navigate these new
17 waters.

18 The FDA's anticipated use of target
19 action dates are an important step in the right
20 direction. Amneal now has more than 100 ANDAs
21 pending review, none of which has a goal date. We
22 have a heightened concern about the future of our

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1 first-to-file submissions. As the FDA has
2 indicated, it intends to focus on new submissions
3 beginning October 1, 2014. The Agency has said
4 that it will issue target action dates only for
5 prioritized applications, and this creates an
6 intolerable level of uncertainty around critical
7 first-to-file ANDAs.

8 On behalf of Amneal, I request the FDA
9 to issue target action dates for every first-to-
10 file submission within 60 days. In addition, we
11 request the FDA to open its channels to allow for
12 early and frequent communication on these
13 immensely important filings. Our common goal can
14 only be met through a stronger partnership, and I
15 assure the Agency that Amneal and the generic
16 industry stand together with you. We recognize
17 the hard work and dedication of the FDA, and we
18 are committed to working with the Agency in its
19 efforts to continually improve the ANDA approval
20 process. Thank you again for the opportunity to
21 speak on behalf of Amneal Pharmaceuticals.

22 MS. TOUFANIAN: Thank you, Ken. Any

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1 questions from the panel?

2 MR. FLANAGAN: Sorry. I do have a
3 question. Thank you very much.

4 So on the communications transparency
5 issue with respect to the first-to-files, you
6 know, we're building a robust RPM staff, and
7 hiring and training to make that happen. They
8 won't be able to be -- in the immediate short
9 term, they're not going to be like legacy OGD
10 staffers who have been here for decades and can
11 give you a sophisticated read on the regulatory
12 path forward on that submission; right? As a
13 practical matter, if we're going to give you some
14 sort of update, it probably needs to be kind of
15 formulaic, enough into the review so that we have
16 something to report, but far enough back from the
17 goal date so that it gives you enough advanced
18 notice.

19 It's the same question that I had for
20 Mr. Gaugh, is in your view, which data points in
21 general are the most helpful to you in trying to
22 plan a product launch? What data points do you

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1 most crave?

2 MR. CAPPEL: Right. So I'm not punting,
3 but from my experience, each product really it's
4 like a person with its own personality, and so the
5 issues that you're dealing with each product are
6 so different. So, for example, chemistry may be
7 the critical datapoint for certain products, but
8 then if you're dealing with REMS or ADF, then the
9 labeling is clearly critical as well. You know?
10 So it's hard to really give you a clear answer, I
11 wish I could, but I think it's very fact
12 sensitive.

13 DR. UHL: Can I build on Keith's? Just
14 so -- I understand your point, but there is a need
15 for consistent processes, and so where are there
16 similarities that would be helpful for us so that
17 we can find these touchpoints, which Keith is
18 trying to elucidate from you? So I understand
19 every product is unique, but not all products are
20 entirely unique. There are a range of similarities
21 across them.

22 MR. CAPPEL: I agree.

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1 DR. UHL: And that would be helpful for
2 us to hear.

3 MR. CAPPEL: Right. So I think maybe
4 what we could do as an industry is go back and
5 discuss trying to put some comments into the
6 docket for you and maybe put different buckets of
7 projects together, and obviously there will be one
8 miscellaneous, which is going to be difficult, but
9 we'll talk about that.

10 DR. UHL: Because you would hate to hear
11 us say back to you that everything is unique, so
12 we can't create any process.

13 MR. CAPPEL: Of course. I realize that.
14 I realize that I've heard a lot of that today, and
15 we talked about that at lunch, that it's a problem
16 that we need to work together to overcome. You
17 shouldn't be put in that position by us, and we
18 don't want to be put in that position by the
19 Agency.

20 MR. FLANAGAN: And I think the message
21 we do want to send today as an Agency is that we
22 do get it, we do understand that you need some

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1 information for product launch purposes. We
2 understand that.

3 MR. CAPPEL: Great. Thank you very much
4 for your time.

5 DR. UHL: Thank you.

6 MS. TOUFANIAN: I just have one follow-
7 up request. I think I will be the one giving
8 everybody homework today. One of the things you
9 mentioned was increased communications with regard
10 to ANDAs that are approaching a 30- or 40-month
11 forfeiture date. I would encourage you in your
12 comment to identify precisely when and what
13 mechanisms you would want us to use for those types
14 of communications.

15 MR. CAPPEL: Okay. Thank you very much.

16 MS. TOUFANIAN: Thank you.

17 Carolyn Huntenburg, from Momenta.
18 Welcome.

19 DR. HUNTENBURG: My name is Carolyn
20 Huntenburg. I'm with Momenta Pharmaceuticals, and
21 I thank you for the opportunity to talk about from
22 Momenta's perspective. Much of what I am going to

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1 say has been said throughout the day, so I'll go
2 ahead and start.

3 Momenta believes that in order to bring
4 new generic drugs to the market effectively,
5 frequent and informative and timely communications
6 between the FDA and the ANDA sponsor are critical.
7 Timely two-way communication calls for both
8 parties to anticipate and/or respond to the
9 actions necessary to bring new generic drugs to
10 market in a safe, efficient manner.

11 One of the key components of the GDUFA
12 program is transparency, which includes
13 communication to the industry. Transparency and
14 communications were critical issues during the
15 GDUFA notifications. One of the principle reasons
16 for paying a user fee was to establish a
17 predictive process that will support industry to
18 be able to provide safe, effective, and affordable
19 medications to patients.

20 Over the past year, since the
21 implementation of GDUFA as well as complete
22 response letters, our experience has been that

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1 meaningful communications about ANDA status has
2 become significantly restricted. This restriction
3 and allowable and substantive communication
4 between the ANDA sponsor and FDA is dictated by
5 OGD policy where OGD staff are not allowed to
6 provide ANDA sponsor with any specific information
7 regardless of whether it is critical or not until
8 the complete response letter is received. This
9 restrictive communication has undoubtedly delayed
10 the sponsor's ability to react to the information
11 when received and likely results in a delay in
12 approval. These issues will be only further
13 magnified by the complexity of applications
14 received by the FDA increases.

15 Patients benefit from earlier approvals.
16 If there are more timely informal communications,
17 particularly with complex applications, the
18 applicant can work in parallel on important
19 additional development requirements while the FDA
20 reviews other aspects of the filing. This will
21 allow parallel processing and would significantly
22 improve the advancement of approval dates.

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1 Currently, if all feedback is held, then the
2 effort of the Agency is magnified in scope for
3 each review, and the applicant sits idle during
4 the review period, which is a highly inefficient
5 process.

6 Momenta strongly urges the FDA to
7 implement an effective ongoing and substantive
8 communication process between the industry and the
9 FDA throughout the ANDA review process. By doing
10 so, the use of resources and times on both sides
11 is conserved. The benefit of increased
12 communication will surely reduce inefficiencies in
13 the process that currently exist and, more
14 importantly, assure timely access to affordable
15 generic medicines. Thank you very much for this
16 opportunity.

17 MS. TOUFANIAN: Thank you. Any
18 questions from the panel?

19 (No audible response.)

20 MS. TOUFANIAN: Thank you for your time.

21 DR. HUNTENBURG: Thank you very much.

22 MS. TOUFANIAN: Carole?

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1 DR. BEN-MAIMON: I'm struggling whether
2 or not to use these glasses or not.

3 I also want to thank the Agency for this
4 open dialogue. I think if you put all of the
5 exchanges we're having between the exchanges you
6 have with GPhA, those at the FDA quarterly, and
7 these ongoing forums, I think it really does add
8 value to ensuring in the long term we get to where
9 we need to go, which is obviously taking care of
10 patients.

11 You may or may not know, I'm a physician
12 by background. I'm President of the Generic
13 Division of Impax Laboratories. We develop,
14 manufacture, and sell generic drug products. We
15 are a mid-sized company, and so I actually
16 represent companies that are small to mid-size in
17 some of my remarks, which may differ from some of
18 our larger colleagues.

19 And you also know this is a very
20 diversified industry. From the morning, you heard
21 from CMOs. We have our API suppliers. We have
22 small companies and mid-size companies, and then

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1 our very large colleagues. And not all of our
2 needs are always the same, and that's a challenge
3 for you, and we acknowledge that.

4 It's really interesting to me that, as
5 Marcie stated, we're coming up on the 30-year
6 anniversary of Hatch-Waxman, and as we all know,
7 Hatch-Waxman struck a very subtle but very
8 important balance between the brand and the
9 generic industry, and it was intended to stimulate
10 -- and I think this is really a crux of what we're
11 talking about here -- it was intended to stimulate
12 competition, and in stimulating competition, it
13 actually accomplished two goals, one was cost
14 control for pharmaceutical products, but the other
15 was it stimulated innovation in the brand industry
16 as well because if you had competition, you were
17 going to start innovating and creating new things.
18 And so keeping that balance as we move forward and
19 ensuring that competition exists both in the
20 industry and for branded products when appropriate
21 is really I think what we're actually talking
22 about as we move forward. Patients and consumers

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1 obviously have benefited through this competition
2 and the availability of lower cost products.

3 In the last 10 years, as you heard
4 earlier, we saved over a trillion and a half
5 dollars. \$239 billion of that was just in 2013
6 alone. This is as a direct result of the
7 availability and access to generic drugs, so it's
8 crucial that as GDUFA is implemented, we don't
9 undermine patient access to high-quality, low-cost
10 generics.

11 Competition is critical to the continued
12 success of Hatch-Waxman. Maintaining competition
13 serves the public good and decreases health care
14 costs.

15 With that in mind, focusing on complex
16 products where there are no generics available and
17 a pathway for those is important. Focusing on
18 first generics and P4 filings and ensuring access
19 at the earliest legal point is important, but that
20 doesn't minimize the need and let us lose sight of
21 the need for competition where the science may be
22 simple or where there are multiple products out

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1 there that could at any point become an issue for
2 shortages. So looking at all of these
3 applications is important.

4 And I'm very sensitive to the need to
5 prioritize. And I don't want to underestimate the
6 challenge that exists at FDA with the volumes of
7 applications you have. That said, it is only
8 through competition that we actually achieve our
9 goals, increasing access and controlling costs.

10 So although it is critical to ensure
11 that the first generic is approved and available
12 at the earliest legal date, accomplishing that
13 goal is just not enough, it doesn't get us where
14 we need to go. In order for competition to thrive
15 and truly maximize value to the consumer, it is
16 essential that the Agency continue to prioritize
17 and approve multiple applications for the same
18 references to drug. In fact, the opening
19 paragraphs of the GDUFA goals letter clearly lays
20 that purpose out.

21 By bringing greater predictability to
22 the review process and ensuring greater

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1 transparency with regard to review time, GDUFA
2 intended to increase and expedite access to low
3 cost, high quality generic drug products. I think
4 it's important to remember that if you talk to
5 generic customers, they would find that price
6 decreases with the introduction of each and every
7 generic drug drives down costs. These costs
8 continue to decrease with the entry of multiple
9 generics, even the fourth, fifth, and sometimes
10 sixth and seventh generic drugs. So simply
11 looking at the very first one is really the
12 beginning of the story, it's not the end of the
13 story.

14 In addition, all products have a product
15 lifecycle. Even older products in mature markets
16 where there have been multiple approvals and
17 intense competition don't always exist and stay on
18 the market. There are many products that we all
19 know exist have 5, 7, 10 approved ANDAs, but there
20 may only be two products commercially available.
21 In some of these cases, ANDAs are discontinued,
22 plants are closed, applications are withdrawn,

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1 whatever the reason, the market ends up being only
2 a very few commercially available products.

3 Because these products have no patents,
4 they may actually be more attractive to smaller
5 companies because they don't have to pay the
6 litigation fees and sometimes the cost of
7 development or the path to approval is more
8 straightforward. So they seem simple and they
9 seem unimportant, but if you look at it in the
10 eyes of the consumer, they actually are very
11 important. And so with that said, it is really
12 important that we continue to look at these
13 products.

14 The approval of these ANDAs may aid in
15 preventing drug shortages. As we know, it's an
16 incredible problem, but there are many cases in
17 the industry where there are only two products on
18 the market, something happens to the API supplier
19 of one, something happens to the ability of that
20 company to manufacture, and all of a sudden we're
21 facing a shortage in those arenas, and they're not
22 always foreseeable. It also maintains

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1 competition, which will also increase and ensure
2 the continued low cost availability of these
3 products.

4 So with that in mind, first generics I
5 think really, like I said, are incredibly
6 important, but we need not to ignore all the
7 others.

8 It is for these reasons, while I
9 recognize the importance of reviewing and
10 approving the first generic, that's not where we
11 can stop. Timely approval of subsequent generics
12 is immensely important to a healthy generic
13 market. Each and every ANDA, whether submitted in
14 year 3, 4, or 5 of GDUFA implementation or whether
15 submitted in year 1 or 2, or, for that matter,
16 sitting in the pile of more than 3,000
17 applications in the backlog, serves to ensure a
18 robust generic supply. This in the end serves
19 patients and consumers and ensures access to low
20 cost generic drug products.

21 I really want to assure the Agency that
22 all of us in this room are sensitive to the

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1 magnitude of what we're undertaking. Quite
2 honestly, I've worked on the brand side and the
3 generic side, and I think PDUFA pales in the face
4 of GDUFA. The dollars involved are very
5 different. The length of review, the types of
6 data, the number of applications for any one
7 reference listed drug is a real challenge. And so
8 I don't think it's that we aren't sensitive to the
9 issues, we are very sensitive to the issues, and,
10 as Marcie said, I think we want very much to
11 partner with the Agency.

12 I also want to say something else about
13 small and mid-sized companies that I think is
14 important. It may appear to the Agency that those
15 companies are not engaged in this process. They
16 are very much engaged. We just don't have the
17 resources that some of the bigger companies do.
18 We don't have somebody dedicated to government
19 affairs. I am it. So we use our industry
20 association often as a resource to help supplement
21 some of our issues and to engage with you because
22 we don't have the number of people that we can

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1 just dedicate somebody to the issues that you deal
2 with.

3 And so I think if we can reach out -- if
4 some of the smaller companies, you can reach out
5 to them, you can hear some of the issues that we
6 deal with that not all of the big companies may be
7 dealing with. A lot of the smaller companies
8 don't have P4s, they just don't do them because
9 they don't have the legal wherewithal, they don't
10 have the financials, to support the P4
11 environment, but it's the small companies
12 that ultimately become big companies.

13 And I've worked for many small companies
14 who quite honestly 20 years ago were very small
15 and today they're really big. And so it's those
16 small companies that actually grow and help
17 improve and ensure the competition and the success
18 of Hatch-Waxman. So we look forward to working
19 with you, we look forward to the implementation of
20 GDUFA, and we look forward to GDUFA2.

21 So I'll open it to questions.

22 MS. TOUFANIAN: Thank you very much for

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1 your comments. Any questions from the panel?

2 DR. UHL: Yeah, I have questions. So I
3 recognize what you're saying about the smaller
4 companies maybe not having a stake in the ground
5 for the P4 first-to-files. So do you have any
6 suggestions, recommendations, et cetera, around --
7 because your point is don't leave the other ones
8 behind.

9 DR. BEN-MAIMON: Yeah.

10 DR. UHL: There may be circumstances
11 where the not first-to-file is a bolus of a large
12 number of applications.

13 DR. BEN-MAIMON: Yeah.

14 DR. UHL: So are there recommendations
15 on how do we prioritize that or how do we look at
16 that?

17 DR. BEN-MAIMON: And it's a struggle.

18 DR. UHL: Yeah.

19 DR. BEN-MAIMON: It's a struggle because
20 obviously in an ideal world you would have the
21 resources to approve all the applications in a
22 timely fashion, and we know it's not likely to

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1 happen and it's clearly not likely to happen in my
2 lifetime.

3 MR. FLANAGAN: We'll get there.

4 DR. BEN-MAIMON: What?

5 MR. FLANAGAN: We'll get there.

6 DR. BEN-MAIMON: So obviously at least
7 in the short term we need to look at that.

8 And I've sort of toyed around with
9 ideas, and I would like to go back, and we will
10 file something to the docket, but the concept of
11 really trying to look at an argument for the
12 public good, I've sort of thought about, is there
13 something that's similar to the benefit-risk
14 assessment that you do on a brand product that
15 would allow you to make the arguments on a generic
16 product? But then that throws it sort of back in
17 your line where you've got to go through all these
18 benefit-risk assessments and trying to figure out,
19 well, which one fits where?

20 And so I think we, as an industry, have
21 to hash it around, but what I really wanted to do
22 today was really introduce the concept that it's

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1 not so obvious. And it's important to the small
2 companies, but more important, like I said, it's
3 important to consumers because it's a lot of the
4 smaller companies that are manufacturing the older
5 drugs that aren't quite as sexy where companies
6 have gone out of the marketplace, and we are at
7 risk either for shortages or for less competition
8 and therefore not meeting the requirements or the
9 intent of Hatch-Waxman.

10 And so I think we need to toss it around
11 as an industry, but I think opening the dialogue
12 was really my intent.

13 MS. TOUFANIAN: Thank you.

14 Anything else?

15 MR. SHIMER: I have a comment. One of
16 the things -- you know, I've worked at the Office
17 of Generic Drugs for a little over 14 years now,
18 and one of the things I've seen over time is when
19 we do endeavor to get multiple applications
20 approved for a specific drug product by a goal
21 date, it's very seldom that all of those folks end
22 up launching their products, yet that all ends up

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1 being work on our reviewers' shoulders, so we have
2 multiple highly skilled technical reviewers
3 spending a lot of time reviewing these for the end
4 result of an approval but a product that doesn't
5 appear in the marketplace, and we end up hearing
6 time and again we need all these approvals to get
7 -- drive prices down, yet ultimately when we have
8 10 or 12 or 14 approvals for a drug, not everybody
9 goes to market. How would you suggest that we, as
10 an agency, balance that in any of our
11 considerations? Could we or should firms state
12 that they will go to market for a specified period
13 of time?

14 DR. BEN-MAIMON: So I hear you and I
15 think that's a really important point because we
16 all know of a bunch of different situations.
17 There are the 10 or 12 approvals and only 6
18 launch. We know the resources are still spent on
19 the others. There are situations more recently,
20 quite honestly, where there were companies decided
21 not to launch and were sorry because only four or
22 five companies came out and then there was a

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1 shortage in the marketplace and really prices did
2 hold up. So from a perspective of the industry,
3 they wish they had been there.

4 There are situations clearly where you
5 spend resources and we pull applications. And
6 that's a very big issue I think is more that we
7 can't -- we are making business decisions. If the
8 drug isn't going to be profitable, if we can't
9 even make back the money on our validation
10 batches, why would we launch? And where that
11 occurs, whether it's at 4, 5, 6, or 7, I can't
12 tell you, but the fact of the matter is -- and I'm
13 going to be a little bit of a bull in a china
14 closet, and I'm not meaning to offend anybody, all
15 of those applications pay user fees, so they're
16 entitled to a review technically. So, I mean, if
17 you don't want to charge the seventh, eighth, and
18 ninth, that may be a solution. I'm only kidding.
19 But the fact of the matter is in the user fee
20 world, there is an obligation to pay the user
21 fees. I mean, that's sort of I think where a lot
22 of us feel about the backlog issue, is we paid

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1 backlog fees.

2 Now, again, I understand you have
3 thousands and thousands of applications with
4 limited resources and lots of new people and this
5 isn't all going to work itself through in 6
6 months, I get it, and we run companies and we have
7 our own challenges, but you can see from our
8 perspective that we obviously file the application
9 with the intent to launch. We don't make the
10 investment in the R&D dollars and in the GDUFA
11 numbers and all that. Sometimes delays occur and
12 we get in too late, and so we don't launch the
13 product.

14 But I would also say one other thing,
15 and that is that an approved product still has
16 value, an approved ANDA still has value, and there
17 are also situations where, at least at our
18 company, we have chosen not to launch but 6 or 8
19 months later we decide the market is actually more
20 attractive than we thought it would be. We go
21 back and we make sure we have done all of our
22 validation and everything and we do launch. So I

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1 think an approved application is an application
2 that still I think has value to every company.

3 MS. TOUFANIAN: Thank you very much.

4 MR. LAWRENCE: Good afternoon. My name
5 is Leonard Lawrence, and I'm from Sovereign
6 Pharmaceuticals, and we're that small company that
7 Carole was just talking about. We have about 130
8 people in our company. We're a contract
9 manufacturer, and we do contract manufacture of
10 both generics and NDAs. We also have filed some
11 NDAs and ANDAs under our own name for somebody
12 else to distribute for us because we have no
13 distribution capabilities. So we kind of fit in
14 with all of the things that were discussed today.
15 And so I would like to bring up some information
16 regarding some of the things that were talked
17 about this morning and this afternoon. I have a
18 series of questions for you -- not questions but
19 comments. One is we support some of the comments
20 we're talking about on contract manufacturing this
21 morning about maybe some exemptions for contract
22 manufacturing, so we're pushing that to the owners

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1 of the application. We also support the
2 possibility of a reduced fee for us because we do
3 make a very small profit on what we do make, so
4 maybe a sliding scale or 10 percent of profit or
5 something like that that might be associated with
6 the GDUFA fees because we do push those fees on to
7 our customers. Some are hemming and hawing about
8 it, others are grudgingly accepting it. However,
9 it does increase the cost of generics, and so the
10 cost of generics are going to go up. That's
11 eventually going to be passed on to all customers.

12 That said, I have a series of topics I
13 would like to discuss. One is -- it was just
14 brought to my attention -- that the ANDA checklist
15 was just kaput and I think that was a bad idea, a
16 really, really bad idea, because the content and
17 format and the other guidance documents that are
18 coming out are piecemeals that kind of explain
19 some of the sections associated with that, but not
20 having a whole entire list of what's required in
21 an ECTD, we have that list, what's required ECTD,
22 but not everything in there is required for an

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1 ANDA. So it really gives companies, especially
2 smaller companies, an opportunity to make sure
3 that we have all the information that's needed to
4 be included in an ANDA. In fact, one of the
5 things, being in charge of regulatory affairs for
6 the company, one of the things that we do is we
7 take that list, that checklist, and we put it in
8 Word format, and we link it, so it's like a table
9 of contents in the application, so we link every
10 single thing so it makes it very easy for the
11 reviewer to say, "Okay, you got this, you got
12 this, you got this." By taking it away, then I
13 think it makes it more difficult for us to make
14 sure we're not missing everything and makes it
15 more difficult for you to make sure everything is
16 there. So I would suggest that you reconsider
17 bringing that back in as a tool for the industry
18 to use.

19 Some of the other topics that I do have,
20 talking about the backlog, we do have several
21 applications in the backlog, and we're just
22 concerned that they're not going to get lost in

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1 this whole transition into the GDUFA, and we feel
2 like the GDUFA is a good idea because you have a
3 plan to move forward because going before wasn't
4 working really well because you kept on getting
5 backlogs, and so it's a good thing to move forward
6 to have a plan to move there, but we want to make
7 sure that the applications that are in the backlog
8 don't get lost. If you look at it in the Year
9 2017, I believe it says that 90 percent of the
10 backlog will have a decision made on it. Well,
11 that leaves 10 percent of the applications over 5
12 years or more without any type of decision made on
13 it, and that's a long time. And if you have
14 3,000, well, you've got 300 applications, that's
15 significant. And to a small company like us, that
16 makes a big difference because we are dependant on
17 these applications. We have a little bit of them,
18 we don't have a lot of them, and we're actually
19 getting more, but we're still dependent on these
20 applications, so it can make or break a smaller
21 company in what we do.

22 The next topic is some of the things,

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1 difficult things, that I come across in an
2 application is the IID. I know it was talked
3 about earlier today. We make some liquid products,
4 and it's very difficult with the way it's written
5 to use a tablet for an excipient for a liquid
6 product because tablets don't use the same
7 excipients as a liquid product. You don't use
8 much glycerin or propylene glycol in a tablet than
9 you would in a liquid, so it makes it very hard.
10 And so we end up having to write this huge
11 justification for having a product that -- an
12 excipient that has been accepted in the past that
13 now can be a refuse-to-receive. Also, being a
14 contract manufacturer, we may know that another
15 application has a certain level in it and it has
16 been approved, however, we're making this other
17 application for somebody else, and we can't cross-
18 reference those applications, and so it makes it
19 really difficult, so we end up having to do this
20 complex time-consuming process to justify every
21 time. And my suggestion is that if the IID, until
22 the database is more fully populated, that it may

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1 -- we get a stay on the refuse- to-receive issue
2 associated with that if we're within a reasonable
3 amount of time, again if it is listed as a food
4 product and it's listed in the CFR. There are
5 other references. We're not trying to just give a
6 whole -- a higher amount of excipients in there.
7 However, but if it's been a standard across the
8 industry for a long time, then maybe we should get
9 a little bit of relief from that until that IID is
10 there because it makes it very difficult for an
11 application.

12 Another thing that we've come across
13 that is a policy issue that I think needs to be
14 addressed is the fact that some of the chemicals
15 that we get we need to be within 1.5 micrograms
16 per day. Well, we get that a lot. However, the
17 FDA has already issued toxicology studies to
18 toxicology programs saying that you can have more
19 than that. Also, for example, one of them is a
20 flavoring agent that's commonly used in food, yet
21 we're to keep it down 1.5 micrograms per day,
22 which we can, however, just to go into the

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1 justification for that is very, very time-
2 consuming and onerous on us, so I would like to
3 consider that if there is an established level of
4 toxicity, that you look at that first before
5 forcing that onto a complete response letter.

6 Also, controlled correspondences. One
7 of the things that's associated with controlled
8 correspondences is the fact that we are trying to
9 develop product, but if we don't get a response
10 back within 9 months, then it makes it very
11 difficult because we have somebody that wants to
12 make it and give us money to make it, which is
13 what we're in business for, one of the reasons,
14 and we can't make it because we don't get an
15 answer, and so it makes it very difficult, the
16 time delay, and I know that it will be better, but
17 even 4 months is a long time for certain type of
18 controlled correspondences.

19 And I understand there is a level of
20 difficulty, but I didn't hear anything about
21 prioritizing some of the controlled
22 correspondences, ones that are easy to get done

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1 that are quick, 5- minute answers like Q1/Q2.
2 That's probably not a whole difficult time. You
3 go back to what the NDA is and you can see, are
4 you within 5 percent? Yes or no. It doesn't seem
5 like to be that difficult, yet it's taking months
6 and months and months to get that type of
7 information.

8 Also, putting requirements on
9 generalized requirements, I think it's more of a
10 procedural thing. For example, we do make some
11 solutions and they are oral solutions, and they
12 are pretty much water, and we keep on getting this
13 viscosity thing coming back in there where we need
14 to put a viscosity, and that's really the
15 viscosity is like less than 10. Really there is
16 not really any viscosity to it, yet we're asked to
17 put a viscosity spec in when it really doesn't
18 seem to make sense for it. Now, if it was a syrup
19 which was thick or something like that, it might
20 be applicable, but sometimes it's not applicable.
21 So maybe look at when those type of responses come
22 back, is it really appropriate for this type of

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1 product?

2 Also, the last thing I would like to
3 talk about is the USP. There was a guidance
4 document put out in 2004 on discretion use of USP
5 compendium method changes, but then when the new
6 draft guidance came out, it does say that for a
7 change in USP, you need to do a CBE-30 if you're
8 going to delete a test or you're going to relax a
9 test. However, I understand for active
10 ingredients that's probably not anything that you
11 would want to do, but for excipients, it's
12 creating a lot of difficulty because either we
13 file it or our clients have to file a CBE-30 to do
14 it, and by the time you get that chain moving and
15 getting it there, the reality is if you have a new
16 application that has the current USP in it, you're
17 going to approve it most likely that way, so it
18 really doesn't affect the other one, it's just a
19 process, and you're just adding more to your CBE-
20 30 pile.

21 So those are my comments.

22 MS. TOUFANIAN: Thank you very much.

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1 Any questions from the panel?

2 (No audible response.)

3 MS. TOUFANIAN: No? It sounds like
4 you've put a lot of thought. I would encourage,
5 as we have with all the speakers, to submit to the
6 docket.

7 MR. LAWRENCE: Yes, we will be doing
8 that. Thank you.

9 MS. TOUFANIAN: Thank you.

10 So now in the afternoon we'll go ahead
11 and take a 15-minute break, reconvene at 2:45 for
12 the remainder of the comments. Thank you.

13 (Break.)

14 MS. TOUFANIAN: This afternoon we'll
15 have four more comments starting with John.

16 MR. DUCKER: Unlike Carole, I don't need
17 to think about whether I need the glasses or not.

18 (Laughter.)

19 MR. DUCKER: So good afternoon,
20 everybody. My name is John Ducker. I'm the
21 President and CEO of Fresenius Kabi USA. So I'm
22 not one of these technical guys, don't get too

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1 tough with me on the questions.

2 Thank you for the opportunity to share
3 our experience of the GDUFA implementation thus
4 far. This is a topic that is of critical
5 importance to my company, and my hope is that
6 through dialogue and public hearings like this
7 one, positive change will take place in how the
8 FDA and the generic pharmaceutical companies work
9 together to achieve our common goal of better
10 serving patients and those who care for them.

11 Fresenius Kabi is a global health care
12 company with more than 30,000 employees that
13 specializes in life-saving medicines and
14 technologies for infusion, transfusion, and
15 clinical nutrition. In the United States, we are
16 the second largest supplier of generic injectable
17 pharmaceuticals.

18 U.S. headquarters is near Chicago in Lake
19 Zurich, Illinois. Our portfolio comprises more
20 than 100 injectable drugs and approximately 400
21 dose presentations and includes oncolytics,
22 anesthetics, analgesics, and a wide range of anti-

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1 infectives and other critical care drugs.

2 Fresenius Kabi invests heavily in
3 research, development, and manufacturing
4 operations in the United States and overseas, and
5 the return on these investments relies on the
6 timely approval of our ANDA and prior approval
7 supplements.

8 The promise of GDUFA back in 2012 was to
9 achieve three critical public health goals:
10 improved safety through an increase in inspectors
11 and inspections, creating a level playing field
12 between foreign and U.S. manufacturers; improved
13 access by expediting the approval of low cost,
14 high quality generics; and bringing greater
15 predictability to review timelines, and improve
16 transparency by identifying the facilities
17 involved in the U.S. supply chain and improving
18 the Agency's communications and feedback to the
19 manufacturers.

20 The FDA said it would need additional
21 resources to achieve these goals and made a
22 commitment to drug developers that with new fees

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1 paid to the FDA, we could expect over time
2 measurable improvement in the backlog of drug
3 approval applications in communications and in
4 compliance activities.

5 The GDUFA commitment letter further
6 anticipates at least the aspiration, as Cook said,
7 that during the first 2 years of GDUFA things
8 would not get worse and that productivity would be
9 maintained. Unfortunately, our experience since
10 October 2012 is just the opposite. In the 5 years
11 prior to GDUFA, Fresenius Kabi's average approval
12 time for an ANDA was around 17 months. Today the
13 average is more than 36 months and rising. At the
14 same time, a lack of communication during the
15 approval process has added uncertainty and
16 unpredictability that has further slowed access to
17 lower cost generic medicines.

18 On the positive side, the Agency has
19 been doing a better job of prioritizing approvals
20 and importation of medicines where there has been
21 a drug shortage. In some cases, our products have
22 been approved in weeks, enabling Fresenius Kabi to

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1 help alleviate critical shortages. And I would
2 like to take this opportunity to express our
3 appreciation to FDA's Office of Drug Shortage. I
4 think this is the type of working relationship
5 that could serve as a model for the Agency in
6 terms of information sharing and collaboration.

7 Our experience with drug shortages that
8 are not on shortage tells -- I'm sorry, with drug
9 approvals that are not on shortage tells a very
10 different story. Fresenius now has more than 50
11 ANDAs pending review, none of which has a goal
12 date, and we are concerned about the future of
13 these submissions because the FDA has indicated
14 that beginning October 1st this year it intends to
15 focus on new submissions in order to hit
16 obligatory performance metrics.

17 For the 3,300 total backlog submissions,
18 the Agency has said it will issue target action
19 dates only for prioritized applications. The
20 remaining applications are therefore likely to be
21 further delayed and the drugs that are caught in
22 this regulatory limbo may lose value as generic

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1 prices fall or other companies receive approvals.

2 These drugs represent hundreds and hundreds of
3 millions of dollars of R&D investment to the
4 industry.

5 So on behalf of Fresenius Kabi, I
6 request that the FDA allocates dedicated resources
7 to reduce the ANDA and PAS backlogs in a timely
8 manner and that the Agency issues a target action
9 date for every backlogged application within 6
10 months.

11 Many of you have a service background,
12 and this is an expression that Keith used when he
13 addressed the CEO Summit I think a couple of weeks
14 ago, and it's the principle that no file will be
15 left behind. I think that's critical, Carole
16 talked to it earlier, and I think it's critical to
17 us.

18 Turning to transparency, things
19 unfortunately have deteriorated here as well. As
20 you've heard, the planning and execution of a
21 generic launch is complicated and takes many, many
22 months. Unless manufacturers have line-of-sight to

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1 approval dates, they cannot start these
2 preparations since GDUFA FDA is communicating
3 less, not more.

4 As an example, my company filed a
5 Paragraph 4 ANDA in September 2012, and we have
6 had no response from the Agency in 2 years despite
7 Paragraph 4 filings supposedly being one of the
8 FDA's priorities. When we inquire -- and we do
9 regularly, believe me -- we receive a standardized
10 response asking us to contact the Agency in 3
11 months. We might as well talk to an answering
12 machine. Market formation for this drug is
13 expected to take place in May 2015, and 2 years
14 after filing we still have no idea of whether
15 Fresenius Kabi will have the opportunity to
16 participate. It is deeply frustrating and
17 challenging to manage our business in this
18 communications vacuum.

19 I think maybe some of you experience
20 that vacuum and that frustration in the restaurant
21 at lunchtime. You study the guidelines, the menu,
22 you submitted your order in plenty of time, no

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1 food arrived. You finally managed to track down
2 your project manager or waitress who could only
3 tell you that the kitchen has a backlog of 3,300
4 orders and she can't tell you when your food will
5 arrive. Frustrating. And unfortunately we had a
6 deadline, too, to be back here at 5 past 1:00, so
7 I know some of you didn't get food. So you know
8 what it's like; right? This is the experience of
9 our life.

10 My second request to you, therefore, is
11 that the FDA provides clear and open communication
12 to applicants. If our target action date is still
13 2 years away, tell us so that we can tell
14 physicians, patient groups, and GPOs, and just as
15 important, plan our business in manufacturing.
16 Allow us to be part of the prioritization process.
17 Not all of our submissions have equal priority,
18 not all of them have equal commercial value. So
19 we would like to help the Agency focus its limited
20 resources appropriately, and this, too, requires a
21 greater level of communication than we have today.

22 So thank you for the opportunity to

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1 speak today. I encourage you to support the
2 changes I've outlined, as they will have a
3 positive effect on the FDA's mission, reputation,
4 and on the U.S. health care system. We would
5 welcome the opportunity to work more transparently
6 and effectively with the Agency and we hope that
7 this meeting will be the start of such a process.

8 Thank you.

9 MS. TOUFANIAN: Thank you very much.

10 Any comments from the panel?

11 Yeah, go ahead.

12 DR. UHL: Thanks, John. I appreciate
13 your comments this afternoon. So about your
14 request that all applications be given a target
15 action date, how would industry respond -- or
16 think about this because that plays into the
17 prioritization scheme as such -- because of other
18 aspects of GDUFA, the hiring, training, et cetera,
19 so there will be more staff and more capacity. So
20 being given a target action date that's 2 years
21 out, that's not fixed because that could very well
22 move. So you would want to know about every

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1 single application that you have pending with a
2 target action date that's not fixed.

3 MR. DUCKER: Well, it depends on -- then
4 a target action date has little value if you don't
5 consider it to be fixed or some level of
6 commitment. I understand that a target action date
7 would be a date by which you anticipated giving a
8 complete response. Now, that may not be met 100
9 percent of the time, that I also understand.

10 But we're encouraging a dialogue here.
11 We're all adults, and I think we're not going to
12 hold you accountable to everything you say. There
13 seems to be a fear when we communicate with the
14 Agency that you don't say anything to us in case.
15 You know? And we want to find a way in which we
16 can have a dialogue with you that is responsible
17 on both sides, and that requires trust, and that
18 trust will only come through more and more open
19 communication. But, yes, specifically, I would
20 like to know, even if that date is 48 months from
21 now, and even if it's not a guaranteed date, I
22 would rather know that because it allows me to

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1 plan. We've got this 50 ANDA backlog. We don't
2 know whether they're going to be approved in 3
3 months, 6 months, or 3 years. In 2017, we think
4 90 percent of them might be out; right?

5 DR. UHL: Right.

6 MR. DUCKER: Or at least have a complete
7 response.

8 DR. UHL: Or they'll be acted upon.

9 MR. DUCKER: Exactly. But, you know, we
10 have no knowledge at all, and 2017 is a long time
11 away, and we have to plan business. We have to
12 set budgets, we have to decide whether we're going
13 to lay people off waiting for those applications
14 to arrive, whether we're going to close down
15 manufacturing lines waiting for those applications
16 to arrive. Any transparency, even if it's
17 arranged, even if you took those 3,300 and said
18 these are A's, these are B's, these are C's, these
19 are D's, and these are E's, allow us maybe to
20 comment on that and say, well, we think that E is
21 really important to us. You may think it's a
22 fifth generic, but we think it's very important

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1 for these reasons, can you elevate it to a C? We
2 have that process. And then you can say, well,
3 all the A's, they're going to have 12 months, B's
4 are going to be 18 months, C's are going to be 24
5 months, whatever it is, but give us something
6 because this complete absence of information is
7 killing us, at least it's killing me.

8 DR. UHL: I don't have a follow-on
9 question.

10 MS. TOUFANIAN: Thank you very much.

11 MR. DUCKER: Thank you.

12 MS. TOUFANIAN: Tim?

13 MR. AMES: Well, I wanted to thank the
14 panel for the opportunity to make a comment at
15 this open session, but for the sake of time, I'm
16 going to make this really brief. I did want to
17 extend my sincere appreciation to the OGD people
18 and other people from other parts of the Agency
19 for putting together a Part 15 meeting where we
20 could provide you with comments and you could
21 listen to the comments from all of us.

22 I was going to comment, and I'm going to

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1 send these into the docket on three areas where I
2 think you could do some guidance development in
3 the area of generic drug development. And they
4 include post-approval changes to tentatively
5 approved PEPFAR application to allow for CBE type
6 changes. The next would be to provide some
7 clarification and guidance and clarity on
8 inspection process revolving around the biomedical
9 research facilities involved in bioequivalence
10 studies both of clinical and analytical
11 facilities. And then to reiterate what David
12 Gaugh said about the suitability petitions, how
13 they could be addressed and provide some metrics
14 around the suitability petition so that they could
15 be handled in an expeditious fashion. So I thank
16 you, and we will send in our comments to the
17 docket.

18 DR. UHL: Can I just ask a clarifying
19 question?

20 MS. TOUFANIAN: Yes, please do.

21 DR. UHL: So thanks, Tim, for that. In
22 your comments to the docket related to clarity on

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1 inspections and BE studies, will you be more
2 specific about what it is you're looking for
3 clarity on?

4 MR. AMES: Absolutely.

5 DR. UHL: Okay. Thank you very much.

6 MR. AMES: We'll take care of that in
7 the docket. And thank you.

8 MS. TOUFANIAN: Thank you.

9 Candis?

10 MS. EDWARDS: Thank you for allowing me
11 to come back. So I wanted to address the
12 definition of first generics. You may not like
13 what I'm going to say, but I have something
14 interesting, let's put it that way.

15 So in addition to these general accepted
16 criteria for the category of first generics, which
17 today includes a first-to-file Paragraph 4 ANDA
18 with a 180-day exclusivity, a first-to-market ANDA
19 for which there is no generic competition and no
20 blocking exclusivity, and also drug shortage
21 products -- those are the three categories that
22 are routinely prioritized today -- I would like to

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1 propose a couple of additional categories that
2 could be considered to be included in the
3 definition for first generics.

4 The first category would be a product
5 for which the sponsor receives documented evidence
6 from an external source, such as a consumer or
7 pharmacy, wholesaler, distributor, saying that the
8 product is not commercially available or that the
9 product has limited availability. However, the
10 product has not yet made it to the FDA's drug
11 shortage list. And we've had several situations
12 where we've experienced that and have provided
13 that information to the Agency in order to ask for
14 their consideration to expedite a review. And
15 this occurs in this fluidity of this whole
16 industry that we're in where it will come and go
17 with the specific products, so we would ask you to
18 look at that category of products.

19 Another area is a product that is
20 supported by one APA manufacturer who would
21 provide API to all ANDA holders. If we were able
22 to include products in that category where someone

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1 were coming in with a different API manufacturer
2 than what existed, even though there might be
3 other ANDAs approved, that would help mitigate the
4 risk associated with a potential shortage due to a
5 single-source API drug product, and that would
6 definitely have a positive impact on our health
7 care system, which is what we're looking for when
8 we look to define or make -- broaden this
9 definition.

10 And the other concept goes to asking the
11 Agency to work with the firms to prioritize let's
12 say the 10 top percent of ANDAs pending at OGD,
13 pending OGD approval for longer than 18 months,
14 that would be defined by a sponsor based on
15 accessibility and affordability of a specific
16 product that would potentially bring added value
17 to patient care and also have the potential to
18 possibly positively impact the health care market.
19 So it goes to who was speaking before me, the same
20 concept that says there are some -- you know, for
21 example, Amneal has over 100 ANDAs pending. We
22 have about 8 percent of our ANDAs pending,

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1 actually greater than that, that are pending
2 longer than 18 months, and so if we were able to
3 look at that bucket of ANDAs and say if you're
4 going to prioritize in order to address the
5 backlog, here is how we would ask that you
6 consider let's say the top 10 percent in that
7 category, we would look to have these prioritized
8 because we would feel that they would have the
9 most impact on a health care system and provide
10 the most added value into the whole market.

11 So those are some thoughts on how we
12 could potentially broaden that scope and also help
13 FDA to give them the ability to prioritize and
14 have a positive impact on the marketplace.

15 MS. TOUFANIAN: So one clarifying
16 question with respect to that last category.
17 Would that be from your description that would be
18 restricted to the backlog --

19 MS. EDWARDS: Probably so. That would
20 help, yeah.

21 MS. TOUFANIAN: And that would be sort
22 of a one-time identification?

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1 MS. EDWARDS: A one-time, yes.

2 MS. TOUFANIAN: Any questions?

3 (No audible response.)

4 MS. TOUFANIAN: Good.

5 MR. READ: Just one. It strikes me that
6 your first one could almost be described as pre-
7 shortage.

8 MS. EDWARDS: It could be, yeah.

9 MR. READ: So it's an interesting one in
10 terms of trying to avoid a shortage before it
11 happens.

12 MS. EDWARDS: Before it occurs, yeah.
13 And I think we get information. We may, since
14 we're dealing in solid products, we may get
15 information. We have more direct contact with the
16 consumer, so we may get information before it
17 makes it through the processes at the Agency in
18 order to get officially identified as a drug
19 shortage product.

20 MS. TOUFANIAN: Anything else?

21 (No audible response.)

22 MS. TOUFANIAN: All right. Thanks very

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1 much.

2 MS. EDWARDS: Okay. Thank you.

3 MR. DILORETO: Good afternoon. My name
4 is John Diloreto. I am the Executive Director of
5 the BULK Pharmaceuticals Task Force. And I'm
6 going to talk about a subject that I haven't heard
7 too much today about, and that has to do with
8 facility inspections. I heard it broached a
9 couple of times. But when we began our discussions
10 a few years ago under the original negotiations
11 with GDUFA, one of our major concerns had to do
12 with two aspects of facility inspections. One
13 certainly was protecting the safety of the drug
14 supply chain making sure that any drugs coming
15 into the country met that same high standard from
16 foreign facilities as they do from domestic
17 facilities. And at the time, domestic facilities
18 were being inspected at a rate of about every 2-
19 1/2 years. Despite a legislative requirement that
20 they be done every 2 years, 2-1/2 years was
21 certainly close enough that no one was going to
22 complain. But the second aspect of that certainly

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1 was leveling the playing field that the domestic
2 manufacturers had to have a quality program in
3 place to make sure that they met their regulatory
4 obligations while it was felt that a lot of
5 foreign facilities were actually skating by and
6 never being inspected in some cases. So we felt
7 like GDUFA was an excellent opportunity to kind of
8 bridge that gap, understanding that it was going
9 to take several years to hire the people, train
10 the people, put them in place before actual
11 inspections can be done at a frequency that was
12 considered parity between domestic and foreign
13 facilities, which is why within the GDUFA
14 commitments the first couple of years there aren't
15 any real inspection goals. Those goals for
16 inspections typically are all at the back end of
17 GDUFA.

18 That said, we were a little dismayed to
19 see within an HHS memorandum earlier this year
20 that FDA is scaling back by 40 percent the number
21 of domestic routine surveillance inspections that
22 it plans to conduct in FY2014 and 2015. When we

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1 all signed up for the program, I don't think we
2 expected to see a reduction in domestic facility
3 inspections, we expected those to remain largely
4 the same with the real increase being done on the
5 foreign facility side, understanding that it was
6 going to take a time for the staff and resources
7 to be put in place to do that, but we are here
8 expressing concern about that reduction in
9 domestic facility inspections.

10 Now, you might ask, "What's the big
11 deal? We've got a couple of years to meet our
12 goals." We do, but we also have to keep in mind
13 that many of our domestic facilities who are doing
14 business with other countries have to have an
15 inspection done every 3 years, and if we are at 2-
16 1/2 years to begin with and we are going to reduce
17 that number by 40 percent, that certainly means a
18 large number of facilities which are not going to
19 get inspected within 3 years and in fact may not
20 within 4 or 5 years. And we understand that this
21 is a complex situation, which is why we also were
22 emphasizing a risk-based prioritization for when

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1 these facility inspections were conducted. We
2 felt certainly pre-GDUFA there were far too many
3 inspections being conducted at facilities because
4 they were easy or close, not necessarily for
5 reasons having to do with concerns over quality of
6 products being produced at that facility.

7 So while we're encouraged about the
8 program thus far, we're concerned about the
9 reduction of domestic facilities here, and we
10 would like to make sure that when we reach parity,
11 that that parity is for both foreign and domestic
12 facilities and that we're still remaining in that
13 2-1/2 year range, which is what we all negotiated
14 a couple of years ago. And that's all I have.

15 MS. TOUFANIAN: Thank you. Any comments
16 or questions?

17 (No audible response.)

18 MS. TOUFANIAN: All right. Thank you
19 very much.

20 MR. DILORETO: You're welcome. Thank
21 you.

22 MS. TOUFANIAN: So that concludes our

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1 session today. Keith will have some closing
2 remarks, but before that, I just want to once
3 again encourage comments submitted to the docket.
4 A transcript of today's proceedings, as Martha
5 indicated at the beginning of the day, should be
6 available in about a month. And we encourage you
7 to watch FDA's websites for other developments.

8 MR. FLANAGAN: And my only closing
9 remark is I would like to thank our colleagues who
10 put this together. That's Connie Wisner, Shaniece
11 Bowens, Tawni Schwemer, Ashley Jones,
12 Shannon Bacote, Pat Downs (ph), and Kim
13 Giordano, as well as Maryll and Martha.
14 Thanks.

15 MS. TOUFANIAN: Thank you, everybody,
16 for coming.

17 (Whereas, at 3:12 p.m., the Generic
18 Drug User Fee Amendments of 2012 Public
19 Hearing on Policy Development --
20 Request for Comments Part 15 Public
21 Hearing was adjourned.)

22

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1 CERTIFICATE OF COURT REPORTER

2 I, MICHAEL FARKAS, the reporter before whom the
3 foregoing hearing was taken, do hereby certify
4 that the witness whose testimony appears in the
5 foregoing deposition was duly sworn by me; that
6 the testimony of said witness was recorded by me
7 and thereafter reduced to typewriting under my
8 direction; that said deposition is a true record
9 of the testimony given by said witness; that I am
10 neither counsel for, related to, nor employed by
11 any of the parties to the action in which this
12 deposition was taken; and, further, that I am not
13 a relative or employee of any counsel or attorney
14 employed by the parties hereto, nor financially or
15 otherwise interested in the outcome of this
16 action.

17 

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20 _____
MICHAEL FARKAS

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1 CERTIFICATE OF TRANSCRIBER

2

3 I, DEBORAH ARBOGAST, do hereby certify that
4 this transcript was prepared from audio to the
5 best of my ability.

6 I am neither counsel for, nor party to this
7 action nor am I interested in the outcome of this
8 action.

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A handwritten signature in cursive script, appearing to read "Deborah Arbogast", is written over a horizontal line.

DEBORAH ARBOGAST

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