

*Food and Drug Administration - Public Workshop
CDER and You: Keys to Effective Engagement*

April 3, 2018

*A Matter of Record
(301) 890-4188*

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<p>Page 10</p> <p>1 P R O C E E D I N G S</p> <p>2 (9:02 a.m.)</p> <p>3 Introductions and Opening Remarks</p> <p>4 DR. WHYTE: Good morning, everyone. We're</p> <p>5 going to go ahead and get started. I know there</p> <p>6 are some traffic issues, but in the interest of</p> <p>7 time, we'll go ahead and get started since there's</p> <p>8 a bunch of folks online as well, and we try to end</p> <p>9 on time.</p> <p>10 For those folks in the room, all of you</p> <p>11 should have gotten this packet of information when</p> <p>12 you checked in, which has some information which I</p> <p>13 think you'll find useful, which is an</p> <p>14 organizational chart of the Center for Drug</p> <p>15 Evaluation and Research, as well as a case study,</p> <p>16 which we're going to talk a little bit about later.</p> <p>17 Then in the spirit of having fun at the</p> <p>18 meeting, I want you all to pick up one of these</p> <p>19 clickers. They should be at your table. We're</p> <p>20 going to have some audience response and hopefully</p> <p>21 it will be informative. No one will be judged.</p> <p>22 All the answers are anonymous, so I can encourage</p>	<p>Page 12</p> <p>1 The workshop is being recorded for archival</p> <p>2 purposes, but if for some reason you wanted to</p> <p>3 watch it again, you're welcome to. We'll provide</p> <p>4 copies of all the slides if you want to have them,</p> <p>5 and we'll make them available on line as well as</p> <p>6 all of our contact information.</p> <p>7 We're going to start off with a welcome by</p> <p>8 our center director, Dr. Janet Woodcock. As many</p> <p>9 of you know, she's the director of the Center for</p> <p>10 Drug Evaluation and Research here at the FDA. She</p> <p>11 has led many cross-cutting initiatives. While at</p> <p>12 the FDA, she introduced the concept of</p> <p>13 pharmaceutical risk management in 2000.</p> <p>14 As a new approach to drug safety, she's led</p> <p>15 the pharmaceutical quality for the 21st Century</p> <p>16 Initiative since 2002. Prior to joining CDER, she</p> <p>17 was the director of Office of Therapeutics Research</p> <p>18 and Review with CBER, which is the Center for</p> <p>19 Biologics Evaluation and Research, and during my</p> <p>20 four and a half years here at the FDA, she really</p> <p>21 has been the champion of patient engagement, and</p> <p>22 ever since I came here to FDA have talked about how</p>

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1 do we measure what's clinically meaningful to
2 patients, how do we hear the patient voice, and
3 really talked about trying to change the culture of
4 the agency and the center.
5 I remember when I was meeting with her prior
6 to coming, she said it's almost like a huge ship,
7 and if we can move this ship even a few degrees, we
8 will have made progress. So I'm not sure how many
9 degrees we have moved it, but I know there is some
10 movement as we think about patient engagement.
11 So it's my pleasure to introduce Dr. Janet
12 Woodcock.
13 (Applause.)
14 Presentation - Janet Woodcock
15 DR. WOODCOCK: Thanks very much, John, and I
16 do think PASE has helped us with some of those
17 degrees of movement of this ship. So I thank you
18 and your staff because a lot of contributions have
19 been made to get us more outward facing and more
20 engaged with the public. The topic of this
21 workshop today is engagement with FDA CDER, the
22 drug regulators, and how might one do that.

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1 First of all, I could say I understand how
2 daunting a task this might be. Before I came to
3 the FDA, which was long ago, I was a doctor taking
4 care of patients, and I had a need to get one of my
5 critically ill patients a drug called thalidomide.
6 And little did I know what a history that had with
7 the FDA and so forth.
8 So I attempted to locate the FDA. I called
9 all these different people and everything, and I
10 said I want to get this drug thalidomide, and they
11 mentioned things like the Code of Federal
12 Regulations. I said, "What's that?" I got all what
13 I considered sort of bureaucratic speak and run
14 around, and I tried and I tried. Finally somebody
15 told me you have to find somebody who's making
16 thalidomide. And of course then I found it wasn't
17 really being imported into the United States, and
18 that would be a huge problem, and it would be very
19 difficult, and I couldn't find anybody to give it
20 to me.
21 Hopefully, things have changed since then.
22 There is more transparency to the agency, but I

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1 tell you this story to say at one point, you know a
2 lot more about CDER right now than I did at that
3 point. It was very daunting. It was kind of black
4 box. There wasn't really open portals for which
5 those citizens who wished to interact with the
6 agency had an easy access to figure out what to do
7 or whether something was possible.
8 Still today, I think we suffer. People,
9 citizens, whether they're representing patient
10 groups, or consumer groups, or a pharmaceutical
11 developer, or some other stakeholder, you may get
12 back a very polished lawyer that has answers that
13 really are difficult to make heads or tails of what
14 we're saying. And I think, John, what you were
15 talking about, there's a lot of misunderstanding
16 about what we can and cannot talk about.
17 We still struggle with plain, ordinary
18 language and just telling people like it
19 is -- here's the scoop -- so that you understand
20 where you stand. I think one of the major issues
21 is that people here are very busy, the scientists
22 and doctors. They're often heads down working on

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1 the data and looking at evidence and judging
2 evidence both in clinical trials. Is the trial
3 safe to proceed? Are they doing the right designs?
4 Are they studying the right endpoints and so forth?
5 And then everybody looks at the marketing
6 applications and did they demonstrate what they
7 needed to? Is this drug going to be okay when it
8 goes out on the market? And then we have millions
9 of reports of adverse events all the time, and we
10 have to sort through those and make sense of those.
11 So much of our large scientific staff is
12 working on that. Last year we approved, for
13 example, 1400, I think, generic drugs, and we
14 processed many more than that, probably over -- we
15 processed thousands of them and sent them back to
16 the manufacturer. So much of our staff is engaged
17 in doing that work on behalf of the public,
18 surveilling the adverse events, surveilling the
19 facilities that make drugs and so forth. So it's
20 hard for them to switch gears from that extremely
21 scientific activity that they do and then face
22 outward and work with the general stakeholder

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1 communities.

2 So we have been trying for years to develop

3 better interfaces so that anybody who comes to talk

4 to us, whether they're small business, whether

5 they're a patient or patient advocacy group, they

6 know where to go and how to get entree into the

7 agency, and then kind of how to work the lever so

8 that somebody will hear their case or they have

9 somebody to talk to get their questions answered.

10 Our Division of Drug Information answers

11 thousands of emails and calls every year, thousands

12 and thousands, and yet there seems to be an

13 insatiable appetite for information about drugs and

14 health, and about the drug development process, and

15 about whether generic drugs are good enough, and

16 whether biosimilars are actually the same as other

17 drugs; all these questions, and I had this side

18 effect and could it be related to the drug I was

19 taking, and so forth and so on.

20 At a higher, more integrated level, beyond

21 personal questions, we have hundreds of

22 stakeholders, why aren't you moving development for

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1 our orphan disease fast enough; why aren't you

2 developing new endpoints for this very serious

3 disease such as, say, Alzheimer's? A lot of people

4 don't realize -- and partly because we need to

5 effectively communicate with them, -- we're funded

6 as a regulatory agency. We aren't funded to do

7 research.

8 A lot of Americans think we do all the

9 clinical trials, for example, that the companies do

10 and that NIH funds and so forth. They think we do

11 them. So if anything goes wrong, they call us,

12 like why didn't you do this trial about this drug?

13 There is just a tremendous amount of

14 misinformation. So many stakeholders, some of whom

15 are highly sophisticated and many of whom really

16 were like me with the thalidomide, never heard of

17 the federal Code of Regulations or whatever and

18 really don't understand the FDA whatsoever, except

19 that we want something, and they're part of the

20 potential solution.

21 In addition to setting up better

22 transparency, one thing we try to do is put more

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1 information out, like the snapshots that PASE has

2 done because people ask us everyday -- they were

3 asking us why don't you put more women in trials,

4 why don't you put more elderly in trials. So now

5 we're putting out the numbers. First it's like, we

6 don't do the trials but here are the people the

7 trials had in them, and this has helped I think

8 tremendously to elevate the level of dialogue about

9 that particular issue.

10 So we're trying to have more transparency.

11 But then we also are trying to have better avenues

12 to work back and forth so that people can get their

13 questions answered and also can interact with the

14 appropriate part of CDER that they want to interact

15 with.

16 Some things we will discuss today, how to

17 set up a meeting with CDER, how to request a

18 meeting outside of the drug development process,

19 which we have very structured meetings for generic

20 drugs and new drugs and so forth, but for other

21 stakeholders, how do you do that? We're trying to

22 get a system in place -- we have gotten a system in

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1 place, but we really need to make it work, how to

2 get a meeting with the right people and make sure

3 that if you meet with the center, that your agenda

4 is fully vetted and the right people are at the

5 table to engage with the issues.

6 So that's something we've done. We've tried

7 to improve transparency. We've tried to improve

8 our outreach and the amount of information that is

9 available to people, and then we also need to

10 improve this back and forth so that people can come

11 in and get their questions answered, or advance

12 their own agenda, or let us know what their agenda

13 is. But for that to happen, we need to have at

14 least semi-informed stakeholders.

15 The first five calls I made to the FDA back

16 in the day of trying to get thalidomide, I was very

17 ineffective because I didn't even know what an IND

18 was, so I was starting at the most basic level of

19 asking information. It's a very inefficient

20 process, and at the time, I had to ask many people

21 and learn many, many things to the point

22 where -- and I had actually participated in

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1 clinical trials. I had done a lot of things, but I
2 didn't know all this bureaucratic regulation
3 underlying all this.
4 One of the most important things is that we
5 help the level of engagement to the point that
6 we're dealing with informed stakeholders who at
7 least can formulate in their own minds what they
8 want from us so they can ask the question. We
9 almost need a leading edge of interaction that we
10 inform everybody about what we do, what we don't
11 do, what you can expect from us, and what actually
12 some other agency does or things we aren't actually
13 doing. No, we can't do a clinical trial in this
14 area. We don't do clinical trials. We're not
15 funded to do clinical trials.
16 FDA may fund a clinical trial very rarely on
17 some raging issue, but we don't get appropriations
18 to do that, so it's not our mission really. If
19 people can fix our role in their mind more firmly,
20 then we can have a better back and forth, or people
21 can go and make their point to an agency that does
22 do clinical trials and that would be appropriate to

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1 talk to about that.
2 I think that's why this kind of meeting is
3 so important. You're already much more informed
4 stakeholders than our average stakeholder out
5 there. You knew about this meeting and would come
6 and interact with us. The more we can get an
7 informed level of stakeholders out there, then you
8 can help a lot of the other people, people you may
9 represent a part of your group or whatever; to
10 understand how to formulate their questions what
11 the agency can and can't do; what is appropriate to
12 pressure us to do in which it won't be useful
13 because we're not really in charge of that thing,
14 whatever it might be that people might want.
15 So I would encourage everybody today, ask
16 your questions. Get as much information as
17 possible. Reach the highest level of mutual
18 understanding as we possibly can because this will
19 only inform the dialogue over the next year. We
20 really do want to serve all of our stakeholders,
21 and we want to hear their voices, but we want to do
22 it in an effective way and hopefully a way that's

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1 efficient both for you and for us so that you won't
2 be like me, or your various constituents won't be
3 like me, floundering around through a multiple,
4 multiple, multiple range of phone calls and
5 investigations trying to figure out something that
6 actually is very simple when somebody explains it
7 to you in plain language.
8 So I thank PASE for putting this on. I
9 thank all of you for showing up and the people
10 online, too. I think this will be a very useful
11 exchange, and we'll, again, tip the axis of that
12 ocean liner yet a little toward our ultimate goal
13 of really serving our stakeholders well. Thank
14 you. Thanks, John.
15 (Applause.)
16 DR. WHYTE: Thank you, Dr. Woodcock.
17 We do have a section leader today in our
18 Jeopardy, which is all about acronyms. So as
19 Dr. Woodcock talked about, what is that CFR? What
20 is that IND? We tend to develop a parlance here
21 that we forget many people don't understand. And
22 there's no reason why you would know some of these

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1 terms unless you actually participated, but it does
2 help to become familiar.
3 Remember I said we're going to make it
4 interactive? So I ask you to pick your clicker
5 that we're going to use, and you'll have an
6 opportunity to meet many folks on my team, and
7 we're going to start with Noah Goetzel. I asked
8 everyone to provide a fun fact; some people did,
9 some people didn't. I meant to mention, some of
10 you may know, Dr. Woodcock is an avid gardener. So
11 if you all are going to send her an email, if you
12 start with some gardening conversation, that's a
13 good tip you can use because she is very much a
14 gardener.
15 Noah's fun fact is that he ranked second on
16 his high school track team for the fastest burrito
17 mile where race participants had to devour a 1-
18 pound Qdoba burrito and then run a mile on the
19 track. So if you have any questions about that,
20 you can ask him.
21 So he's going to quiz you, and then I'll
22 come back up and talk a little more.

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1 Audience Response Questions - Noah Goetzel
2 MR. GOETZEL: Thank you, Dr. Whyte.
3 Hello, everybody. My name is Noah Goetzel.
4 I'm an ORISE fellow in Dr. Whyte's Office of
5 Professional Affairs and Stakeholder Engagement,
6 PASE. How is everybody doing today, first of all?
7 You guys doing all right? Everybody good? Find
8 this place okay?
9 (Audience responds.)
10 MR. GOETZEL: That's good to hear.
11 Are you excited to learn how to interact
12 with the regulatory scientists here at FDA Center
13 for Drug Evaluation and Research?
14 (Audience responds.)
15 MR. GOETZEL: Yes? You guys are excited.
16 That's good to hear. Well, we're delighted to have
17 you because we want to empower stakeholders like
18 you to share your unique perspectives. Whether
19 you're a patient, a caregiver, an academic
20 researcher, or a healthcare provider, or any other
21 type of representative here today, we're interested
22 in helping you guys share your voice with the FDA.

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1 So before we get into our impressive slate
2 of presenters and presentations, I have a few
3 questions for you guys. I'm going to turn the
4 tables. You're going to answer these with your
5 clickers, which are in the center of the tables,
6 and we can go ahead and get started with the first
7 question.
8 Is this your first time attending a meeting
9 at the FDA? Click A if the answer's yes and B if
10 it's no. I'll give you a couple of seconds to send
11 in your answer choices.
12 (Audience responds.)
13 MR. GOETZEL: Let's check out the results.
14 For 80 percent of you, it's your first time here
15 coming to the FDA, so welcome, everyone, and only
16 20 percent have been here before. I apologize.
17 I'm sorry. Eighty percent of you have been here
18 before. Welcome back.
19 (Laughter.)
20 MR. GOETZEL: All right. Next question.
21 How confident are you in understanding the
22 different functions of the Center for Drug

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1 Evaluation and Research? A, not at all confident;
2 B, somewhat confident; C, very confident. More
3 confident than I am in terms of reading answer
4 choices.
5 (Laughter.)
6 (Audience responds.)
7 MR. GOETZEL: Everyone send in your answer?
8 Let's see. So most of you are in the middle;
9 58 percent said somewhat confident, and then we
10 have 20 percent who said you're really not at all
11 confident right now, and 22 percent are very
12 confident. So hopefully by the end of this
13 presentation, you'll become a little bit more
14 confident in terms of what we do here at CDER.
15 I've got one more question for you guys.
16 Finally, how confident are you in your ability to
17 navigate through engaging with CDER? Same choices,
18 A, not at confident; B, somewhat confident; or C,
19 very confident.
20 (Audience responds.)
21 MR. GOETZEL: Let's check out the responses.
22 Okay. So once again, a lot of you are in the

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1 middle. We have more people this round; 44 percent
2 saying that they're not at all confident in
3 engaging with CDER, and then 2 percent of you are
4 the experts, you're very confident, but most of
5 you, 53 percent, somewhat confident.
6 The goal again, after the presentation,
7 everyone's going to be very confident and engaging.
8 That will wrap up the ARS presentations. We're
9 going to keep going back to these clicker questions
10 throughout the day to keep you on your toes, and
11 the questions are going to get tougher. So this
12 was the easy round, and it's going to get more
13 difficult.
14 I want to give a quick shout out to our
15 social media staff here at CDER. We are tweeting
16 this event, so throughout the day, you'll see
17 information about the different speakers and
18 presentations. You can feel free to follow along
19 and join the conversation. Just follow the FDA
20 drug information account, that's FDA_drug_info, and
21 the hashtag for this public workshop is
22 #CDERandyouengagementworkshop.

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1 So we look forward to hearing your responses
2 and want to make sure that everyone has the
3 opportunity to find out what happens and what we
4 cover at our event today, even if you're not here
5 in person or following along with our webcast.
6 Next up, we've got a video for you guys.
7 During the ARS questions, I asked how confident you
8 are in understanding the functions of CDER, and a
9 lot of you said you're kind of somewhat confident.
10 So I want to make sure that you have the
11 opportunity to learn more about what we do in terms
12 of the drug approval process, and you'll hear a ton
13 of presentations today. My colleague in PASE,
14 Lieutenant Commander Sadhna Khatri, will be leading
15 our presentation on what CDER can and can't do.
16 This video, which you can search on the
17 internet or on the Professional Affairs Stakeholder
18 webpage, will tell you five things you need to know
19 about the drug approval process. So you can go
20 ahead and just Google if you're trying to find the
21 FDA five things you need to know video, and you can
22 enjoy this video that we have for you. It will be

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1 just two quick minutes.
2 (Video played.)
3 MR. GOETZEL: There you have it. We're
4 going to have a lot more presentations today about
5 what CDER does here in the FDA and how to engage
6 with us. Thanks very much. Enjoy the
7 presentations.
8 (Applause.)
9 DR. WHYTE: I want to thank Noah. Noah is
10 what's called ORISE fellow. It's acronyms all
11 over. I'm not even sure what ORISE stands for.
12 But essentially, Noah is similar to an internship.
13 It's time to come here and spend, and learn about
14 the FDA. And I know he didn't know all those
15 acronyms before he got here. He certainly didn't
16 know CDER and IND and all of that.
17 But I really want to thank him for the work
18 that he's done, especially for this workshop. He's
19 the youngest person on our team, so that's why it's
20 always -- he's in charge of our social media and
21 all the other efforts. But really, he's done an
22 enormous amount of work helping to bring this

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1 together. So I wanted to thank Noah. And he has a
2 podcast, too. I don't want to get in trouble like
3 other people I mentioned, but he's big in basket
4 ball. Go Villanova. Okay.
5 With that, I'm very pleased to talk
6 about -- we have something new to announce at this
7 meeting since many of you have been to previous
8 meetings. And a challenge has been, over the
9 years -- and Dr. Woodcock referenced it -- it's
10 hard to figure out who do you meet with if you want
11 to have a meeting. And it's hard to contact
12 anybody here. How do you possibly find out? I
13 mean, I don't know who answers the phone and
14 directs you to the right number. And does anybody
15 call anybody anymore anyway? You just kind of
16 email. So how can you figure out who do you meet
17 with and how do you get a meeting?
18 Recognizing that, we have created and just
19 launched an online system for meeting requests for
20 stakeholders outside of regulated industry, and
21 we're affectionately calling it ESMR, the External
22 Stakeholder Meeting Request. And if you have a

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1 better acronym for it, we're always willing to
2 listen. This is an attempt really to make it easy
3 for folks to request a meeting on drugs, and you
4 don't even need to know who you need to meet with.
5 And Chris Melton is going to come up and
6 demonstrate it live, and hopefully it will work.
7 Do we have anyone here from Texas?
8 (Show of hands.)
9 DR. WHYTE: Okay. Chris' fun fact, so he
10 says, is that he's from a small town in Texas
11 called Jefferson. I don't know if it's Thomas
12 Jefferson or Jefferson Davis. But he says it's the
13 most haunted town in Texas.
14 Karen, is that true? I don't know, but
15 we'll find out. But he's going to come up and
16 demonstrate the ESMR system. Thank you.
17 Presentation - Christopher Melton
18 MR. MELTON: Thank you, Dr. Whyte.
19 Good morning, everyone. I wanted to go back
20 to Noah's fun fact. Were you able to keep the
21 burrito down after you ran the lap? Great.
22 As Dr. Woodcock and Dr. Whyte alluded to,

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1 the whole point of ESMR, it's a three-part
2 solution, and the system, and the part I'm going to
3 go over, is the website. That will be facing you.
4 As Dr. Whyte alluded to, I'm a health
5 communications specialist in the engagement staff,
6 and I want to go over the parts for the web page.
7 And as I transition through the workshop, I will
8 basically go through the live demo and show you
9 everything that will need to be seen. Before I get
10 into the demo, I will use about 5 to 7 minutes to
11 give you a brief live demo, and then from there, we
12 will move into the Q&A section.
13 Before I go to the live demo, just to give
14 you some background, parts of the 21st Century
15 Cures Act mandated integrating patient experience
16 into the drug development process, and that
17 increased patient centricity. CDER has increased
18 the number of interactions with external
19 stakeholders, specifically with patient advocacy
20 groups, with diverse needs and expectations in the
21 understanding about the drug development process.
22 The current environment at CDER was that

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1 there was a lack of consistent processes for
2 external non-industry stakeholders. I just want to
3 continue to highlight that we're focusing again on
4 non-industry stakeholders because there are already
5 established pathways for the pharmaceutical
6 industries or what we call the industry
7 stakeholders.
8 Now, the downside of that was that the
9 communication wasn't as clear and we weren't able
10 to have transparency between groups. And the whole
11 point of this is to keep transparency between the
12 meetings and all of our review divisions as we meet
13 with these stakeholders.
14 Moving back to Dr. Woodcock's vision, she
15 recognized that meetings with advocacy groups,
16 healthcare professionals, and other non-industry
17 stakeholders is vital to our work. Dr. Woodcock's
18 vision was to create a user-friendly process for
19 external, non-industry stakeholders to easily
20 request meetings for drug development and drug
21 safety matters.
22 Once we got the approval and go-ahead from

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1 Dr. Woodcock, we started the planning and
2 development process of the web page. With guidance
3 from the PASE's director, Dr. Whyte, and assistance
4 from our colleagues in the Office of Strategic
5 Programs, the Office of Program Regulatory
6 Operations, and the Office of Communications, we
7 successfully launched the system on February 9,
8 2018.
9 What I would like to do is go over the web
10 page with three specific parts. As you can see
11 here, we're going to look at Resources for You.
12 This is an area where you're able to get specific
13 information for CDER's drug divisions and then also
14 about the Professional Affairs and Stakeholder
15 Engagement. We also have information for other
16 meetings. There may be requests that come out that
17 are not regulated to drugs, and you have other
18 areas that you need to go to. So we ask that you
19 contact OHCA, and we have that information here.
20 Finally, the last part, what I will go into,
21 will be the Request a Meeting on Drugs itself,
22 which is the intake form, and we have two spots

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1 where that can be accessed. Again, as you see,
2 this web page is very straightforward and simple,
3 so we want to keep that just nice and clean and
4 easy to access.
5 Going to the table, looking at Resources for
6 You, as you can see, this is going to give you a
7 list of all the different offices within CDER. And
8 as Dr. Woodcock mentioned, if you're not aware of
9 all the different offices or divisions, we have
10 this information here where it's easily accessible
11 for you to see prior. Then again, we will also
12 manage that on the triage process. And here
13 looking at other meetings within FDA, this will
14 show established pathways that are currently
15 available to have other meetings within FDA.
16 For the sake of time, I pre-filled out a
17 form using a test, but once you're ready to submit
18 your request, you'll click on the button, and it
19 brings up your form. Now, on this form here, you
20 can see that you have key information such as the
21 requester's name, email address, name of the
22 organization, and phone number. And all of these

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1 are the key essential information that we need to
2 run the meeting and get the key factors that are
3 needed.
4 Once that entered -- and again, I'll go to
5 my test -- you click the "submit" button, and then
6 that goes to our CDER PASE inbox. And you'll get a
7 response that within 7 business days, someone from
8 PASE will get in contact with you, and we will then
9 start triaging the meeting process.
10 With that, we will move to the question and
11 answer section, and if anyone has any questions,
12 please feel free to go to the microphones. And
13 we'll have a runner also bring the mic around so
14 you can ask any questions.
15 Questions and Answers
16 FEMALE AUDIENCE MEMBER: Hi. I just have a
17 question on the form. I didn't see like if you
18 already had a contact at FDA, is there a place in
19 that form that you can enter their name to help you
20 with your process of routing it to the right
21 division or person?
22 MR. MELTON: Good question. Currently right

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1 now, there's not a section in the form where that
2 could be done, but what we will do when we call it
3 with the initial information, that's when we can
4 tease out that information for the people that you
5 currently have relationships with.
6 DR. WHYTE: I think the other point is we do
7 have a section on there about proposed attendees.
8 It's all free form as well, so I think you could
9 add in there the contact that you have. This is
10 meant to simplify a process as well, so we don't
11 want to duplicate anything.
12 The reality is, many folks, and probably
13 folks that are here, do have some organizational
14 awareness. So what we've talked to our colleagues
15 is for meetings that are already taking place.
16 There's already a set plan, and our friends and
17 colleagues in the Office of Hematology and Oncology
18 Products and oncology in general have very good
19 relationships with patient groups. We're just
20 ourselves going to put it into the system because
21 at the end of the year, the system will also allow
22 us count.

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1 So it's important to understand, for the
2 center and for the senior leadership, how many
3 meetings have we had on patient engagement and what
4 are the patients and other groups -- this is also
5 for other groups other than regulated industry, so
6 it could be health professional, physician groups.
7 What are they coming to talk about? Are they
8 coming in to talk about neurologic diseases, or are
9 they coming in to talk about psychiatric
10 conditions? Is it dermatologic issues?
11 In the past, we had to do this all manually,
12 which is very hard to do. And again, this really
13 is a way to encourage dialogue, to encourage
14 engagement, which is two ways. So it's a good
15 point. We don't want to duplicate anything or
16 complicate anything. In many ways, with the
17 free-form text, people can just add that in. And
18 we do promise to get back to folks within
19 7 business days. That doesn't mean that we'll have
20 a meeting in 7 business days, but we're certainly
21 going to get back to you to start the process.
22 MR. MELTON: Any more questions? We have

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1 another one.
2 MS. FOXWORTH: This is Phyllis Foxworth from
3 the Depression and Bipolar Support Alliance. Thank
4 you so much for being here. When I first started
5 engaging with the FDA, I certainly was not a
6 professional patient. I'm just a patient and a
7 caregiver of other patients. I still don't
8 consider myself a professional patient.
9 So my question is -- the form is great, and
10 maybe we'll cover this throughout the day. But the
11 real question is, why would I want to schedule a
12 meeting and what is the type of meeting I'd like to
13 schedule given that I'm not a professional patient?
14 MR. MELTON: With that, when you're asking
15 you're not a professional patient, there's a
16 progress. One reason would be for initial
17 information that you would need to access, we can
18 schedule a meeting and a fact-finding. Then it
19 also could be another meeting for whatever you
20 need. But the whole point is getting the
21 information of your main goal. Even though you're
22 not a "professional," quote, patient, whatever your

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1 need would be, we would tease that out from
2 discussions with you, and then decide what would be
3 the best route forward with the meeting.
4 DR. WHYTE: Sorry. I keep jumping in. And,
5 Phyllis, it's nice to see you. I don't think we
6 view people as professional patients or not
7 professional patients. I'm not even sure
8 necessarily what that means. But what we hear from
9 the public is this need for information, this unmet
10 clinical need that they're concerned about drug
11 development in a certain space, and they may not
12 even use those terms; or they're concerned about
13 side effects; or they want to know why aren't there
14 drugs for lupus. Why aren't there drugs for a
15 certain neurologic disease? In many ways, we're
16 responding to folks, and there are many in the rare
17 disease community that have this desire to impact
18 the lives of their loved ones.
19 So there is no set agenda of what people
20 have to talk about to us, and in many ways, we
21 can't tell you what you should or shouldn't talk
22 about. We can tell you what we can't talk about;

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1 for instance, if a drug's currently under review.
2 But we really want to encourage that dialogue.
3 When we talk about how do we measure what's
4 clinically meaningful to patients, it's hard to do
5 that unless you actually engage with patients. And
6 Dr. Woodcock often talks about that patients are
7 experts in their own disease, and you may have
8 heard her say that. So in order to do that, we
9 have to engage with patients. And I'm particularly
10 using that term "engage" because it's a two-way
11 communication. And historically, the information
12 on both sides has been pushed out. The agency
13 pushes out information that they want their -- and
14 advocacy groups push information back to us. And
15 we really have to have engagement and two-way
16 communication.
17 So part of that is -- you're right -- that
18 folks don't even know the FDA or think about the
19 FDA. And that's part of our goal, to try to
20 educate folks more about the drug development
21 process, and Dr. Woodcock talked about that. But
22 really, nothing's off the table in terms of what

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1 you can ask to talk about.
2 MR. BARTEK: Guessing that there's probably
3 a full range of responses that one could expect
4 from such a request, might you give us an idea of
5 what that range might be. I doubt every request
6 gets a meeting.
7 DR. WHYTE: Sure. And he's from Texas as
8 well or he raised his hand. Part of it is to have
9 that phone call or to contact folks after the
10 meeting request. And I will tell you, just from
11 phone calls that I have made, people are always
12 surprised when they get a call from us. They're
13 shocked as if somehow we were unplanning to do
14 anything.
15 But our goal is to call people. Everything
16 doesn't always have to be these long emails. And
17 what we have in the agenda that we ask people, and
18 what I'm pushing folks on my team, is what is the
19 ask. So when we call you, I really want to know
20 what do you want to meet about, and we push even
21 more in terms of what do you want the FDA to do as
22 part of this meeting?

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1 So that really dictates what kind of meeting
2 is it. Is it simply that you want to make us aware
3 of the severity of the disease and what's on
4 people's minds? Is it you don't feel there are
5 right endpoints; you're confused about certain
6 information? And I will tell you, all the requests
7 that have come in so far, our goal is really to
8 have a low bar for meetings, meaning we're trying
9 to encourage engagement.
10 So right now we are having a lot of
11 in-person meetings, but we're also thinking about
12 and interested in hearing people's viewpoints. And
13 it might be kind of a D.C. type of thing where
14 everyone likes to have a physical meeting, and in
15 many ways I think we can accomplish a lot by having
16 WebEx meetings or something of that nature, or
17 conference calls, because that also allows people
18 that may not have a lot of resources. Many of them
19 are caregivers and can't take two days of travel to
20 come to White Oak in Maryland. So we're really
21 trying to think through that as well.
22 But the default in a way is to have a

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1 meeting. What that means is open to what folks
2 want to accomplish. I've been in the past on calls
3 where -- Dr. Woodcock talks about people think we
4 do clinical trials. I've been on calls where
5 people think we make drugs, and we don't. So we
6 also don't want to waste people's time to come in
7 for a meeting on an area where we don't have
8 regulatory authority. But our goal is to -- we're
9 setting up a system to have meetings, so our goal
10 is to honor those requests for meetings.
11 MR. MELTON: Okay. That will be our last
12 question. What I'll do briefly is give the URL
13 again so you guys can have a chance to write it
14 down. We should have it come back up right here.
15 (Pause.)
16 MR. MELTON: So what I will do, it's
17 fda.gov/requestameetingondrugs. Thank you and have
18 a good day.
19 (Applause.)
20 DR. WHYTE: See, we need all the young
21 people to do our A/V stuff. If you only remember
22 one thing today, if you remember

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1 fda.gov/requestameetingondrugs, that is progress,
2 and you will be on your way to being an effective
3 advocate, because part of the challenge is figuring
4 out how do you meet with us and who do you meet
5 with, and we're going to help you do that. So I
6 really want you to remember that. I want you to
7 promote that. I want you to talk about that to
8 your friends and colleagues.
9 Now we're going to try to provide a little
10 more about what we do here at CDER. And most of
11 you have been at meetings, so you most likely know
12 that CDER is the Center for Drug Evaluation and
13 Research. So we work on drug issues. Our
14 colleagues you'll hear from later might work on
15 devices at the CDRH, or CBER, the Center for
16 Biologics, and we'll talk a little bit about that.
17 I'm going to introduce now Selena Daniels,
18 and she's a team lead in the clinical outcome
19 assessment staff in the Office of New Drugs. And
20 she's going to talk a little bit about how do we
21 incorporate patient experience data to inform the
22 FDA. And it tells me that Selena is also a yoga

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1 instructor. And here is Selena. Namaste.
2 Presentation - Selena Daniels
3 DR. DANIELS: Thank you, Dr. Whyte, and I
4 think the slides have transferred.
5 Good morning, everyone. My name is Selena
6 Daniels, and as Dr. Whyte mentioned, I am a team
7 lead on the clinical outcome assessment staff here
8 in CDER. And for those who aren't familiar with
9 our role, we provide advice to the Office of New
10 Drug review divisions in CDER in matters pertaining
11 to the development of clinical outcome assessments
12 and related endpoints. Today, I will be discussing
13 how you can engage with FDA to collect patient
14 experience data.
15 The patient perspective is an important part
16 of the medical product development process, and FDA
17 values the use of patient input to help foster the
18 development and availability of safe and effective
19 drugs. An article was published in JAMA in 2015
20 highlighting the importance of engaging patients
21 across the spectrum of medical product development,
22 and some of the key take-aways from this article

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1 was that capturing the patients' voice in medical
2 product development is important. And if you can
3 successfully capture it, it can transform the
4 patients' experience of health care. One way to
5 capture the patients' voice is to include clinical
6 outcomes that are meaningful to patients from their
7 perspective.
8 Our ultimate purpose here at FDA is to
9 understand patients' perspectives on benefits and
10 risks. When reviewing medical products, we look to
11 see if the medical product has shown some type of
12 clinical benefit to patients in the assess clinical
13 outcome and from their perspective. I know I just
14 threw out a couple of regulatory terms here, so I'm
15 going to define them real quick.
16 Clinical benefit is a positive clinically
17 meaning effect on an intervention. In other words,
18 it's a positive effect on how patients feel,
19 function, or survive, and that can be how long a
20 patient lives and how a patient feels or functions
21 in daily life. This includes both improvement, but
22 also may a delay in deterioration of a certain

<p style="text-align: right;">Page 49</p> <p>1 symptom or aspect of that condition. Clinical 2 outcome is an outcome that describes or reflects 3 how an individual feels, functions, or survives, 4 and this can be assessed using clinical outcome 5 assessments. Typically, this could be a 6 questionnaire or this could be a task. 7 An important part of regulatory 8 decision-making is to carefully assess patients' 9 views on benefits and risks. For those who aren't 10 familiar with the 21st Century Cures Act, this is 11 an initiative to enhance the process of delivery 12 and development for disease treatments, and this 13 act now includes new statutory provisions for 14 patient-focused drug development. What this means 15 is that FDA is trying to incorporate the patient 16 perspective in a more systematic way for benefit- 17 risk assessment and taking into account patient 18 experience. 19 What is patient experience? The patient 20 experience in a medical product development context 21 essentially incorporates the patient's journey 22 throughout the course of their disease or</p>	<p style="text-align: right;">Page 51</p> <p>1 patients' wants, their needs, and their preferences 2 are represented in activities related to medical 3 product development and evaluation. 4 There are various different elements that 5 could comprise patient experience. Again, as I 6 mentioned, it could be disease symptoms. It can be 7 the burden of living with a disease, the burden of 8 managing the disease itself, impacts from the 9 disease or impacts from the treatment on activities 10 of daily living; patients' views on currently 11 available treatment options as well as unmet 12 medical needs; and again, patient preferences. 13 So how do you collect patient experience 14 data? FDA recommends using qualitative methods, 15 quantitative methods, or mixed methods to collect 16 robust and meaningful patient experience data. 17 This table provides a high level overview of these 18 different types of methods that can be used, the 19 first being qualitative methods. 20 Qualitative methods just includes the act of 21 just talking to patients. This could be using 22 direct communication to explore or confirm the</p>
<p style="text-align: right;">Page 50</p> <p>1 condition, which includes patient's views, 2 feelings, their needs, actions, preferences, and 3 interactions with respect to their disease and its 4 treatment. 5 Section 3002(c) of the 21st Century Cures 6 Act describes patient's experience data as data 7 collected by any persons that are intended to 8 provide information about patient's experience with 9 the disease or condition, and this can include 10 disease symptoms. This can include disease 11 impacts, experience with treatments, inputs which 12 outcomes are important to them, patient 13 preferences, or anything that's just an important 14 issue that's defined by patients. 15 So who should communicate patient experience 16 data? Of course, patients themselves. However, 17 there are instances where they may not be able to 18 communicate this, and in those instances, it can be 19 informed by input from patient partners and 20 clinicians. A patient partner may be an individual 21 patient, a caregiver, or a patient advocacy group 22 that engages other stakeholders to ensure that the</p>	<p style="text-align: right;">Page 52</p> <p>1 meaning of interpretation of a topic from the 2 participant's perspectives. An example of a 3 qualitative study could be having a focus group or 4 having interviews with patients where they're 5 describing their experience or their condition. 6 And the potential scientific objective for this 7 type of study would be related to experiencing or 8 exploring the most important aspects of that 9 disease. 10 Quantitative methods are characterized by 11 quantifying the data or using numbers, and this 12 generally entails statistical methods that are 13 summarizing this collected data. In regard to 14 collecting patient experience data, this could be 15 collected by the use of a tool such as a 16 questionnaire or a survey. 17 An example of a quantitative study may be 18 just surveying the patient's experience using a 19 questionnaire, and that questionnaire has a closed 20 set of questions where patients are selecting 21 response options most suitable for their response. 22 And it creates a score, which is numerical data.</p>

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1 The potential scientific objective for that method
2 could be related to developing a symptom
3 questionnaire from those questions.
4 Lastly, mixed methods is basically using
5 both qualitative and quantitative data. And an
6 example of a mixed-methods study could be surveying
7 a group of patients with a questionnaire, but then
8 also tagging along an interview component just so
9 patients can be able to further describe their
10 responses with more detail just in case the
11 response options didn't allow them to do so.
12 A potential scientific objective could be
13 related to determining whether maybe symptom
14 severity or symptom frequency is more important to
15 them by looking up both the scores that are coming
16 from the questionnaire as well as the patient
17 quotes that are coming from the interview portion.
18 So overall, each of these methods can allow one to
19 understand patients' experiences, their
20 perspectives, and feelings.
21 The importance of collecting patient
22 experience data can inform medical product

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1 development and enhance regulatory decision-making
2 to address patient needs because, as we know, which
3 was stated earlier, patients are experts in their
4 own disease and condition, and they're the end
5 users of these medical products once medical
6 product development is complete.
7 As far as timing on when to collect patient
8 experience data, this can be before and throughout the
9 medical product development process. FDA does
10 encourage pre-competitive collaboration, so even if
11 you're not in an individual drug development before
12 that stage, you can start collecting patient
13 experience data.
14 Anyone can collect and submit patient
15 experience data. This includes patients. This
16 includes family members or caregivers of the
17 patients; patient advocacy organizations; disease
18 research foundations; researchers; medical product
19 manufacturers; and you may need to collaborate with
20 subject matter experts in this field to help you,
21 but anyone is able to collect and submit patient
22 experience data.

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1 To submit patient experience data, there are
2 various pathways that exist. FDA will be issuing
3 guidance on how to submit this data, so please stay
4 tuned. Again, in regards to the content and the
5 formats in terms of how to submit that data, it
6 also depends on the purpose and the type of data
7 that is being submitted. From a regulatory
8 perspective, patient experience data is used to
9 inform clinical trial design, clinical trial
10 outcomes, trial endpoint development and selection,
11 but it's also used in our regulatory reviews, which
12 includes benefit-risk assessments.
13 To summarize everything, patient engagement
14 is critical throughout the medical product
15 development process, and the way you can best help
16 FDA is by using scientifically sound methods to
17 collect robust, meaningful, sufficiently
18 representative patient input to inform medical
19 product development and regulatory decision-making.
20 That concludes my presentation, and I will
21 open it up to questions and answers. There are
22 mics, and I know there are runners around as well.

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1 Questions and Answers
2 MR. BARTEK: Thank you, Selena. Can I ask
3 about -- I would just say so many of our patient
4 groups are now looking at new technologies for
5 collecting patient data before and during clinical
6 research. I'm wondering to what extent the
7 developers of these new technologies -- I'm
8 thinking of wearables and carriables and so
9 forth -- are collaborating with you and your
10 office, and others of your colleagues here at the
11 FDA, in advance, maybe in the pre-competitive space
12 so that when they develop these technologies and
13 the way they'll be used with our patients to see
14 how they feel and function on a daily basis in
15 their own environments -- so important to the
16 endpoints that we're trying to develop -- that they
17 would provide technologies that would be useful for
18 the regulator.
19 DR. DANIELS: No, most definitely. We are
20 having engagements with some of the individuals
21 that are using these technologies, and we are open
22 to those novel methods. And we will be describing

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1 some of those novel methods in the guidance that
2 comes forth for submitting patient experience data.
3 Are there any other questions?
4 Questions and Answers
5 FEMALE AUDIENCE MEMBER: Thank you so much.
6 That was very helpful. Do you have any published
7 guidance that details for -- again, I don't want to
8 use that word "non-professional," but I just think
9 it's clear to make, that as patients, we're not
10 scientists. So is there any guidance that's
11 published that says what your criteria is as the
12 definition of a scientific study as opposed to a
13 non-scientific study?
14 DR. DANIELS: The guidance that's going to
15 be put forth this June, the draft guidance on
16 collecting patient experience data, is written
17 using plain language, so it will go into the
18 details of what are the best practices to do. But
19 again, we also are encouraging if you are a patient
20 or patient advocacy group to contact or collaborate
21 with these subject matter experts because they do
22 have the expertise to help you create these studies

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1 and use these methods to collect that data.
2 MALE AUDIENCE MEMBER: Is that the same
3 guidance [inaudible - off mic]?
4 DR. DANIELS: Yes.
5 MR. BARTEK: Just a question. You're
6 focusing on obviously clinical studies and stuff in
7 your discussion. Will the guidance include, or the
8 experience data that you're collecting include,
9 things like how patients feel about size, shape,
10 color, other kinds of physical attributes that
11 sometimes can be a big issue from a patient
12 perspective in terms of problems they have in
13 taking the dose and that type of thing?
14 I know this is becoming a much bigger issue,
15 and FDA has some guidances on physical design
16 characteristics, et cetera. Will your data
17 collection incorporate patient information on those
18 kinds of things as well as more clinical type
19 details?
20 DR. DANIELS: This first guidance on
21 collecting patient experience data is going to be
22 focused mainly on the methods that are being used

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1 to collect the data, but we do have a series of
2 patient-focused drug development guidances that are
3 going to be coming forth after this as well that
4 will focus on how to elicit the most important
5 concepts from patients. And it might touch upon in
6 terms of some of those things, factors that you
7 mentioned as well. But this guidance coming out in
8 June, the draft guidance, will be focusing mainly
9 on the methods and how to create representative
10 inputs of talking to the right patients.
11 DR. HO: Thank you so much. This is Calvin
12 Ho from the Tuberous Sclerosis Alliance. I was
13 wondering if the June guidance will also be
14 addressing using patient registries as a source for
15 patient experience data.
16 DR. DANIELS: The draft guidance will be
17 talking about different sources to use. Of course
18 that could be focus groups; it could be registries.
19 So it will touch upon that as well as what types of
20 sources can be used to collect patient experience
21 data.
22 FEMALE AUDIENCE MEMBER: Hi there. I

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1 represent a patient community that is not yet a
2 formal group. It's a rare, loosely defined group
3 of individuals. Is that kind of non-starter in
4 terms of creating or pulling together patient
5 experience data or the non-professional aspect of
6 their community, does that make a difference at
7 all?
8 DR. DANIELS: No. Like I mentioned, anyone
9 can collect data. I mean, we do encourage you to
10 engage with us like if you want to know what the
11 objective is and how to proceed, in that sense.
12 You can do meeting requests as was mentioned in the
13 previous session.
14 I think that was the last question. Thank
15 you, guys. Have a great day.
16 (Applause.)
17 DR. WHYTE: Thank you.
18 One other point that Dr. Woodcock often
19 talks about is when we're trying to collect
20 information, there is a science to patient
21 engagement. Sometimes there is this tension
22 between the biologic sciences, which many of the

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1 folks that FDA are trained in, and the social
2 sciences, which is very much collection of data,
3 but that can be just as rigorous as the biologic
4 sciences. And sometimes when folks are thinking
5 about a survey, they go on the process, which is
6 well intention, but then there's not the science
7 behind it. Someone might put it up on their
8 website and have the first 30 people come, and
9 that's useful information, but that may or may not
10 be effective in a regulatory process.

11 So that's why we want to have these meetings
12 and early on have that discussion about what you're
13 trying to do in terms of collecting information
14 because there really is a science behind it. We do
15 have on the website,
16 fda.gov/requestameetingondrugs, those circumstances
17 for which there are other types of meetings, such
18 as the ones Selena talked about, but we can help
19 facilitate that for you.

20 Now we're going to hear about the rare
21 disease program because as I referenced early on,
22 many of the folks that we hear from are in the rare

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1 disease community. I do want to recognize Larry
2 Bauer in the back who really has been a champion of
3 the rare disease program and rare disease advocacy.

4 Larry, could you stand up and be recognized?
5 I know many folks know you. You really have done a
6 terrific job over many years in really addressing
7 the issues of the rare disease community.

8 (Applause.)

9 DR. WHYTE: We're going to hear about the
10 rare disease program right now, and I'm delighted
11 to introduce Dr. Lucas Kempf, who is the acting
12 associate director of the rare disease program in
13 the Office of New Drugs.

14 Presentation - Lucas Kempf

15 DR. KEMPF: I am Lucas Kempf, the new acting
16 director for the rare diseases program. My fun
17 fact is I spent the last week in a car with my
18 children driving cross-country, and I found out
19 this morning that Kansas doesn't necessarily have
20 the high speed internet to transfer my slides. So
21 I'm not entirely sure which version of my slides
22 are going to be in this talk, so please forgive me

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1 if we skip through some stuff that maybe needs to
2 be updated. Obviously, this is the FDA, so I have
3 no disclosures.

4 As far as the rare diseases team, we're a
5 small team that's located in the Office of New
6 Drugs, the immediate office. Why are rare diseases
7 important? Rare diseases as defined in the
8 regulation of the United States is any disease that
9 affects less than 200,000 people. This means in
10 this country, we've only recognized probably about
11 7,000 rare diseases. And this number keeps
12 increasing year by year because as our
13 understanding of disease gets better and genetics
14 are improving, we're understanding some of these
15 things that we're calling common diseases actually
16 have a genetic or very specific underlying
17 etiology.

18 Now, even though we call these rare, they're
19 affecting about 1 in 10 people in the United
20 States. Cumulatively, this means a fairly large
21 number of people in the United States are actually
22 affected by a rare disease.

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1 The challenges in drug development for rare
2 diseases is that primarily since these affect very
3 few people, a natural history is often barely
4 understood or characterized. These diseases
5 themselves tend to be serious, life threatening,
6 and lacking approved therapy. For us at CDER this
7 is important because there are very specific
8 regulatory programs that Congress has passed to
9 help develop drugs for serious life-threatening
10 diseases, and especially rare diseases.

11 The small population make it very difficult
12 to recruit and design these drug trials. The
13 disorders themselves may be diverse. And as we
14 heard earlier, since there is very little known
15 about these diseases, it's very hard to know what
16 endpoints should be derived for these drug trials.
17 What are meaningful clinical outcomes in these
18 populations may not be well understood, and
19 biomarkers for the improvement in these settings
20 may often be lacking.

21 It is frequently a lack of drugs that have
22 been developed previously for these diseases, so we

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1 don't know exactly how to do this. So frequently,
2 these are completely novel programs, and nobody's
3 entirely sure what the outcome should be as opposed
4 to something for like major depression, where there
5 are 16 or more different drugs that have already
6 been approved. Also, about 50 percent of these
7 disorders affect children, so there are special
8 ethical considerations that you have to use when
9 you're doing trials in children.

10 The rare diseases program, the reason we
11 exist is to facilitate, support, and accelerate
12 drug development for these rare disorders. The
13 ways that we do this is a series of different kinds
14 of responsibilities and programs that we enact. We
15 help develop CDER policies and procedures through
16 guidance developments and interactions with the
17 senior staff.

18 We help develop good science in the areas of
19 rare disease, so we develop a database of all the
20 new drugs that are being developed to help inform
21 the agency's understanding of what we need to do to
22 help develop these sort of drugs. We also develop

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1 workshops to elicit external device to inform our
2 internal thought processes about ways things should
3 be done.

4 An example is this. We recently had a
5 workshop on rare disease trial designs, which is
6 fairly successful. Several hundred
7 biostatisticians all showed up to discuss the ways
8 that you could design trials when you only have a
9 handful of patients and you can't necessarily use
10 the standard statistics in that sort of fashion.

11 Internally what we do is we help educate our
12 staff because a lot of the staff come in with not a
13 lot of rare disease experience, and then suddenly
14 they get an application that involves some small
15 population of only a hundred people. How do they
16 even approach that drug development program. So we
17 run a 101 course for our new reviewers, and we also
18 have an advanced study day-line course that we
19 educate our staff yearly.

20 We also do external training. We give
21 presentations at national and international
22 meetings and interact with workshops. We do a lot

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1 of patient-focused drug development group meetings
2 either here at the FDA or the ones that are being
3 externally led to help our community develop
4 meaningful data coming out of those meetings that
5 will help inform the drug developers about the
6 needs of the patient groups.

7 Internally, we also help work on one of
8 these acronyms, the PRV program, priority review
9 voucher, which is an incentive that Congress has
10 given drug companies to develop drugs for rare
11 pediatric diseases. We also are members sitting on
12 the Rare Disease Council within the FDA, and we
13 work with our external groups such as NORD. We
14 have a cooperative agreement with them to help
15 develop some of these registries that develop the
16 information that we were discussing earlier.

17 We're also charged with working
18 collaboratively with our stakeholders. We work
19 with the NIH on a joint task force. We work with
20 their rare disease annual meeting and work with
21 TRNDs and NCATS to help them with their natural
22 history study initiative. Also with the patient

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1 groups, we work in these face-to-face meetings that
2 PASE, P-A-S or OHCA helped set up.

3 We give presentations to the stakeholder
4 groups when they have meetings to help them go
5 through some of the regulatory hurdles that they
6 may be encountering as they partner with drug
7 companies for drug development. We help National
8 Organization for Rare Diseases have their annual
9 meeting, review their program, and help set up
10 their poster sessions.

11 So why is this all important? If you just
12 look at drug development currently, this is a graph
13 of new molecular entities. These are the brand new
14 drugs. They've never been developed before, so
15 there is this special category. And as you can
16 see, year by year, they're kind of going up in the
17 United States.

18 Now, when you look at how many of these new
19 drugs are for rare diseases, and you look at year
20 to year, just looking at the last three years,
21 about 40 percent of all new molecular entities that
22 are being developed in the United States are for

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1 rare diseases. This is a considerable part of
2 current drug development.
3 I'll just kind of skip by that. These
4 programs for rare diseases, when you look at that
5 40 percent -- these is our most recent updated
6 numbers -- about 56 percent of those are first in
7 class. These fast-track, breakthrough, and
8 priority reviews, those are accelerated programs
9 that involve more interaction with the staff. And
10 we're seeing that, at least in the United States,
11 72 percent in this last year were of rare disease
12 drug development was first done here in the United
13 States.
14 This is ever-increasing. In order to get a
15 rare disease drug designation, you send in an
16 application that tells the agency that you're
17 developing your drug for a rare disease, and we
18 chart this. As you can see, the number of
19 designations and requests that are coming in are
20 accelerating over the next couple of years. So
21 this is going to become a larger and larger portion
22 of the agency's drug portfolio. We're going to

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1 skip by that. This is the rare disease priority
2 review determinations for the pediatrics, so that
3 also is going up.
4 Another important part of our program for
5 those of you who have been here before -- and it
6 seems 80 percent of you all have -- in the last
7 years, we've developed an EMA-FDA rare disease
8 cluster. This cluster is helping facilitate and
9 accelerate drug development due to the fact that we
10 recognize that rare disease drug development is an
11 international program. It's almost impossible to
12 do a drug development program just in the United
13 States. Therefore, we need to have greater
14 coordination between what you're being asked to do
15 in the EMA and the advice that you're getting of
16 what you should do in the FDA.
17 So what we've started up in the last year is
18 monthly meetings with the EMA to help coordinate
19 and collaborate with them in the advice that we're
20 giving in all phases of drug development, even in
21 the IND, in the early drug -- or even before some
22 drugs are being developed, we help coordinate. We

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1 help coordinate in the advice that we're giving in
2 the early IND phase. Also, when drugs are under
3 review, our reviewers also are now allowed to
4 collaborate with the EMA to understand the data
5 that they're receiving so that both sides of the
6 Atlantic are coming to you with similar
7 conclusions, hopefully.
8 We help identify the trial endpoints, trial
9 designs; determine how we're going to be flexible
10 on both programs; help try to define what the size
11 of these trials might need to be to determine the
12 safety for these populations; and then share
13 scientific evaluations of these products. So when
14 we look over the course of the last year, some data
15 on what we've been doing, we've had about a total
16 of 53 agenda items in the last year broken down
17 into informing each other, about a third; protocol
18 assistance; and then actual product discussions are
19 things that are in active review.
20 When you just look at the active advice
21 areas, a lot of it is in this protocol assistance
22 discussion. These are things that are in early

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1 development that we're going to see the fruits of
2 in the next couple years as we coordinate the drug
3 development across the Atlantic. When you look at
4 the outcomes of these medians -- so there is about
5 30 different item -- about 90 percent of those, we
6 actually come to an alignment in our understanding.
7 About 63 percent of the time those discussions led
8 to actual actions being done on those different
9 development programs.
10 When you look at the ones that are actually
11 being reviewed actively as NDAs, about 20 percent
12 of the time, it actually changed regulatory action.
13 So we're having an early effect just in this last
14 year or so.
15 Obviously, as we heard before, request a
16 meeting is the best way to put in your request to
17 talk with the agency. With our program, we meet
18 frequently with patient groups and drug companies
19 to help facilitate folks' interaction with the FDA
20 to make things smooth. You can obviously directly
21 contact us or go through request a meeting. Thank
22 you.

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1 Questions and Answers
2 DR. HEALY: Thank you. Kevin Healy from
3 Roivant Sciences. A lot of great information and a
4 lot of work you're doing there, but certainly the
5 rare diseases cut across CDER and CBER. I wonder
6 if you could explain a little bit about your
7 team -- you mentioned the placement within
8 CDER -- and how that can apply for development of
9 biologics, and even with the EMA-FDA cluster.
10 DR. KEMPF: So biologics themselves fall
11 into both CDER and CBER. We throw around these
12 terms. An NDA is for a new drug application. A
13 BLA is for biological applications. A lot of the
14 BLAs are actually done in CDER, so antibody
15 products, small nucleotide RNAs, those sort of
16 things, all fall in CDER. But we do coordinate
17 with them.
18 CBER itself has a group of rare disease
19 professionals. It's not quite as organized as a
20 program itself like we are, but the council that we
21 meet, CBER is on that. CDRH is on that. We're on
22 that. The Office of Orphan Products is also on

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1 that. So we all meet together to make sure that we
2 coordinate. CBER is also part of our educational
3 program, so when we develop our educational
4 internal meetings, they have members to help define
5 that agenda with us.
6 So while we have the defined program, we're
7 always working collaboratively. Actually, some of
8 the EMA cluster meetings, we bring in folks from
9 CBER because the EMA doesn't necessarily break it
10 up the same way. They just say we want to talk
11 about this product, so we put it on the agenda.
12 Do I have any other questions?
13 DR. LUO: Hi, Dr. Kempf. My name is
14 Michelle Luo. I'm from the Office of Women's
15 Health. I think I have two questions. First, in
16 the device review, they have HD, called
17 humanitarian device exemption. Usually, the
18 patient has less than 4,000, but that's before
19 definition. So they're only looking for more
20 safety, not the effectiveness or efficacy. I was
21 wondering for the drug review, do you assess both
22 safety and efficacy? That's my first question.

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1 The second question is, based on the new
2 21st Century Cures Act, they've changed the
3 definition of rare disease. If I'm correct, from
4 4,000 to not more than 8,000. So my question is,
5 are you thinking this definition change will cause
6 the volume of the CDER submissions on rare disease,
7 and what's the effect that can be leading to this
8 definition change? Thank you.
9 DR. KEMPF: I think you're referring to the
10 definition for humanitarian device exemption. That
11 didn't change the definition for drugs. The drug's
12 definition is the same. What did change recently
13 is with the pediatric group review, is that it used
14 to say the majority of your patients had to be
15 pediatrics, or that was being interpreted as over
16 50 percent.
17 There is some realization that that was
18 leaving out some very important groups, so they
19 changed the definition to say that the serious and
20 life-threatening aspect of the disease has to
21 primarily affect pediatrics because if you look
22 epidemiologically, you could see a small population

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1 of patients who are children and may pass away, but
2 then a less affected group may continue living.
3 And then the general population would be higher,
4 though the serious aspect that you're trying to
5 develop your drug for could be affecting this small
6 group, and then they wouldn't get the pediatric
7 review voucher, which wasn't the intent of Congress
8 initially.
9 Did that answer all your question? Thank
10 you.
11 Are there any other questions?
12 (No response.)
13 DR. KEMPF: Thank you.
14 (Applause.)
15 DR. WHYTE: Thank you. And now we're going
16 to test your knowledge, so get out your clickers.
17 And we're going to have Jamie Bishop, our program
18 manager, come to the front. And her fun fact,
19 which is very hurtful for someone who worked at
20 Discovery Channel for a decade is she says she
21 doesn't watch television.
22 So let's hear your questions.

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1 Audience Response Questions - Jamie Bishop
2 MS. BISHOP: Good morning, everyone. The
3 first question is, who develops and tests new drug
4 products before they reach the public, A, FDA; B,
5 physicians and healthcare systems;
6 C, pharmaceutical companies and other
7 investigators; D, a consortium of international
8 regulatory authorities, including the European
9 Medicines Agency; and E; all of the above?
10 Please select the corresponding answer on
11 your clicker.
12 (Audience responds.)
13 MS. BISHOP: The correct answer is C, and 54
14 percent of you picked C.
15 The next question is about the rare diseases
16 program at the FDA. The rare diseases program
17 within CDER, A, provides training to medical
18 reviewers on rare disease drug development; B,
19 collaborates with the National Institutes of Health
20 to accelerate drug development; C, works
21 interactively with rare disease stakeholder
22 organizations; D, works to speed the review and

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1 fda.govrequestameetingondrugs and submit a simple
2 meeting request form; D, submit a letter of intent
3 to patientfocus@fda.hhs.gov that indicates your
4 interest in conducting an externally-led,
5 patient-focused drug development meeting; or E,
6 both C and D.
7 (Audience responds.)
8 MS. BISHOP: The correct answer is E. Thank
9 you.
10 DR. WHYTE: I am glad no one chose the No
11 Trial Left Behind Act.
12 With that, we are running a little ahead of
13 schedule, but we'll take a roughly 20-minute break.
14 We'll definitely start promptly by 11. You saw the
15 question about stop by and ask if anyone's free for
16 lunch. I do want to remind people, if you want to
17 eat lunch and you didn't pack your lunch, you
18 should consider placing an order for lunch. I know
19 many of you folks have been here before, but in
20 theory, you cannot get to the cafeteria without an
21 escort, so it may or may not happen; sometimes it
22 does, sometimes it doesn't. I do not want anyone

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1 approval of drugs that treat rare diseases; and E,
2 all of the above.
3 (Audience responds.)
4 MS. BISHOP: The correct answer is E, all of
5 the above.
6 The third question is, what initiatives did
7 the FDA launch in 2013 to gain patient perspectives
8 on specific diseases and their treatments through a
9 series of patient meetings to better inform the
10 drug review process? A, Clear Path Initiative; B,
11 Pharm More Information Campaign; C, No Trial Left
12 Behind; and D, the patient-focused drug
13 development.
14 (Audience responds.)
15 MS. BISHOP: And the correct response is D.
16 My final question is, what can public
17 stakeholders like you do to request to meet with
18 the experts from the FDA Center for Drug Evaluation
19 and Research? A, nothing, you're out of luck; B,
20 stop by the White Oak campus uninvited and ask FDA
21 security guards very nicely if any CDER division
22 directors are free for lunch; C, visit

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1 to get cranky at 2:00 because they haven't eaten.
2 So get a plan in place for the next
3 20 minutes. And after lunch, we are going to play
4 Jeopardy, and we're going to divide into teams. So
5 socialize among yourselves and start to think about
6 who your team will be, and then you can tweet out
7 that you won Jeopardy, FDA Jeopardy at FDA.
8 So see you again in about 20 minutes. Thank
9 you.
10 (Whereupon, at 10:37 a.m., a recess was
11 taken.)
12 DR. WHYTE: At this time, I'd like to
13 welcome Dr. Elizabeth Hart up to the podium.
14 Dr. Hart is a medical officer in the Division of
15 Gastroenterology and Inborn Error Products in the
16 Office of New Drugs, and she's going to provide
17 insight into the needs of the CDER drug review
18 divisions. And a fun fact about Elizabeth is that
19 she has worked on four continents and traveled to
20 six, and has competed in multiple triathlons.
21 More to hear on what you did on all those
22 continents. Thank you. Antarctica?

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1 DR. HART: No, that's the only one.
2 DR. WHYTE: All right. Thank you.
3 Presentation - Elizabeth Hart
4 DR. HART: Thank you for having me. Good
5 morning, and welcome to everyone. My name is
6 Elizabeth Hart, and as he said, I am a medical
7 officer in the Division of Gastroenterology and
8 Inborn Error Products within the Office of New
9 Drugs, within the Center for Drug Evaluation and
10 Research. This morning I'm going to talk about the
11 needs of the CDER review division, specifically a
12 little bit about what we do, the regulations behind
13 what we do, and then where are there opportunities
14 for patients and patient advocates to get involved.
15 I have no disclosures.
16 The primary work of the CDER review
17 divisions is to evaluate the efficacy and safety of
18 new drug applications by sponsors. We don't
19 determine the priorities. We don't determine which
20 drugs are being evaluated for different diseases,
21 but whatever comes in we evaluate. So we can't
22 prioritize. That's up to sponsors, as you got in

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1 the questions.
2 The drug evaluation process is very
3 important to our shared goals of having safe and
4 effective new therapies for patients in need and to
5 do that review as quickly as possible so that these
6 new drugs can be marketed and available if they are
7 determined to be safe and effective. In order to
8 aid sponsors in the drug development process, we
9 are involved, and are willing to be involved from
10 the early stages of drug development, and continue
11 to be involved postmarketing to further assess
12 safety.
13 A little bit about the drug development
14 process. Typically people think of it starting at
15 the IND phase, which is when an investigational new
16 drug is being evaluated for use in humans in the
17 United States. However, there's actually a huge
18 amount of work that happens before a drug ever
19 reaches that point. There are issues with the
20 discovery and the nonclinical research. But also,
21 particularly for rare diseases -- and I will come
22 back to this a little bit later -- are issues

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1 related to understanding the disease and how to
2 measure important outcomes. And there's also a
3 role for all of you there as well.
4 After a drug has an IND, it goes through the
5 clinical development process. There are phase 1
6 studies to determine safety and tolerability; then
7 there are phase 2 studies, which are dose ranging,
8 proof of concept; and phase 3 studies are
9 considered to be the pivotal safety and efficacy
10 studies at which point an NDA for a new drug
11 application or a BLA for a biologic license
12 application can be submitted, is evaluated and
13 reviewed, and then there is continued evaluation in
14 the postmarketing setting.
15 That's the brief process. There are
16 regulations that determine all of these.
17 Specifically, the 1962 drug amendments to the Food,
18 Drug, and Cosmetic Act requires the establishment
19 of effectiveness of the drugs as a prerequisite to
20 marketing approval. That effectiveness is further
21 defined as substantial evidence, and substantial
22 evidence consists of adequate and well-controlled

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1 investigations performed by qualified individuals.
2 And then the results have to be determined to
3 evaluate the effectiveness of the drug involved on
4 the basis of which it could fairly and responsibly
5 be conducted, that such experts -- that the drug
6 will have the effect it purports and is represented
7 to have under the conditions of use prescribed,
8 recommended, or suggested in the labeling or
9 proposed labeling thereof. A lot of regulations.
10 I have not memorized them all.
11 Let me talk a little bit more about the
12 adequate and well-controlled studies because these
13 are the hallmark of moving a drug to market. It's
14 important to distinguish the effect of a drug from
15 other influences, including spontaneous change,
16 placebo effect, and biased observations. An
17 adequate and well-controlled study must have
18 multiple characteristics. I want to highlight just
19 a few of them.
20 One is that there are appropriate controls
21 for valid comparisons -- it seems obvious but it's
22 actually much more challenging in

<p style="text-align: right;">Page 85</p> <p>1 practice -- appropriation selection of subjects; 2 and well defined and reliable methods of assessing 3 that response, as well as adequate measures to 4 minimize bias and perspectively planned analysis 5 with rigor. 6 Once these studies are performed, how do we 7 determine clinical benefit? And that is also 8 defined for us. Treatment benefit occurs when a 9 drug positively affects how a patient feels, 10 functions, or survives, as discussed previously by 11 Dr. Daniels. But these are really important points 12 because it gets to things that are important to 13 patients. That clinical effect must be clinically 14 meaningful in the context of the given disease. So 15 we're not talking about just statistical change. 16 We're talking about clinically meaningful change to 17 outcomes that are important to patients. 18 This all sounds very straightforward on 19 paper, but the challenges come in practice. These 20 challenges are amplified, as Dr. Kempf said, when 21 it comes to rare diseases. First of all, with 22 rare diseases, we're dealing with small</p>	<p style="text-align: right;">Page 87</p> <p>1 instruments, all need to be figured out for each of 2 these diseases. 3 It's not easy, but it's doable. And as you 4 can see from the previous examples, there are 5 multiple new molecular entities that have been 6 recently approved for rare diseases. But to 7 develop more of them, where do we start? We 8 actually start with the end in mind. This is a 9 picture from Namibia, one of those countries I 10 travel to, and it's really important to recognize 11 that the path isn't always smooth or easy, but it 12 is possible. So think about what is going to be 13 clinically meaningful and evidence of benefit, and 14 then how do you design an adequate and 15 well-controlled trial to measure that. 16 What can patient and patient advocates do to 17 facilitate drug development? There are certain 18 steps irrespective of what industry and different 19 sponsors are doing to develop drugs that apply to 20 disease-specific populations. This includes 21 understanding the disease by performing natural 22 history studies, which I will discuss in more</p>
<p style="text-align: right;">Page 86</p> <p>1 populations, which means even more so there are 2 limited opportunities for study and replication. 3 Every patient always counts, but especially in rare 4 diseases and in rare disease trials. 5 There's an additional challenge of the 6 disease being heterogeneous, so these differences 7 can't always be dealt with because of the small 8 samples based on statistical analysis. So you want 9 to make sure that results aren't being driven by 10 outliers and that you understand, again, that 11 effect is coming from the drug versus it is based 12 on change in the population. 13 There are problems that sometimes we just 14 don't even understand the disease manifestations, 15 so making sure that the drug is targeting something 16 that is meaningful and being able to distinguish 17 effects of the drug from effects of the disease. 18 With rare diseases, as we mentioned, there are a 19 whole variety of them, and, unfortunately, many of 20 them don't have available drugs, which means that 21 there's no precedent for drug development. That 22 means that endpoints, outcome measures, tools,</p>	<p style="text-align: right;">Page 88</p> <p>1 detail; provide the patient experience data, which 2 Dr. Daniels talked about earlier this morning; and 3 then to also, if possible, validate those 4 qualitative and quantitative assessment methods; 5 and when trials are being performed, encourage 6 participation. 7 A little bit about natural history studies. 8 These are comprehensive studies that are designed 9 to characterize the disease over time, starting 10 from the pre-symptomatic phase through the early 11 symptomatic, through the late symptomatic, and then 12 either to resolution of the disease to stable 13 disability or death. 14 It's really important that these studies 15 capture as much of the population as possible and 16 identify variables that correlate with disease 17 progressions and outcomes in the absence of 18 experimental therapies; and as things move more 19 towards personalized medicine, understanding the 20 different features that impact the disease are 21 especially important. These studies are not the 22 same as registry studies, but they can be performed</p>

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1 prospectively or retrospectively.
2 So what do we do with these natural history
3 studies when they're available? They really
4 provide the scientific framework for rigorous
5 investigation that allow us to understand disease
6 outcomes and variability within disease
7 populations. This can inform trial design as far
8 as endpoints, determining a homogeneous population
9 to study, and then can also help to determine what
10 is a sample size to detect effect.
11 Rarely, but sometimes they can serve as
12 external controls for a pivotal study.
13 Particularly in rare diseases in which the disease
14 course is highly predictable, the endpoints are
15 objective, and there can be a dramatic treatment
16 difference, an external control can be used. But
17 in order for that to be realistic, the population
18 and the assessments in the treatment trial, the
19 experimental trial, and the natural history study
20 have to be equivalent and comparable.
21 I think that this provides a basis for
22 rethinking that progression from IND to BLA, and I

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1 think it's really set on the foundation on planning
2 and natural history studies, and understanding the
3 disease, particularly in rare diseases, and what
4 effects and tools can be used. I offer this as a
5 new thought of how to think of the regulatory
6 framework of rare disease, starting early with
7 understanding the disease even before there is
8 potentially a specific compound for drug
9 development so that once there are potential
10 compounds available, the framework has been done
11 and a clinical trial can happen sooner and be
12 designed better.
13 The other thing, again, as Dr. Daniels
14 talked about this morning, is getting that patient
15 experience data to inform clinical endpoints to
16 ensure that it's the bothersome signs and symptoms
17 associated with the disease that are assessed
18 rather than symptoms that might not be as common or
19 as problematic, so that if a drug is effective, it
20 can be appropriately assessed on symptoms that
21 matter. Then along those lines also ensure that
22 the impact of the condition on functioning and

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1 quality of life is assessed, and patient experience
2 data can also determine and help to inform the
3 risk-benefit assessment as far as patient
4 preference for side effects, but in so many other
5 ways.
6 The assessment tools are really important.
7 For, again, rare diseases, we can sometimes take
8 tools that have been developed from one population
9 and use them for another, but sometimes that's
10 problematic. So designing and validating both
11 patient and observer and clinician-reported
12 outcomes in the rare disease is really important,
13 and that can be started early.
14 Then lastly, clinical trial participation.
15 Patient participation is necessary for clinical
16 trials and new drug development. Recently, we've
17 been hearing some concerns sometimes expressed as
18 far as enrollment in placebo-controlled trials, and
19 I just wanted to emphasize that each patient really
20 needs to evaluate any clinical trial and make a
21 determination for themselves whether it's something
22 that that individual wants to participate in. But

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1 in order to advance science and develop new drugs,
2 the information that can be gleaned from a
3 controlled trial is really important and will often
4 give us the information about whether or not a drug
5 is effective sooner than other trial designs.
6 My conclusions are the best access for
7 patients to effective therapy is an approved drug.
8 Patient engagement and early entry into the
9 development process is important to informing drug
10 development and regulatory decision-making. And
11 you can help the FDA by early engagement and use of
12 scientifically sound methods to collect
13 representative patient data for natural history
14 studies and endpoint selections and measurements.
15 Thank you.
16 (Applause.)
17 Questions and Answers
18 DR. HART: Any questions?
19 MS. NIZAR: Yes.
20 DR. HART: Great.
21 MS. NIZAR: Hi. My name is Neena. I'm from
22 the Jansen's Foundation. I'm president and

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1 founder. I had a question. Our disease population
2 has about eight patients across the world, so when
3 you're talking about a clinical trial for such a
4 population, what would the control group be?
5 DR. HART: Yes. These are very much the
6 challenges. Sometimes in that setting, we will use
7 an external control group, so having that natural
8 history, depending upon what it is and what the
9 endpoints are, is a possibility. Sometimes there
10 can be a delayed start. There can be a comparison
11 within individual comparison. It really depends
12 upon what the symptoms of the disease are, what the
13 heterogeneity of the disease is, and really what is
14 that natural history, because that can inform
15 potential clinical trial designs. But it is
16 possible.
17 MS. KRUSE: I'm Caroline Kruse. I'm from
18 the Platelet Disorder Support Association. I am
19 curious about biosimilars. It's my understanding
20 that the FDA has approved 9 biosimilars, 7 in 2017.
21 Are there any concerns about long-term data,
22 interchangeability, labeling, and what role do you

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1 see biosimilars playing in the rare disease space?
2 Thank you.
3 DR. HART: Yes, biosimilars have a different
4 pathway, as you alluded to, than new drugs. They
5 are in between the ANDAs and the new drug. So
6 there is a lot of potential and opportunity in that
7 space. I am not the most appropriate person to
8 speak about that space, though.
9 MS. FOXWORTH: Hi. It's Phyllis Foxworth
10 again. Selena this morning shared that there would
11 be guidance around the patient experience data, and
12 I was just wondering if you can expand on how once
13 that patient experience data is captured, what's
14 the process for getting it to the appropriate teams
15 that do the drug reviews?
16 DR. HART: I wish Selena was still here to
17 answer that, but there are a couple of
18 different -- my understanding is that there are a
19 couple of different pathways set up to do that, to
20 make sure that that information is available, and
21 there are different ways as far as sharing that
22 data.

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1 Other questions?
2 (No response.)
3 DR. HART: Thank you.
4 (Applause.)
5 DR. WHYTE: In terms of biosimilars, Leah
6 Christl is the point person at the center on that
7 topic, and if you have questions about
8 interchangeability, we do have a lot of information
9 on site. We have a continuing medical education
10 program on biosimilars. We have specific language
11 about interchangeability and what that means. You
12 can follow up directly with me after the meeting,
13 and I can put you into contact with Dr. Christl or
14 point you in the right way to the questions.
15 I know even though sometimes we say there's
16 a lot of information on our website, and I did say
17 that, it can be hard to find, and it's not always
18 written in the best language. But biosimilars is a
19 topic where we've gotten lots of questions, and we
20 really do have a centralized process to help
21 address those issues, whether it's from the
22 perspective of a physician wanting to understand

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1 more about biosimilars -- and they tend to be more
2 of specialty physicians, rheumatology, GI -- or
3 patient groups who might have a question as to what
4 a biosimilar is and conflating biosimilar with
5 generic. So I'm happy to follow up on that and
6 specifically the issue of interchangeability.
7 In terms of also getting information to the
8 review divisions, which is a great point, that's
9 why we really need to have a coordinated process.
10 And Selena and her team really are figuring out all
11 those best strategies to get the information to the
12 review division, but it also goes back to that
13 point early on when I said to you we want to hear
14 from you early on in terms of the drug development
15 process.
16 Today we're focused on the FDA, but
17 remember, there's really a continuum of drug
18 development. And in many ways, the time for
19 patients to engage on drug development is not only
20 at the time when an NDA has been submitted and a
21 decision has to be made whether to approve or not
22 approve, it's very early on in the process, and

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1 talking to sponsors and working with sponsors in
2 terms of what those endpoints might be, or working
3 with the agency and trying to think through does
4 there need to be guidance on what those endpoints
5 are to foster drug development.
6 So that's why I encourage you to talk often
7 and talk early to us, and we'll figure out for you
8 how to get that information to the review division.
9 And what I often like to say -- and Dr. Woodcock
10 has joked the agency is full of introverts, and now
11 we're trying to create a system that relies upon
12 extroverts. And I guess I'm one of the few
13 extroverts and I'm trying to hire extroverts.
14 But you also want to keep in mind the review
15 divisions look at data, right? That's how they're
16 going to make decisions. So how do we capture and
17 package that experiential data in terms of a way
18 that reviewers can use? How do we get it into that
19 regulatory framework? Patient engagement really is
20 an iterative process. I also want to say we're
21 talking a lot about patients here, but remember,
22 this is about all stakeholders who aren't sponsors

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1 to have this type of interaction with the agency.
2 The sponsors already have lots of strategies and
3 tools to interact with us.
4 At this time, I'm going to turn to my
5 colleagues to find out whether we're going to
6 do -- okay. We are going to do the clickers, and
7 we're going to have Portia Seals, who's on our team
8 at PASE, who tells me that she participated in the
9 Olympic ceremonies at the Atlanta games. I'm just
10 going to leave it at that. She told me not to
11 expand on it.
12 MS. SEALS: The opening ceremony is not
13 actually in the Olympics.
14 DR. WHYTE: Oh, participated in the opening
15 ceremony. See I made it bigger; she participated
16 in the Olympics. You kind of did; just the opening
17 ceremonies, but that's still pretty good.
18 Audience Response Questions - Portia Seals
19 MS. SEALS: Question number 1, among the
20 world's preeminent regulatory organizations, which
21 approves new drugs the fastest? A, European
22 Medicines Agency; B, U.S. Food and Drug

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1 Administration; C, Health Canada; D, Japan's
2 Pharmaceutical and Medical Device Agency; or E,
3 Australia's Therapeutic Goods Administration?
4 (Audience responds.)
5 MS. SEALS: Sixty-seven percent of the
6 audience answered correctly with B, U.S. Food and
7 Drug Administration.
8 Question 2, the FDA considers all of the
9 following factors during the drug approval process
10 except, A, biological markers; B, patient-reported
11 outcomes; C, company stock prices; or D, clinical
12 outcomes?
13 (Audience responds.)
14 MS. SEALS: And of course the correct answer
15 is C, to keep ourselves out of trouble.
16 The next question, during a drug shortage,
17 the FDA can, A, manufacture more drugs to meet
18 demand; B, allow drugs to be imported from other
19 countries; C, force a manufacturer to produce
20 drugs; or D, none of the above?
21 (Audience responds.)
22 MS. SEALS: Wow. The actual correct answer

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1 is B, allow drugs to be imported from other
2 countries. So there you learned something.
3 The last question is, the FDA determines the
4 cost of drugs and whether insurance plans can cover
5 these medicines, A, true; B, false.
6 (Audience responds.)
7 MS. SEALS: And the correct answer is B,
8 false. Thank you.
9 DR. WHYTE: I'm going to be honest. I'm a
10 little disappointed in those that did not say that
11 the U.S. Food and Drug Administration approves
12 drugs the fastest. And perhaps you're saying,
13 "Well, John, you should have parsed it more
14 carefully to say that, for the most part, the FDA
15 approves drugs fastest in the world," because that
16 is the truth, and we have lots of references to
17 prove that, including New England Journal articles,
18 if you need it. But again, today really is
19 designed to help folks understand our processes and
20 learn a few things about the FDA, and correct any
21 misinformation that's out there.
22 One of the biggest challenges that we have

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1 in talking to stakeholders -- and you're hopefully
2 getting the theme that we're very interested in
3 talking to stakeholders and engaging with
4 stakeholders. There are instances where even if we
5 were to agree with what you're saying, there may be
6 instances where we cannot communicate to you what
7 our understanding on the issue is because there may
8 be current regulatory actions planned, and we can't
9 even tell you if we're planning regulatory action,
10 which can be very frustrating for people because
11 you often will come and have an excellent
12 presentation, and then you feel you're not really
13 getting anything in return because we don't seem to
14 be responsive.

15 You shouldn't view that as we're not
16 interested, or that we don't care, but there are
17 circumstances where we cannot necessarily indicate
18 what is happening. And we do have to do a better
19 job of more effectively communicating that to
20 stakeholders so you don't leave with the impression
21 that we don't care, we're not interested, or we
22 don't agree.

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1 Lieutenant Commander Sadhna Khatri, who
2 works with me and is a good friend and colleague,
3 is going to help tell you what CDER can and cannot
4 do by law; not what we don't want to do or want to
5 do, but again -- and this is a very important
6 conversation, and Dr. Woodcock alluded to it, that
7 we often don't explain to stakeholders that there
8 are these circumstances where we can't give you the
9 information perhaps that you would like.

10 Lieutenant Commander Khatri's fun fact is
11 that she participated at the White House with
12 Indian dance, as part of an Indian festival. So
13 it's with great pleasure that I call to this podium
14 Lieutenant Sadhna Khatri.

15 (Applause.)

16 Presentation - Sadhna Khatri

17 LCDR KHATRI: Dr. Whyte, thank you for the
18 introduction, and welcome to all of you who came to
19 attend in person at this beautiful White Oak
20 campus, and also to those on the Web. Welcome to
21 each and every one of you. My job this morning is
22 to tell you something that you want to know but

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1 probably also something you may not want to know,
2 and to really go into some of those issues around
3 the limits of our ability to engage. So let's
4 start with CDER's mission.

5 CDER's mission is to promote and protect the
6 public health by ensuring that safe and effective
7 drugs are available to Americans. This is a very
8 succinct mission statement, but it encompasses a
9 lot of activities. CDER routinely consults with
10 American people in making its decisions about the
11 drugs that they use. It holds public meetings to
12 incorporate expert and consumer input into its
13 decisions. The center also announces many of its
14 decisions in advance so that the members of the
15 public, academia, industry, trade associations,
16 consumer groups, and professional societies can
17 comment and make suggestions before decisions
18 become final.

19 In addition, CDER holds annual public
20 meetings with consumers and patient groups,
21 professional societies, and pharmaceutical trade
22 associations to obtain enhanced public input into

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1 its planning and priority-setting practices. Over
2 the years, the policies have changed and laws have
3 become stronger, but the center's present and
4 future mission remains constant. That is to ensure
5 that the benefits of drug products made available
6 to the public outweigh all known risks.

7 Ultimately, patients are the focus of all CDER
8 activities, and we need to engage with them

9 First, let's start with some of the things
10 you really want to know, and that's where the
11 opportunities for engagement are. This has changed
12 over the last decade since I have been involved
13 with the drug development here at FDA. Patient
14 input is now playing an important and increasing
15 role in development and regulation of medical
16 products. A large number of patient activities are
17 in progress at CDER.

18 You can see on the slide the multiple
19 different opportunities for patient engagement with
20 FDA. You heard early this morning my colleague,
21 Chris Melton, mention about the external
22 stakeholder meeting request system, which the

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1 professional affairs and stakeholder engagement
2 staff has launched recently. There exists your
3 opportunity to request meetings with CDER.
4 The next is the patient-focused drug
5 development meetings. This is turning out to be
6 perhaps the most effective and best way to bring to
7 us patients' understanding and experiences of the
8 disease. We have speakers on today's agenda who
9 will be talking about the patient-focused drug
10 development in detail, so I'm not going to go into
11 detail with that.
12 Next, we have the advisory committee
13 meetings, and most of these advisory committee
14 meetings do have a patient representative assigned
15 to the AC meeting -- that's what we call it in
16 short -- to present their point of view. Patient
17 representatives are selected to participate in an
18 AC meeting, and this is an opportunity for public
19 dialogue. Patient representatives are considered
20 government employees for the duration of the time
21 they are serving on the AC committee.
22 We also have public speaking sessions where

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1 many patients often take advantage and come and
2 speak, but they often get about five minutes to
3 make their point of view that is five minutes each.
4 And if you have not witnessed or participated, or
5 seen an AC committee meeting, there are a few
6 recordings on our -- actually a lot of recordings
7 on our website. I would highly recommend you to
8 see that. It's a very neat process.
9 Also, we often encounter patients at
10 national meetings, such as NORD, the National
11 Organization for the Rare Diseases, and we have
12 lively conversations with patients, and we engage
13 with them there. Sometimes patient advocacy groups
14 also request to speak to us on an ad hoc basis, and
15 we invite them here at FDA, and we schedule
16 meetings with the review divisions where they come
17 and express their point of view.
18 Then there are citizens' petitions. Many
19 patient advocacy organizations have the
20 sophistication to submit to us a citizens'
21 petition, which outlined a desired action that they
22 would like us to consider on a point of view for us

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1 to consider. We carefully review those, and they
2 often have a lot of legalistic aspects to them.
3 Finally, we do put out notices in the
4 Federal Register so that the public can be aware of
5 some of the things we are doing such as the
6 guidances. We do carefully review all the
7 comments, sometimes thousands of comments, that
8 come to us from the Federal Register notices often
9 from patients and patient advocacy organizations.
10 One of the most interesting developments for
11 patient engagement has been in the development of
12 guidances. The Duchenne muscular dystrophy
13 community got together and put together a proposed
14 guidance that they then submitted to the FDA, which
15 we then reviewed and used as the basis of our own
16 guidance on the development of drugs for Duchenne
17 muscular dystrophy.
18 We often receive lots of emails, letters,
19 and phone calls. Sometimes the advocacy
20 organizations seem to think that that is the most
21 effective way, to bombard us with thousands of
22 emails. While certainly it does get our attention,

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1 I can tell you that it's probably not the most
2 effective way to be able to get your opinion across
3 to us. And we are in the age of social media.
4 FDA also has an FDA Facebook page where patients
5 can engage with FDA and give their opinions.
6 Earlier during the day, you heard Dr. Selena
7 Daniels. She spoke about patient voice. Patient
8 voice is important to us because patients bring
9 insight to a disease. Patients provide insight on
10 issues, problems, and/or questions that are
11 important to patients and their family members. We
12 also recognize not just one patient represents the
13 entire patient community of that particular
14 disease. Patients have a vested interest and
15 diversity of opinions and varied perspectives both
16 in terms of risk tolerance and potential benefits,
17 so it's important for us to identify what matters
18 and what is important for the patient. This will
19 help us in the development of clinical trials that
20 are meaningful and realistic, and will raise FDA's
21 awareness.
22 Dr. Whyte early on mentioned that the

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1 science of patient engagement is used in
2 integrating the patient's voice into the regulatory
3 process to better enable patient's perspectives to
4 shape product development and approval. What value
5 can patient engagement add? Better designed
6 clinical trials; faster recruitment and improved
7 retention; cutting time and cost of product
8 development; help develop meaningful endpoints and
9 measurements; contribute valuable data to patient
10 registries and natural history registries; and
11 medical products that better reflect outcome and
12 quality-of-life measures most important to
13 patients. So it is very important for us. We want
14 to hear from you.

15 FDA desires to be transparent, but often
16 can't because of the law. We do want to have a
17 dialogue. We want to hear from you, but often when
18 we are talking to you, we are constrained, and it's
19 very uncomfortable for us because we really want to
20 be able to talk back, but we can't, and that's
21 predominantly because of the law. I met a couple
22 of you during the break, and we were talking about

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1 some things. I was restricted in giving my answers
2 because of the law, again, and I did express that.

3 We do operate under strict laws regarding
4 confidentiality in regards to our knowledge,
5 opinions, and what we are saying and discussing
6 with sponsors during drug development and the
7 review process because that's a very confidential
8 relationship that we have with the sponsor during
9 that period of time.

10 This greatly restricts our ability to
11 discuss or even mention the existence of specific
12 products that are under review or development
13 during that period of time. And I know sometimes
14 it frustrates the patient community that we can't
15 directly tell them what we are thinking and what we
16 think needs to happen next, or what we even think
17 of what has happened so far, but the whole reason
18 is that it's really designed to protect the
19 sponsor, and this is congressional action and law.
20 It's to protect their commercially sensitive
21 information.

22 You can imagine that if you met with me at

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1 the break, and I tell you what FDA is thinking
2 about a product in development, what our current
3 thinking is and what our plan is, and you have a
4 cousin who is a stockbroker, and you happen to meet
5 them at a dinner party, and you mentioned to them
6 what I had said, you can well imagine, he goes out,
7 and you can see how bad it could be.

8 The other area that I need to talk about is
9 bias, fairness, and consistency. We really do try
10 to be consistent in our approaches, and it's hard
11 because FDA is a very large organization made up of
12 thousands of people, but we work hard to be
13 consistent in that approach and avoid showing bias
14 to one company over another and rather must focus
15 on the scientific facts presented to us. We do
16 actively think hard about making sure that we are
17 acting in that way.

18 The same thing applies to our work. With
19 the patient organizations, we try to incorporate
20 and dialogue broadly with patients and industry and
21 not just picking one group over another group.
22 Sometimes patient advocacy is fractured, shocking

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1 information. Correct? But sometimes even within
2 small disease groups, we find that there are
3 patient advocates who have one strong view versus
4 another group of patient advocates that have
5 another strong view. So we have to be very careful
6 in listening to both the views and try and
7 incorporate those views into our thoughts.

8 Finally, there is this area of bias. If we
9 see the patients coming in who are paid and
10 selected by the sponsors to present their point of
11 view to us, believe me, we are aware of that. So
12 we also carefully examine that into what we hear
13 and what we know, being a very selected point of
14 view that we may be hearing.

15 As much as we listen and as much as we try
16 to incorporate -- and I think you will hear a lot
17 more details when they discuss about the
18 patient-focused drug development meetings, we
19 really do value what we hear, but we can't always
20 follow what we hear, and we don't always follow.
21 We have to act still in an independent manner, and
22 part of that can be due to the fact that the law

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1 may not allow us to do what you are recommending us
2 to do.
3 You'll be surprised that we even sometimes
4 get phone calls from Congress sometimes telling us
5 to do things, and we say, hmmm, I don't think
6 that's legal, and we sometimes can't always do
7 that. So we may also have a real difference of
8 opinion on the interpretation of the underlying
9 facts. You may or may not be aware, but in fact,
10 if you look at the medical and scientific published
11 literature, less than half of it can be reproduced,
12 so you can't always believe everything you read,
13 even in a medical journal. It doesn't always turn
14 out to be quite the truth.
15 FDA is the only regulatory organization in
16 the world that looks at the actual data. For
17 example, in Europe, they often will just look at
18 the summarizations that were given to them by the
19 sponsors. Here we say, in God we trust; everything
20 else, bring us the data, and we are going to take a
21 very good look at it. So we may have differences
22 and views on the practicality of the

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1 recommendations that are made to us, or as I
2 mentioned before, conflict with the laws or
3 regulations, maybe not in a way that makes it
4 illegal, but what introduces a very different legal
5 risk.
6 Finally, the last two, there can be an
7 inconsistency with the recommendations in our
8 entire policy position or previous decisions. Now,
9 that doesn't mean that we can't change our policy.
10 It does not mean we can't diverge from our previous
11 decisions, but we cannot do that lightly because
12 that would not be fair or consistent. So when we
13 do make a change, it has to be very, very carefully
14 considered and well supported.
15 With that, I'll conclude my presentation,
16 and again, your recommendations, patients'
17 recommendations are very valuable to us, but we
18 always can't follow or do what you're recommending
19 us to do. Thank you very much.
20 (Applause.)
21 LCDR KHATRI: My email address is here.
22 Please feel free to emailed me if you have any

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1 questions. We also have a mailbox for PASE, which
2 is cderpase@fda.hhs.gov. You can email us there.
3 I will be also here for the entire day, and if you
4 have any questions, please feel free to stop me.
5 Thank you.
6 Do you have any questions
7 Questions and Answers
8 MS. NIZAR: Thank you so much. All that
9 information was amazing. I just had a doubt.
10 We're a rare disease organization, and as I
11 mentioned, a very small one. You mentioned the
12 ESMR. You mentioned the PFDD, the ad hoc, the FDA
13 meetings, the advisory committee, the patient rep
14 program. Now, basically my question is, is there
15 like a flowchart. Step 1, where do we go? Step 2,
16 where do we go?
17 LCDR KHATRI: No, there is no flowchart or
18 any sequence in which you should go step 1, step 2,
19 or step 3. Those are the different options for
20 patient engagement, depending upon what works best
21 for you. So as Chris mentioned earlier and showed
22 you, the external stakeholder meeting request

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1 system is an online system, and you will be able to
2 request a meeting with FDA through that system.
3 It's a centralized process. It's a very noble
4 approach, and this is the first time PASE has done
5 it here at CDER. So if you request your meeting,
6 then we will be able to triage your request and
7 connect you with the right people.
8 MS. NIZAR: What's the turnaround time for
9 replying?
10 LCDR KHATRI: Seven days we respond to your
11 request. It's very easy form.
12 MS. NIZAR: Is it similar to the pre-IND
13 request?
14 LCDR KHATRI: I think our form is very
15 simple, and I can talk to you after the meeting or
16 doing lunch, and really walk you through the
17 process.
18 MS. NIZAR: Okay. Yes, I really appreciate
19 that. Also, I just wanted to mention, sometimes
20 it's not always easy to attend these meetings. We
21 took like an hour and a half, maybe two, to
22 actually get here because the roads weren't

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1 accessible. We were literally on the road driving
2 in a wheelchair because we couldn't find
3 accessibility to get here.
4 So it's not always very easy, so email is
5 really our last resort. And sometimes it's not
6 clear on your website either like who is the person
7 that we need to contact, so we're sending like
8 blind emails to people hoping against hope that
9 someone will reply. Thank you.
10 LCDR KHATRI: First of all, I'm sorry that
11 you had to go through that much trouble to travel
12 to the White Oak campus, but this meeting is also
13 on the Web, so it's easily -- people can attend
14 through Web as well. And we do understand the
15 traffic around the Silver Spring area and just
16 coming to the White Oak campus. So we do
17 understand all that.
18 Regarding the emails you mentioned, I gave
19 you two emails, so if you have any questions, we
20 have two emails. You can personally contact me,
21 and I will also give you my card. But it is also
22 on the slides, which will be posted on our website.

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1 Also, PASE has a central email, which is monitored
2 every single day. So every hour we would
3 say -- and we are very quick in responding to any
4 emails which we receive.
5 MS. NIZAR: Thank you so much. I appreciate
6 it.
7 LCDR KHATRI: You are welcome.
8 DR. WHYTE: I think your point is very good
9 about people send emails blindly, and that was the
10 whole impetus, in a way, to create this centralized
11 process, that you don't need to know who you need
12 to contact. You just go to
13 fda.gov/requestameetingondrugs. So it's a fair
14 point, and we acknowledge that it's not easy to
15 navigate literally and figuratively the FDA.
16 So we still have work to do. It's iterative
17 steps along the way. And I want to thank
18 Lieutenant Khatri for that presentation in terms of
19 sometimes it's hard for us to tell you when we
20 can't say things. I liked your line when you said
21 sometimes we'd like to talk back. She means in a
22 good way, the talk back. Some other days may be

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1 different.
2 Are there any other questions that people
3 have? And then we're going to break for lunch.
4 MS. KERKORIAN: You mentioned --
5 DR. WHYTE: I've been sitting next to you.
6 You could have just leaned over.
7 MS. KERKORIAN: -- I know, leaned over.
8 You mentioned the turnaround time for
9 responses to emails, but what is the turnaround
10 time once you've identified the right person? Is
11 there a turnaround time or a ballpark in terms of
12 how quickly a meeting can be scheduled for planning
13 purposes?
14 DR. WHYTE: We're really trying to
15 accommodate stakeholders. What I focus on with my
16 team is we're here for the stakeholders and how do
17 we make it easy for stakeholders. It is kind of
18 changing the mind-set. And for those of you that
19 have been at meetings here at the FDA, we tend to
20 travel in packs. So if you come to a meeting, we
21 may often outnumber the number of attendees you
22 have; that it's 20 people in the room. If

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1 Dr. Woodcock comes, it's 50 people in the room, and
2 that can be a challenge to schedule.
3 So we really do a couple of things. We want
4 to ask the requesters -- sometimes people have a
5 set time period that they want because they're
6 going to be here in the D.C. area for other
7 reasons, so we try to accommodate that as best as
8 we can. And I will tell you that since we've
9 launched, we've had some meetings that have been
10 scheduled and already have taken place within two
11 or three weeks. Other meetings are already set out
12 for a couple of months, and there are a couple of
13 reasons why that is.
14 Often folks want to assemble as many people
15 as they can. And let's be realistic; everyone's
16 not in the D.C. area, so folks have to fly in, and
17 it can be expensive to make a flight at the last
18 minute. And then depending upon the level of the
19 meeting, it can be a challenge scheduling. But
20 we're really committed to this idea of one or two
21 months to really be able to get a meeting.
22 I know that might seem long to some people,

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1 and remember, this is an iterative process that
2 we're trying to be as responsive as we can. We're
3 really trying to explore the idea of WebEx and
4 conference calls. I've talk to a couple of people
5 at the break, and I mentioned it in my remarks. I
6 just find there is this culture of meetings that
7 people physically want to come and meet. And we're
8 fine with that and embrace that, but sometimes that
9 can be challenging to schedule everyone.
10 WebEx can be productive, too, and conference
11 calls. So it's just really trying to consider
12 multiple approaches.
13 We have another question in the back, my
14 biosimilars friend.
15 MS. KRUSE: I just wanted to say that our
16 organization had a meeting back in November with
17 OHOP, which is the Office of Hematology and
18 Oncology Products. I don't mean to set the bar too
19 high, but I had sent an email to Rea Blakey in
20 PASE, and within 10 minutes, I received a response
21 and worked directly with Lieutenant Khatri. And
22 she was so wonderful and stayed in contact with me

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1 every step of the way. And if I didn't follow up,
2 she sent me a reminder email saying "Hey, Caroline.
3 You need to send those slides to me." But it was
4 really a wonderful process to go through --
5 DR. WHYTE: That's great to hear.
6 MS. KRUSE: -- and was not complicated in
7 any way, and just a very, very quick response on
8 the part of the FDA. So thank you for that.
9 DR. WHYTE: And nobody paid you to say that,
10 I feel like we have to disclose.
11 (Laughter.)
12 DR. WHYTE: That's great to hear.
13 MR. BARTEK: And this is another unpaid
14 solicitation.
15 DR. WHYTE: Okay. Oh, whoa. Let's keep
16 them coming.
17 MR. BARTEK: Just a quick comment. With all
18 the discussion about how to request a meeting and
19 how important it is to have meetings, one thing
20 that hasn't been terribly emphasized is the
21 importance of meeting with your sponsor, with the
22 pharmaceutical company at meetings that they

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1 request and are on their schedules, like pre-INDs
2 meetings, after phase 2 meetings, and so forth.
3 And the FDA can't invite us as patient advocates or
4 patients to those meetings.
5 The sponsor has to do that. But you can go
6 to a pre-IND meeting to represent your patients,
7 and you can become a very important aspect of the
8 conversation with the review divisions at those and
9 other scheduled meetings with sponsor.
10 DR. WHYTE: That's a very good point. And
11 as you know from most of those meetings, the
12 sponsor has to allow it, and the sponsor may or may
13 not allow it. We have often stated, and
14 Dr. Woodcock herself has stated, that there is
15 nothing that precludes patients or other persons
16 from attending these meetings, but they are the
17 sponsor's meeting, so folks would have to be guests
18 of the sponsor. We cannot include -- force that
19 participation.
20 I think that's a very good point. And
21 again, it also goes to the idea that patient
22 engagement and stakeholder engagement is along the

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1 continuum of drug development. It's not just at
2 that time when an NDA, a new drug application
3 package, is before the agency. And I think that's
4 a very important point, but it's also a good point
5 to emphasize that it can often be hard for
6 individual patients, for caregivers, to get through
7 to a sponsor, to get to that point to say this is
8 important to me, and we need to think through those
9 strategies as well.
10 Any other questions?
11 (No response.)
12 DR. WHYTE: All right. So we're going to
13 break for lunch. When we come back, we'll start
14 promptly at 1:00. We are going to have a fun 30
15 minutes, not that these last few hours haven't been
16 fun. But we're going to break up into four groups
17 at the front, where we're going to play FDA
18 Jeopardy, and we're going to test your knowledge.
19 There are no prizes other than your bragging
20 rights.
21 Technically, I don't think I'm allowed to
22 call it Jeopardy. I think it's licensed, but you

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1 get the point. So get sugared up and be ready to
2 have some fun promptly at 1:00. Thank you very
3 much.
4 (Whereupon, at 12:02 p.m., a lunch recess
5 was taken.)
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1 Team 4 is Kate; Sakshi; Christy; Matt;
2 Jillian.
3 That's the attitude over there.
4 Team 1, we need a sitter who's going to
5 click. Everyone needs to have a point person.
6 This is Team 1?
7 Where is Team 2?
8 (Crosstalk.)
9 DR. WHYTE: Where is Team 2? Huddle behind
10 them
11 Team 3? Who's Team 3? I was at my son's
12 T-ball game yesterday, and he's 5 years old, and
13 that was easier to manage.
14 We're not going to have all white men at the
15 table. Let's have diversity.
16 Team 4? Look at what is happening. Where
17 is the Team 3?
18 (Discussion.)
19 DR. WHYTE: Team 4? Who's Team 4? Over
20 there. That's easy for you over there. Okay,
21 diversity.
22 I'm going to read the instructions. I'm

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1 AFTERNOON SESSION
2 (1:01 p.m.)
3 CDER Jeopardy
4 DR. WHYTE: Are we ready to play some
5 Jeopardy? Are we ready to play some Jeopardy?
6 Woo-hoo! Okay.
7 I still need two volunteers. Is that right,
8 Noah? Two. I need two more volunteers. Don't
9 make me choose you.
10 Let's get the teams ready. Am I reading
11 these off, Noah, or you? Team 1, Katy Riddick;
12 Kevin Healy; Hiren Gadhiya; Janay Johnson; Jim
13 Bender; Alana Broe. Where are you?
14 Team 1? Which one is Team 1 up here? The
15 clicker has to be Team 1. One person will sit
16 here, and the others will go around each team so
17 you can work together to determine what answer
18 you're going to pick.
19 Team 2 is Nadia; Neena; Dave; Calvin; Cara;
20 and Anne Marie [ph].
21 Team 3 is Alysa [ph]; Leyla; Pam; Bill;
22 Brigid; and one more option.

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1 going to give you clues that you'll respond to,
2 remember, in the form of a question. Remember
3 that. You have to answer in the form of a
4 question. There are 5 categories, 100 to 500
5 points, 25 questions in all. The winning team
6 obviously will be the team that after the final
7 Jeopardy has the most points. Remember you're
8 penalized if you don't answer the question right.
9 Now, here's the important point. We've done
10 this for a few years, and I say this. I say it
11 like five times, and it still doesn't work. The
12 way that we're going to play it is you have to let
13 me read the whole question. So don't be doing it
14 while I'm talking because it won't work.
15 (Laughter.)
16 DR. WHYTE: You have to wait until I've done
17 the question, and then you click, because we have
18 tested these. They all work, and I know everyone
19 will want to say it doesn't work. It does. It's
20 the FDA. It's like a device.
21 (Laughter.)
22 DR. WHYTE: Are we operational? It is

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1 randomly determined who will go first. But here
2 are the categories: Acronym Soup; Drugs and
3 Biologics; Play It Safe; Trials and Tribulations;
4 and the Advocacy Cheat Sheet.
5 So randomly selected is Team 4. This is why
6 you need to be near each other. Team 4, Play It
7 Safe for?
8 TEAM 4: Five hundred.
9 DR. WHYTE: Going big. All right. Play It
10 Safe. Remember, wait until I finish reading it.
11 "The FDA can require manufacturers provide the
12 safety strategy to manage serious known or
13 potential risks associated with medicines and
14 manage their use so that patients can continue
15 using them."
16 Now let's see how smart you all are. Team
17 1, in the form of a question.
18 TEAM 1: What is the risk evaluation and
19 mitigation strategy?
20 DR. WHYTE: What is the risk evaluation and
21 mitigation strategy? That is correct, REMS.
22 Team 1 choose again.

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1 TEAM 1: We would like to Play It Safe for
2 300.
3 DR. WHYTE: Play It Safe for 300. This
4 phase of the regulatory process occurs after the
5 FDA has approved a drug or biologic product for
6 marketing in the U.S. The FDA monitors these
7 products to detect serious, unexpected adverse
8 events and take action when necessary. Team 4?
9 TEAM 4: What is postmarket surveillance?
10 DR. WHYTE: What is postmarket surveillance.
11 I'll accept that. Yes, that's correct or it could
12 be phase 4.
13 Team 3, choose again. I'm sorry. That was
14 Team 4 I apologize.
15 TEAM 4: Acronyms for 200.
16 DR. WHYTE: Acronym Soup for 200. Team 1?
17 TEAM 1: What is new molecular entity?
18 DR. WHYTE: That is correct. What is new
19 molecular entity? Choose again.
20 TEAM 1: Acronym Soup for 300.
21 DR. WHYTE: Acronym Soup for 300. PDUFA?
22 Team 2 is on the board, maybe.

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1 TEAM 2: Prescription drug user fee.
2 DR. WHYTE: In the form of a question.
3 TEAM 2: What is prescription drug user fee?
4 DR. WHYTE: That's correct. Remember, we're
5 rules followers here. Okay, Team 2, choose again.
6 TEAM 2: Advocacy Cheat Sheet for 200.
7 DR. WHYTE: Advocacy Cheat Sheet for 200.
8 These three public seminars welcome patients,
9 caregivers, and other members of the public to
10 present data, information, or viewpoints on issues
11 pending before the FDA committee. Team 4?
12 TEAM 4: What are advisory committee
13 meetings?
14 DR. WHYTE: No -- you know, what I'm going
15 to allow it. Let's give it to them. It's really,
16 "What are FDA sponsored public meetings." Advisory
17 committees are one of those types of meetings, so
18 we're going to be lenient.
19 Team 4, choose again. Team 3, you've got to
20 get ready with your clicker.
21 TEAM 4: Acronym Soup for 100.
22 DR. WHYTE: Acronym Soup, playing it safe,

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1 really, for 100. But okay, Acronym Soup. IND.
2 Team 1?
3 TEAM 1: What is investigational new drug?
4 DR. WHYTE: That is correct. What is
5 investigational new drug?
6 MALE PARTICIPANT: I don't think [inaudible
7 - off mic].
8 (Laughter.)
9 DR. WHYTE: Everybody says that.
10 Team 1, choose again.
11 TEAM 1: Acronym Soup for 400.
12 DR. WHYTE: GDUFA. Team 2?
13 TEAM 2: Generic Drug User Fee.
14 DR. WHYTE: In the form of a question.
15 TEAM 2: What is generic drug user fee?
16 DR. WHYTE: Very good. Thank you. C'mon
17 now. Next time we don't give it to you.
18 Team 2, choose again.
19 TEAM 2: Acronym Soup for 500.
20 DR. WHYTE: OND?
21 MALE PARTICIPANT: Office of New Drugs.
22 TEAM 2: What is the Office of New Drugs?

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1 DR. WHYTE: What is the Office of New Drugs?
2 That is correct.
3 Okay. Team 1 is in the lead with 1300;
4 followed by Team 2, 700; Team 4, 500; and Team 3 is
5 getting ready. You're getting ready. I don't know
6 if it's the device or the users.
7 TEAM 1: Drugs and Biologics for 300.
8 DR. WHYTE: Drug and Biologics for 300. I
9 work on drug issues. These types of drugs fill
10 most of the prescriptions in the United States.
11 Although they typically cost less than their brand
12 name counterparts, they're equivalent in
13 terms -- wait till I finish -- in terms of quality,
14 performance, strength, and safety.
15 Team 3? No, that's not right. Which team
16 is it?
17 MALE PARTICIPANT: It's Team 1.
18 DR. WHYTE: Team 1.
19 TEAM 1: What are generic drugs?
20 DR. WHYTE: What are generic drugs. Okay.
21 You've got to wait until I finish talking. I was
22 watching. I was hopeful. What are generic drugs?

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1 Choose again.
2 TEAM 1: Drugs and Biologics for 400,
3 please.
4 DR. WHYTE: Also known as the prescribing
5 information or package insert, this informative
6 communication provides healthcare professionals the
7 necessary information to appropriately prescribe
8 drugs for safe and effective use. Team 1?
9 TEAM 1: What is the product labeling?
10 DR. WHYTE: What is the product label?
11 We'll give it to you. It's usually what is the
12 drug label or what is the packaging prescriber
13 information. But we'll give that to them. What is
14 the prescription drug labeling information? It
15 goes by a couple different terms.
16 Okay. Go ahead. Thank you. You're so
17 courteous.
18 TEAM 1: Drugs and Biologics for 500.
19 DR. WHYTE: These products include vaccines;
20 human blood and blood components; human cells; gene
21 therapy; and tissues. Gene based and cellular
22 products within this category are at the forefront

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1 of biomedical research and may be used for
2 conditions that lack other available treatments.
3 It says Team 4.
4 TEAM 3: What is biologics?
5 DR. WHYTE: You're Team 3.
6 (Laughter.)
7 DR. WHYTE: No, you're Team 2. It's Team 4.
8 TEAM 4: What are biologics?
9 DR. WHYTE: What are biologics is correct.
10 I know, I thought it did, too, but I have to do
11 what the computer says.
12 Okay. Team 4?
13 TEAM 4: Drugs and Biologics for 200.
14 DR. WHYTE: These drug products are safe and
15 effective for consumers to use without a doctor's
16 prescription. Team 3? See, it works.
17 TEAM 3: What is over-the-counter drugs?
18 DR. WHYTE: What are over-the-counter drugs?
19 That's correct. Okay!
20 (Applause.)
21 DR. WHYTE: Woooo! Now we've got a game
22 going. Come on, Michigan! Trials and Tribulations

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1 for 300. This entity seeking to market a drug is
2 responsible for its development and proving it's
3 safe and effective. Team 2?
4 TEAM 2: What is a drug product's sponsor?
5 DR. WHYTE: What is the sponsor? Sure.
6 Okay. Choose again. That's correct.
7 TEAM 2: Let's do Drugs and Biologics for
8 100, please.
9 DR. WHYTE: A substance intended for use in
10 diagnosing, curing, mitigating, treating, or
11 preventing a disease.
12 Team 3?
13 TEAM 3: What's a drug?
14 DR. WHYTE: What is a drug? That's correct.
15 Okay. Choose again.
16 TEAM 3: Let's go Advocacy Cheat Sheet for
17 3[00].
18 DR. WHYTE: Advocacy Cheat Sheet for 300.
19 This FY 2013 to 2017 initiative seeks to gather
20 patient perspectives on their conditions and
21 available treatment therapies in a more systematic
22 way to better inform drug development and

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1 evaluation process.
2 Team 4?
3 TEAM 4: What are patient-focused drug
4 developments?
5 DR. WHYTE: What are patient-focused drug
6 developments? That's fine. Very good. Choose
7 again.
8 TEAM 4: Advocacy Cheat Sheet for 500.
9 DR. WHYTE: Advocacy Cheat Sheet for 500.
10 Wooooo! Okay. You could either take the lead or
11 end up in last place. How much you want to bet?
12 MALE PARTICIPANT: Bet it all!
13 DR. WHYTE: You're going to bet it all?
14 TEAM 4: Everything?
15 DR. WHYTE: Bet it all, 1300, the whole
16 thing. Wow! High risk, high reward.
17 This organization engages with stakeholders,
18 including patients, advocates, and healthcare
19 professionals, to improve their understanding in
20 how the FDA approves and regulates drugs.
21 TEAM 4: What is the P-A-S-E?
22 DR. WHYTE: What does it stand for?

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1 (Laughter.)
2 DR. WHYTE: Okay. Patient Affairs
3 Stakeholder Engagement. What is PASE? Very good.
4 All right. You're in the lead. Wow!
5 TEAM 4: Advocacy Cheat Sheet, 400.
6 DR. WHYTE: Okay. This program helps
7 consumers and healthcare professionals better
8 understand who takes part in clinical trials by
9 providing them with demographic data on the trial
10 participants for FDA-approved new molecular
11 entities.
12 Team 3? Dr. Woodcock mentioned it.
13 TEAM 3: What are [inaudible - off mic]?
14 DR. WHYTE: I'm going to give it to you.
15 It's what are drug trial snapshots? But close
16 enough. Okay. Choose again. Anybody could win
17 it.
18 TEAM 3: I'm still going through a hell of a
19 trial. Trials and Tribulations for 500.
20 DR. WHYTE: Okay. Trials and Tribulations
21 for 500. Also known as compassionate use, this
22 practice refers to the use of an unapproved

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1 investigational medical product outside of a
2 clinical trial.
3 Team 1?
4 TEAM 1: What is expanded access?
5 DR. WHYTE: What is expanded access? That
6 is correct. Okay. Close. Choose again.
7 TEAM 1: We're going to Play It Safe for
8 200, please.
9 DR. WHYTE: Okay. Play It Safe for 200.
10 These entities are required to report adverse drug
11 events to the FDA.
12 Team 3?
13 TEAM 3: What are the drug companies?
14 DR. WHYTE: What are drug companies, drug
15 sponsors? That's correct. Okay. Choose again.
16 TEAM 3: Play It Safe for 4[00].
17 DR. WHYTE: Play It Safe for 400. This is
18 one of the many systems the FDA uses to collect
19 reports on adverse drug events.
20 Team 1? It's multiple answers.
21 TEAM 1: What are PADARS [ph]?
22 DR. WHYTE: What are what?

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1 TEAM 4: What are MedWatch forms?
2 DR. WHYTE: That's better. Okay.
3 (Laughter.)
4 DR. WHYTE: What's MedWatch? Where did you
5 pull that out of all of a sudden? That's good.
6 Okay. MedWatch is one of the answers; FAERS, yes.
7 That's correct. We'll accept it. I think you were
8 thinking FAERS.
9 All right. Choose again. You're back in
10 the lead.
11 TEAM 1: Trials and Tribulations for 200.
12 DR. WHYTE: This phase of clinical trials is
13 typically the final phase before approval and
14 involves human subjects to establish the safety and
15 effectiveness of a drug. I love how I say you
16 cannot click beforehand, and while I'm reading,
17 it's clicking.
18 (Laughter.)
19 DR. WHYTE: Which team? Team 4.
20 TEAM 4: What is phase 3?
21 DR. WHYTE: What is phase 3? That's
22 correct.

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1 Let's just go over, Team 1, 2900; Team 4,
2 2800; Team 1 [sic], 2000; and Team 3, 900. Anybody
3 in theory could win, in theory. Okay. Let's go.
4 TEAM 4: Trials and Tribulations, 400.
5 DR. WHYTE: Trials and Tribulations, 400.
6 This landmark legislation enacted in 2016 builds on
7 the FDA's critical path initiative efforts to
8 foster innovation in the scientific processes for
9 developing, manufacturing, and evaluating medical
10 products.
11 Team 4?
12 TEAM 4: What is the 21st Century Cures Act?
13 DR. WHYTE: What is the 21st Century Cures
14 Act? Very good.
15 TEAM 4: Play It Safe, 100.
16 DR. WHYTE: Play It Safe, 100. This center
17 of the FDA evaluates new drugs before they can be
18 sold, ensuring generic and brand name drugs work
19 correctly, and their benefits outweigh their risks.
20 Team 1?
21 TEAM 1: What is CDER?
22 DR. WHYTE: What does it stand for?

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1 TEAM 1: Center for Drug Evaluation and
2 Research.
3 DR. WHYTE: That's correct. What is the
4 Center for Drug Evaluation and Research? Very
5 good.
6 Okay. Choose again.
7 TEAM 1: Trials and Tribulations for 100.
8 DR. WHYTE: Trials and Tribulations for 100.
9 This drug evaluation study is designed to answer
10 specific questions and discover if promising new
11 treatments are safe and effective.
12 Which team? Team 3. What's your answer?
13 That's not correct.
14 Team 2?
15 TEAM 2: What is a clinical study?
16 DR. WHYTE: That's correct. What is a
17 clinical trial, a clinical study?
18 Okay. Advocacy Cheat Sheet for 100. This
19 is one of the many ways patients and advocates can
20 be more involved in the FDA's drug evaluation and
21 approval process. Multiple answers.
22 Team 1?

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1 TEAM 1: Participation in advisory committee
2 meetings.
3 DR. WHYTE: Participation in advisory
4 committees. That's one of the answers. That's
5 correct. What is participation in advisory
6 committees?
7 MALE PARTICIPANT: Do we get credit
8 [inaudible - off mic]?
9 (Laughter.)
10 DR. WHYTE: Okay. That's very good. Good
11 job, everyone. Now we will enter the final match
12 with the final Jeopardy question -- let's not show
13 it yet -- and see how much you're going to wager.
14 Somebody good in math figure it out.
15 Team 1, how much are you going wager?
16 (Crosstalk.)
17 TEAM 1: We will wager \$1900.
18 DR. WHYTE: I thought they said all. I
19 don't know. You decide. How much?
20 (Crosstalk.)
21 DR. WHYTE: That's \$3100.
22 What about Team 2?

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1 TEAM 2: We're getting all in.
2 DR. WHYTE: All in, 1100.
3 Team 3?
4 TEAM 3: All in.
5 DR. WHYTE: All in, 800; not really.
6 Team 4?
7 TEAM 4: 3100.
8 DR. WHYTE: You're assuming everyone might
9 get the answer wrong except you. Okay. All right.
10 Team 3 could have tried that strategy, too.
11 Let's see the final Jeopardy question, and
12 then you'll write down your response on that little
13 piece of paper in front of you. We'll give whoever
14 gets closest if it's not the right number.
15 This percent of the 46 novel drugs CDER
16 approved in 2017 used at least one expedited
17 development and review method to speed the approval
18 process.
19 We'll give how many seconds? We won't show
20 the answer until we see their bids. We'll give
21 another 10, 15 seconds. Confer among yourselves.
22 (Jeopardy music playing.)

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1 DR. WHYTE: This is exhausting.
2 All right. Time up. Team 1? Don't show
3 the answer yet. We're doing it like the real
4 Jeopardy.
5 (Mr. Goetzel explains procedure.)
6 DR. WHYTE: Okay. We'll start with Team 3?
7 All right.
8 Team 3, what's your wager? Oh, you
9 wagered -- what's your answer?
10 TEAM 3: Sixty-seven percent.
11 DR. WHYTE: I'm going to let us see all the
12 answers, and then we'll do it that way. Because
13 otherwise, then the others won't know. Okay, 67.
14 Team 4, what's your answer? Sixty.
15 Team 2?
16 TEAM 2: A little different, 5 percent.
17 DR. WHYTE: Five? No, that's not right.
18 (Laughter.)
19 DR. WHYTE: You guys have a lot to learn.
20 Team 1?
21 TEAM 1: What is 44 percent?
22 DR. WHYTE: Is that what you wrote down?

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1 Okay, 44.
2 And the answer?
3 MR. GOETZEL: So what did Team 3 -- did they
4 get it right?
5 DR. WHYTE: They said 67. Oh, we don't have
6 the slide with the answer? We're not showing them
7 the answer? I want to look at my notes. The
8 answer is -- and someone is going to win by only
9 off by 1 percent -- 61 percent.
10 (Applause.)
11 DR. WHYTE: And I believe Team 4 said 60.
12 TEAM 4: Yes.
13 DR. WHYTE: All right. Team 4 is the
14 winner. Congratulations. Let's give them all a
15 round of applause.
16 (Applause.)
17 DR. WHYTE: Team 3's still saying those
18 didn't work or something. But good job, everyone.
19 Good job.
20 With that, we're going to talk about -- we
21 have numerous committees and panels to obtain
22 independent expert advice, and if you attended some

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1 of these meetings or you look online, a lot of
2 people talk about the docket. And you might be
3 thinking what's a docket, where is the docket, what
4 does that mean? And we often say submit your
5 comments to the docket.
6 We're going to hear about how do you rock
7 the docket from John Wright -- not John Whyte, John
8 Wright -- from the Division of Dockets Management.
9 We actually have a dockets management division in
10 the commissioner's office. And a fun fact about
11 John is that he's been in the coldest -- the
12 Alaskan interior in February -- and the
13 hottest -- Death Valley, California in July; it
14 really should be the opposite, John -- in one
15 year's time. So we will hear all you need to know
16 about submitting comments to the docket.
17 Presentation - John Wright
18 MR. WRIGHT: Well, good afternoon, everyone.
19 I don't know how much you know about music history,
20 but this is kind of like the Monkeys trying to
21 follow Hendrix. So we'll see what we can do. Oh,
22 yeah, the temperature thing. That was about

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1 20 years ago. I was in the military. The cold
2 part was because they made me. The hot part was my
3 choice.
4 So what do we do at dockets management? I'm
5 going to go through these and answer as many of
6 your questions as possible. But the biggest thing
7 to remember is we do everything. If there's an
8 administrative question for the FDA, it comes to
9 us, and we read it and we determine where it goes.
10 That includes everything from tin cans, to laser
11 beams, to drugs. In fact, I have spent a great
12 deal of time in the past week on the standard of
13 identity for tuna fish believe it or not.
14 We are made up of three teams. First of
15 all, the acronym's at the top. The OCOES, that's
16 Office of the Commissioner, Office of the Executive
17 Secretary, Division of Dockets Management. I hope
18 you know what FDA means. DDM is three teams.
19 We've got the D&D team. That's Dockets and
20 Documents. They handle mostly tobacco dockets,
21 which include things like civil money penalties for
22 selling to underage people, and the Public Reading

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1 Room. The Public Reading Room does a live comment
2 management, and they handle walk-in visitors. All
3 of you are welcome to be a walk-in visitor should
4 you need to submit anything to Dockets. But the
5 most important team is mine just because we do most
6 of the stuff that requires contact with people
7 outside of our office. So that's the biggest thing
8 to remember.

9 This is a small list of things we do. Here
10 it says, "Petitions to the government." Now that
11 can take many forms. Typically, what we see from
12 your community are petitions related to drugs or
13 abbreviated applications for drugs and things of
14 that nature. Sometimes we see advisory petitions.
15 For example, I got one from the country of Spain
16 asking about the identity of a cheese and wanting
17 our advice and things like that.

18 How many of you read the Federal Register
19 regularly? Good. We're responsible for getting
20 the things from the FDA to the Federal Register.
21 For example, if you look in the FR and you get an
22 invitation to come visit the FDA for an advisory

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1 committee meeting, that will have been submitted to
2 the Office of Federal Record by us.

3 If you want to ask the FDA to do something,
4 and it is administrative, what that means is the
5 answer for your question or the action the FDA
6 takes is already decided by the law. Then you can
7 send us a petition, which will compel the FDA or
8 ask the FDA, depending upon the law you are citing,
9 to do or not do something about a drug.

10 The most common types of petitions that I
11 see are for suitability petitions. For example,
12 somebody will want to market a generic drug, and
13 they won't want to go through the whole, long
14 process. So they'll find another drug that's
15 really similar, and they'll say, "Hey. Let me use
16 this drug," and they'll petition us for that sort
17 of thing.

18 We also keep records of all these things
19 going back until I think 1957, and many of these
20 are still active. In fact, some CDER dockets
21 dating back to 1973 are still open. And those
22 things will forever be open because the particular

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1 ones I'm thinking of involve drugs that are
2 recognized as generally safe and not going to
3 bother anybody. Well, every time that gets
4 challenged or questioned, something gets added to
5 that docket, so they will never close.

6 Also, we do information requests. Right
7 here, it says "FOIA requests," but not all of our
8 requests are FOIA. Some of them are far less
9 laborious. For example, if you just walk into the
10 office, you can take care of a FOIA request in
11 20 minutes instead of 20 days because we are pretty
12 responsive, and of course we handle comments.

13 Now, when I say "comments," I'm talking
14 about every single comment for every single
15 activity the FDA might do on a given day. Now, if
16 you can imagine what CDER, just CDER, does in a
17 day, it's quite a bit. There are 13 centers like
18 CDER, and they all do a lot. An example is I think
19 Friday -- no, it was last week, the docket for
20 flavoring in tobacco was opened, and it garnered
21 3,000 comments in two days, and there are two
22 people that manage those. So you can imagine we've

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1 got a lot of things that we have to do, but that
2 said, we are still extremely responsive.

3 Now, petitions, this is what I was just
4 discussing with you here. Some of you may want to
5 do this; some of you won't. But if you do want to
6 submit a petition, you can call us first. Before
7 you go to all the work, if you've never done a
8 petition before, please just call us. A lot of
9 your entities are very small and you can't
10 necessarily afford a regulatory counsel or an
11 attorney, we will help you.

12 For example, we will give you copies of
13 these regulations. 1020, that's generally
14 administrative regulations, what has to be on a
15 piece of paper for the FDA to read it. Right there
16 where it says, "content," that's what everybody
17 looks at, at a citizen petition, the first time it
18 comes to our office. They do not care what it's
19 about. It can be, hey, this petition is going to
20 save the world. All we care about is that right
21 there.

22 So you need to call us, and we will help you

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1 set it up so that it gets accepted without any
2 difficulties. That includes more complex things.
3 For example, if you want to tell the FDA to stop
4 doing something, it requires additional steps that
5 we will walk you through.
6 Now, back to comments here, you may be very
7 interested in comments once you open a docket. A
8 lot of times a special interest group, for example,
9 may have an issue for which they've submitted a
10 petition, and that issue may garner a lot of public
11 interest that that group may not be aware of. So
12 it's an opportunity for them to gauge public
13 interest, public opinion, and things of that
14 nature, so the comments are very, very important to
15 us.
16 Furthermore, we actually do read them all.
17 The comments are collected, deduplicated,
18 categorized, and sent directly to the human beings
19 who actually make the decisions, so they're not
20 wasted. And that includes comments that may be
21 submitted electronically or submitted by very
22 concerned citizens who do it 10, 15 times a day.

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1 We still read them all. And believe me, there are
2 many, many citizens who are very passionate about
3 their voice being heard.
4 Also important to note, if you submit a
5 comment, it will be public. The only time we do
6 not post comments publicly is if they are
7 specifically stated as confidential. That includes
8 everything that you might send to Dockets
9 Management. It will be posted in public. If you
10 want it to be otherwise, again, please call, and we
11 will make arrangements for you to be able to do
12 that. That is very important because stuff will
13 just get posted automatically otherwise.
14 So this is the very, very important screen
15 right here just because I like it, and it's made
16 out of -- I think they're Morgen. Anyhow, this is
17 where I want you all to get your pens and papers
18 out because you actually get our phone number and
19 email, and I want you to use them. The main phone
20 number, the 402-7500 number, that is a number to
21 the public reading room, and they can direct you to
22 pretty much anywhere in the FDA. They're very,

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1 very helpful for a non-public affairs office. That
2 said, they cannot speak for the FDA. They will
3 route you to the right person. A couple of people
4 in my office are me -- and that's me -- and of
5 course, Dynna Bigby. We are always available. We
6 check our emails compulsively, things like that.
7 Do you have any questions? I'm going to
8 back it up here in case you need to make notes.
9 Any questions?
10 (No response.)
11 MR. WRIGHT: Wow! I must have been
12 thorough. That's excellent. Well, thank you very
13 much. Again, if you do have any questions or if
14 anything comes up and you can think of a way that
15 we might be able to assist you, please just let me
16 know.
17 (Applause.)
18 DR. WHYTE: Well, thank you. Now we're
19 going to hear from a panel of my FDA colleagues,
20 and Rea Blakey is going to introduce them. Rea is
21 the communications policy strategist and engagement
22 team lead at PASE. And a fun fact about Rea is

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1 that her name -- R-E-A -- was once used as the
2 answer in a New York Times crossword puzzle. The
3 clue was CNN medical correspondent, and I'll allow
4 Rea to introduce my colleagues. And I'm just going
5 to say, the last time I saw two of my colleagues
6 was at a snowstorm in Philadelphia, and they left
7 me there. I had to come back the next day. So
8 nice to see you again, Andrea and Pujita.
9 Discussion Panel - Rea Blakey
10 MS. BLAKEY: Oooh. I think the young kids
11 call that a burn. Yikes!
12 (Laughter.)
13 MS. BLAKEY: Well, let's not be so formal,
14 ladies. Come on up, and I'll introduce you once
15 you get up here. There are four panelists. We
16 have one other member who is right now involved in
17 a conversation with the commissioner. She will be
18 joining us, hopefully before we all conclude. But
19 I think you're really going to enjoy the
20 presentations from these first three ladies.
21 We tend to work a lot together because we
22 all work generally in the same kind of space that

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1 has to do with patient engagement. I'm in
2 Professional Affairs and Stakeholder Engagement,
3 but of course across the FDA are other offices and
4 agencies that work in the same general space and
5 then have some other offshoots of things that they
6 do.
7 So we're going to discuss some of that today
8 and also talk about what we hope will be an
9 interesting future in regards to patient engagement
10 in general. Obviously, transparency is a major
11 issue for us not only here at CDER but across the
12 FDA, and really if you think about it, throughout
13 the entire government. The public deserves to know
14 what's going on. We really try to address that.
15 Certainly at PASE, you've heard about the
16 request a meeting on drugs opportunity that you
17 have. If you send in your requests, they will come
18 to my office, and we will triage them, and we will
19 do our best to make sure that you get your voice
20 heard. But just in case, there are other avenues,
21 and that's really what this panel discussion is
22 about today, the other avenues that could be

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1 available for you to get your voice heard because,
2 again, we want to hear from you. We want you to
3 have an informed opportunity to inform our process
4 because, ultimately, we work for you.
5 So thank you again for coming. I probably
6 should have said that first because it's important
7 that you're in the room with us to know that we're
8 working on your behalf.
9 I will introduce each of our panelists just
10 as they're about to give their presentations. I
11 will start with Pujita, who I have to say I'm
12 curious about the snowstorm story, but if you don't
13 have time, we'll let it go, but maybe you could
14 fill us in a little bit. Pujita is the acting
15 director of Decision Support and Analysis Team, and
16 that's in the Office of Strategic Programs.
17 Pujita, welcome.
18 Presentation - Pujita Vaidya
19 MS. VAIDYA: Hi, Rea. Thank you so much.
20 As Rea mentioned, I'm in the Office of
21 Strategic Programs. And I know I forgot to send
22 you a fun fact, but I've come with one. So a few

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1 months ago, I was actually in Switzerland and went
2 to the top of Mount Titlis in the Swiss Alps. And
3 there, actually they have the highest elevation
4 suspension bridge in Europe, so it's over 10,000
5 feet up there. So I walked across that.
6 Definitely, it was a breathtaking view, but my
7 heart was pounding. And I am afraid of heights as
8 well, so that makes it even worse, but it was
9 great.
10 I'll be talking to you about FDA's
11 externally-led, patient-focused drug development
12 meetings and the opportunity for stakeholders.
13 (Brief pause.)
14 MS. BLAKEY: In a previous life, I would
15 have said that happens on live TV, however I hope I
16 put the batteries in the right way. I feel a buzz.
17 I think it's happening. Let's test it out. Sorry
18 about that.
19 MS. VAIDYA: Perfect. Great.
20 Before I get started and jump into our
21 initiative, I just want to talk about let's define
22 what patient-focused drug development is. We're

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1 not thinking about FDA's initiative, but in
2 general.
3 Patient-focused drug development, as we
4 think about it here and as we define it, is a
5 systematic approach to help ensure that patients'
6 experiences, perspectives, needs, and priorities
7 are captured and meaningfully incorporated into
8 drug development and evaluation. This is a
9 definition we're really moving forward with. It's
10 a definition that we've included in a glossary that
11 we're coming out with in June. It's going to be
12 part of that glossary, and really, this is the
13 essence of it.
14 So keeping that definition in mind, I want
15 to talk really briefly about FDA's patient-focused
16 drug development, how it came about, and then jump
17 into that externally-led piece. Back in 2012, we
18 in the FDA recognized the need to systematically
19 collect the patient's perspective. Patients are
20 experts in their disease, and they have a very
21 unique opportunity and way to provide their input
22 that could inform drug development.

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1 So keeping that in mind, from 2012 to 2017,
2 what we did was we kicked off the Patient-Focused
3 Drug Development Initiative where we had 24
4 disease-specific meetings to really provide a
5 platform for patients and caregivers and other
6 patient advocates to come to the FDA and tell us
7 how it feels to live with their condition.
8 What happened during that time is that
9 around 2015, we really started seeing and growing
10 external interest and expanding the efforts. As I
11 mentioned, as part of the commitment, we only had
12 24 meetings. That's what we could commit to with
13 our resources. But honestly, there are so many
14 diseases out there, so what we started to do is
15 actually welcome patient organizations to identify
16 and organize their own patient-focused
17 collaborations to generate the similar type of
18 inputs that we were doing here at our FDA-led,
19 patient-focused meetings.
20 These meetings are truly just to provide an
21 important opportunity for patients, caregivers, and
22 other patient representatives to come and talk

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1 about subjects that matter most to them, impact on
2 daily life, current treatment options, and talk
3 about the treatment burden.
4 With that, what we did was we opened this up
5 to the external groups. And while
6 FDA -- definitely we attend these external meetings
7 that are hosted by the patient organization, so
8 it's truly your meetings. Any deliverable that
9 comes out of it or the meeting itself we really say
10 is not considered FDA's sponsored or indoor, so
11 it's truly just your meeting.
12 Now I'd like to go to let's think about
13 planning for this meeting. What are some things to
14 keep in mind? As I mentioned, the key participants
15 and the folks that we really want to hear from at
16 these meetings, whether it's led by FDA or it's led
17 by patient groups, is really the patients, patient
18 representatives, and patient advocates. So that
19 being said, all of the other folks, such as
20 regulatory and federal agencies, including FDA,
21 medical product developers, researchers, and
22 healthcare professionals that are out there, we

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1 want them to be in the audience, but they are
2 really typically in listening mode because it is
3 really giving a platform to the patients and
4 caregivers.
5 One thing I always like to say is the
6 FDA-led meetings, we did 24 meetings with a group
7 of only five of us, so we understand that it can be
8 very resource intensive. And we just want folks to
9 think about if you decide to do one of these
10 meetings, it doesn't necessarily always have to be
11 a stand-alone meeting. There are several groups
12 that have annual conferences, or there may be a
13 scientific workshop that's being planned. So it
14 could be part of those conferences as a session
15 maybe. It doesn't even have to be a full-day
16 meeting. Maybe it's something that you have two
17 hours where you engage with the patients.
18 So there are various options for those. And
19 what we recommend is actually that we have the
20 FDA-led meetings, and that can really serve as a
21 model for you as you're thinking about identifying
22 the disease area that you want to have a meeting

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1 on. We have some criteria laid out that's on our
2 website, thinking about the discussion topics to
3 focus on and what we've typically focused on, the
4 types of questions we've asked, the format that we
5 use. We always use this unique format that you
6 wouldn't typically see here at the FDA where it's a
7 facilitator-led large group discussion. It's very
8 much interactive. We go into the audience and try
9 to get more perspectives from folks in the
10 audience.
11 There's a polling similar to what you've
12 seen today and an interactive webcast. And what we
13 like to see from these are really meeting
14 deliverables such as actual Web recordings,
15 transcripts, and really some type of summary
16 report, let's say, for folks in the future. If
17 they want to refer back to the meeting, the summary
18 reports can really serve as a really good resource
19 for us here at the FDA and for other stakeholders
20 as well.
21 Some key considerations when thinking about
22 this, we do have a letter of intent process, so we

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1 ask that you submit a letter of intent to CDER's
2 Office of Strategic Programs. That's our office
3 that I'm in. Our team is really here to serve as a
4 resource for you, answer any questions, and help
5 you as you start planning the meetings, so we
6 really are here to help.

7 As I mentioned earlier, we understand it is
8 a resource-intensive effort, but sometimes you may
9 actually have the people that you need within your
10 organizations. A meeting planner may not always be
11 necessary or full on-conference organizers because
12 we realize that does cost a lot of money there.
13 And honestly, at the end of the day, active
14 community outreach is very important for these
15 meetings because you want to be able to get the
16 patients and caregivers to ensure a representative
17 group. So we really rely on patient groups and
18 organizations that are out there to get patients in
19 the room for our FDA-led meetings and for your own
20 meetings. Obviously, you have more of the contacts
21 with these groups, so it's even better.

22 At the end of the day, we do want to be

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1 respectful of the time of patients and their
2 caregivers, so we really need to think about it
3 really necessary. Is this the right time to have
4 this meeting? What are we going to do with this
5 information. So taking those into consideration is
6 very important.

7 Just final thoughts, these meetings really
8 do strengthen the understanding of the disease and
9 treatment burden, what we call the therapeutic
10 context. This input from these meetings can
11 support FDA staff as they're thinking about
12 conducting their benefit-risk assessments for
13 products under review or even while advising drug
14 sponsors on their drug development programs. But
15 more broadly, it can support drug development as
16 well by thinking about identifying areas of unmet
17 medical need in the population, identify and
18 develop tools to assess the benefit of potential
19 therapies, and raise awareness and channel
20 engagement within the community.

21 I do want to mention that the reports that I
22 mentioned earlier, the deliverables from these

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1 meetings, if you do conduct an externally-led
2 meeting and you have a summary report, we recently
3 in January launched an external resources page
4 where we're actually housing those reports. So we
5 ask that you house it on your website, and we're
6 linking to those reports so it can be available on
7 our page as well so that we're also sharing the
8 information and making it available for folks.

9 This is just a glimpse of that. If you search
10 "external resources" or "information," you can get
11 more information on this.

12 With that, I will turn it over to Andrea.
13 Thank you.

14 MS. BLAKEY: I just wanted to mention that
15 we are actually interested in your questions and
16 comments after the speakers, so we'll hear the
17 presentations first. We can have a little dialogue
18 among ourselves, but if you're really eager to ask
19 questions, we're certainly open to hearing from
20 you. And there are a few small white cards on each
21 table just in case maybe you want to write it down
22 while you're thinking of it, and then you can ask

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1 it later.

2 I'm glad that I interrupted right before
3 Andrea because she has an interesting fun fact.
4 But because I'm being diplomatic, I'm going to let
5 her share it with you. But I will say that there's
6 also something really particular about her office
7 that is new and should be of great interest to you,
8 so I hope you'll pay really close attention to all
9 of our speakers.

10 Andrea?

11 Presentation - Andrea Furia-Helms

12 MS. FURIA-HELMS: Thank you, Rea. And I
13 apologize for my voice. I have a little something
14 going on, and we'll figure out what that is after
15 this is over.

16 My name is Andrea Furia-Helms, and I'm with
17 the patient affairs staff, newly established. My
18 fun fact is in November, I went to Ireland with my
19 husband on vacation, and we took archery lessons.
20 The final challenge was to hit a balloon on the
21 target, and my husband, who is an ex-Marine,
22 missed, and I got it directly center. And the

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1 winner got to behead the loser, so that was fun.
2 As I mentioned, I'm from the patient affairs
3 staff. We're in our infancy stages. We were just
4 developed in December of 2017, and we work closely
5 with the medical products centers. What we do is
6 we work on cross-cutting issues. Each of the
7 individual centers have their own patient
8 engagement activities such as the patient-focused
9 drug development meetings that are focused on drugs
10 and biologics and Center for Devices, that are also
11 focused on devices. But we work on cross-cutting
12 issues, and we help coordinate and complement and
13 enhance those types of patient-engagement
14 activities where more than one medical product
15 center might be involved. We report into the
16 principal deputy commissioner for medical products
17 and tobacco, which is part of the immediate office
18 of the commissioner.
19 I'm going to talk to you a little bit about
20 the first initiative that came out of patient
21 affairs, and that's the Patient Engagement
22 Collaborative. This is a collaborative forum with

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1 the Clinical Trials Transformation Initiative, and
2 we're establishing an external group to come to FDA
3 and meet with us regularly to talk about patient
4 engagement and how we can enhance those
5 experiences, engage better with you and you engage
6 better with us, and to better learn the regulatory
7 processes.
8 Why are we establishing a patient engagement
9 collaborative? There was an impetus for this.
10 First and foremost, we listened. There was a
11 docket that was opened, and there were several
12 comments from stakeholders saying that we'd like to
13 meet with FDA regularly, which is understandable.
14 Sometimes we are in reactive move where there's
15 something that comes up and we need to hear from
16 you immediately. But it's really important that we
17 hear from you as stakeholders on a regular basis.
18 So we heard loud and clear we need to
19 establish some kind of forum to meet with you
20 regularly and have conversations ongoing, and the
21 laws also. In the recent laws, the 21st Century
22 Cures Act and FDARA, there's a lot about fostering

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1 patient participation and incorporating patient
2 experiences in the process. And we had a model. I
3 had the great opportunity to spend a fellowship for
4 a couple weeks at EMA, the European Medicines
5 Agency, and they've had the Patient and Consumers'
6 Working Party for the last 10 years, where they
7 have organization representatives meet with the EMA
8 regularly to talk about regulatory discussions and
9 patient engagement. Another model is NIH's COPR,
10 the Council of Public Representatives, similarly
11 meeting with the community and understanding their
12 needs and how they can participate more in
13 biomedical research.
14 The membership criteria, obviously patients
15 who have a personal disease experience, caregivers
16 who support patients could be parents of children,
17 a partner, spouse, family member, or friend who
18 serve in a primary caregiving role, and then also
19 representatives from groups that have either direct
20 or indirect experience with diseases.
21 In December we opened the Request for
22 Nominations, and on January 29th, it closed, and we

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1 received 200 nominations, more than expected but
2 pleasantly surprised. So currently we are
3 reviewing and looking at which members are meeting
4 the criteria. So we have a selection committee
5 right now reviewing those nominations.
6 We hope to schedule the first inaugural
7 meeting in late summer, early fall. And even
8 though the comment period has closed and the
9 nomination period has closed, that doesn't mean you
10 won't have an opportunity. The membership will be
11 two to three years staggered appointments, and we
12 are looking for diverse perspectives to come in
13 after the two or three-year appointments to come in
14 and share their perspectives as well. We want to
15 make sure we're including a broad perspective
16 that's not always the same voices every time we
17 have the patient engagement collaborative
18 nominations. If you want more information, there
19 has been a voice blog that was issued on
20 December 20th on the patient engagement
21 collaborative.
22 Another initiative that we're launching is

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1 listening sessions, and this is to better
2 understand the patient experience around diseases,
3 especially in rare diseases. So we created a
4 memorandum of understanding with the National
5 Organization of Rare Disorders. These are pilot
6 listening sessions, so just a little bit of
7 background. Medical officers during their review
8 work, they will sometimes say I don't really
9 understand this particular disease and can you
10 connect me with patients and caregivers so I can
11 better understand the disease, around disease
12 burden, treatment burden? What kind of activities
13 are they limited to due to their disease and how
14 can they improve their quality of life if a
15 treatment were to be developed?
16 So we would have these teleconferences and
17 gather patients and caregivers to share their
18 experiences, and the review divisions find it very
19 valuable and useful. So we're going to pilot
20 listening sessions with NORD, and we're going to
21 develop these in a certain therapeutic area.
22 Really, the goal is to demonstrate added value so

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1 we can hopefully expand to other therapeutic areas.
2 Right now we're in the process of deciding
3 on what the pilot therapeutic area is, and again,
4 it would be a cross-cutting area so that it would
5 include all the medical product centers and the
6 review divisions specific to that therapeutic area.
7 We're in the process of developing a process with
8 NORD for the listening sessions, and we're thinking
9 about including an educational component as well.
10 I think it's important to have some kind of
11 basic understanding in the regulatory process, and
12 I think workshops like this or even webinars and
13 things, that might be helpful as a precursor for
14 joining a listening session. And then we're going
15 to evaluate internal and external feedback, and
16 then develop recommendations on how we will move
17 forward.
18 So that's what I'm sharing with you today.
19 I'm happy to take questions after all the
20 presentations. Thank you.
21 MS. BLAKEY: Thank you.
22 Salina Miller is our next speaker. She's a

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1 health programs coordinator, however, her office
2 has recently changed, maybe in the last 24 hours or
3 so, Salina. Maybe you could update us on that and
4 share a fun fact.
5 Presentation - Salina Miller
6 MS. MILLER: I can't necessarily follow
7 Wonder Woman here, but I did try to pool my family
8 members for a fun fact because I couldn't think of
9 anything myself. I'm full of fun, by the way.
10 Some of them I can share with you, but one I can't
11 share with you. One I will share is that my dad
12 told me that he had applied for me to be the Indian
13 Gerber baby back in -- well, should I tell you back
14 when? But I'm still waiting on the response.
15 Yeah, so that's the fun fact.
16 As far as the office, I work within the
17 Office of Health and Constituent Affairs, which is
18 within the Office of the Commissioner. Yesterday,
19 we announced that the patient representative
20 program will be piloted within the advisory
21 committee oversight and management staff. So that
22 is starting as of yesterday for about four months,

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1 and we're going to be working together to kind of
2 leverage off of each other and learn more about
3 recruitment efforts, streamlines and things. So it
4 should be exciting, so I'm looking forward to that.
5 The FDA patient representative program, it
6 really began in the early or late '80s, early '90s,
7 soon after the HIV epidemic evolved from that. It
8 did roll into including cancer patient
9 representatives, so oncology was a big part of the
10 program as well. And now it really is the flagship
11 program for patient representatives, which are
12 considered special government employees to engage
13 with the agency in a formal process.
14 It's really a mechanism that provides
15 pathways for patients and caregivers to be an
16 active participant in what we do, provide a voice,
17 that important voice, voices that we want to hear
18 from in whatever decisions we make regulatory-wise,
19 and it really furthers the understanding of who we
20 are, and that's such an important part, and
21 provides a presence at the table for patients and
22 caregivers.

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1 We have about 200 FDA patient
2 representatives in the program constantly
3 recruiting. These patient representatives
4 collectively represent anywhere from 300 to 500
5 diseases, conditions, or device experiences. I've
6 listed just a few of these on the slide. We are
7 continuing to recruit. We have areas in terms of
8 opioids, opioid use, naloxone use. Pain is always
9 something we're recruiting for; COPD. There's a
10 host of these that are listed online on the For
11 Patients website of the FDA page.

12 So what do we look for in becoming a patient
13 representative? First, I should really, really
14 emphasize that the agency looks to recruit based on
15 need. That's a very important thing to understand.
16 We are constantly communicating with patient
17 groups, with patients and caregivers directly. And
18 during those conversations, we are learning about
19 what's in their communities, what's in their
20 pipeline; internal conversations with the divisions
21 and the reviewers of what they're seeing; how can
22 we forecast what's really needed in terms of

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1 experiences so that we can start the recruitment
2 process as early as possible.

3 In terms of being a patient rep, we look for
4 certain things, first and foremost, the personal
5 experience with the disease or condition. It
6 doesn't necessarily have to be a patient. We also
7 understand there are certain situations we have to
8 ask for a caregiver to represent, maybe a minor or
9 someone who's unable to represent themselves.

10 Community awareness, it's significant;
11 advocacy experience that is relevant to not just
12 their own experiences that they can share, but also
13 those of their community. That's a very important
14 aspect that we look for, someone who's objective,
15 absolutely; analytical, preferred but not a must.
16 Some of our patient reps do like to delve into the
17 science of what we do, and it's just helpful but it
18 doesn't necessarily have to be the case.

19 Of course conflict of interest. This is an
20 area that is growing. We know that patients are
21 much more engaged in their communities. We also
22 know that there are areas of conflict of interest

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1 that can be an issue, so we try to have that
2 conversation with them early on to really probe and
3 see what are their activities about and is there
4 something that we can do, or a mechanism, or a
5 waiver that we can use to make sure that they can
6 be in the program.

7 Great communication skills. I've had many
8 conversations with patient rep candidates who are
9 so excited to serve but yet when it comes to the
10 communications or if they are gun-shy speaking in
11 front of people, it can be a learning curve for
12 them. But of course commitment to serve, it is
13 really important to emphasize the importance of how
14 we rely on our patient reps to serve on committees
15 and to recognize that assignment as an important
16 aspect of serving.

17 Generally, patient reps intersect with us,
18 both in the drug and biologic development phase
19 early on in the process, as early as when we
20 receive an application. But really it's up
21 to -- as Andrea says, it's up to the conversation
22 with the medical person or the reviewer really, who

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1 can give us kind of a clue into learning more about
2 a disease or condition so they can have these
3 consultations with patient representatives early on
4 throughout the process and get a sense of targets,
5 or benefits and risks, or things that the patient
6 is interested in sharing. That is the opportunity.

7 There is also another area which would be
8 the advisory committees. That stage is really an
9 important and significant part of the patient
10 representative program, and it provides the patient
11 representatives at the table during the advisory
12 committee meeting surveying with other scientific
13 members.

14 The advisory committee meetings, our patient
15 reps are generally considered as temporary voting
16 members. For each assignment, they are screened
17 for conflicts of interest for each assignment. The
18 disciplines, as I said, are other scientific
19 members, and these committees are across all the
20 medical product centers. On average, we have
21 anywhere from about 35, 40, to about 60 assignments
22 per year.

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1 Some of the other ways they can serve, they
2 can serve as consultants, as I mentioned,
3 connecting with the divisions directly, having a
4 telecon with them, sharing their personal
5 experiences and actually being privy to
6 confidential information. Workshops and symposiums
7 also are the growing activities for the patient
8 representatives. It's a little outside of their
9 role as a patient representative, but they
10 certainly are very effective in those areas, and we
11 are continuing to use them.

12 So once they become a special government
13 employee, what happens? We have patient reps who
14 have really no idea who we are, how we're
15 structured, and what are some of the activities.
16 So it is our job in this office to really get them
17 ready to serve. We do a very personalized FDA 101,
18 providing them background on the agency. We have
19 them engage with other more seasoned patient reps
20 that are in the program. We describe how the
21 scenarios are for serving on an advisory committee
22 meeting, for example. We provide regular training

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1 webinars, where they're able to engage with
2 specialists here internally and can ask real
3 questions of them.

4 So it's a closed webinar, and they feel
5 comfortable to ask whatever questions they feel
6 necessary. But they do have that resource, and we
7 do have resources online where we can provide
8 patient reps with information firsthand. And also,
9 every year we have an annual workshop, and at the
10 workshop we have folks who come within the agency
11 with their expertise and are there typically for a
12 day and a half, and they can engage with them. So
13 that's a real significant way that we engage with
14 the patient reps, particularly within the new
15 recruits.

16 Here's just a snapshot of last year's
17 workshop. It kind of gives you an idea of who's
18 all there. There are folks here from the agency
19 and also some of the new recruits from the FDA
20 patient rep workshop. I did not include an email
21 address, so it's fdapatientrepprogram@fda.hhs.gov
22 in case you are interested in becoming a patient

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1 rep.

2 MS. BLAKEY: Thank you, Salina.

3 MS. MILLER: Sure.

4 MS. BLAKEY: Diane Maloney has pulled
5 herself away from very important duties at the
6 commissioner's office to join us today. And Diane
7 actually represents the Center for Biologics, so
8 she has a slightly different perspective but no
9 less interesting than the other speakers.

10 So welcome, Diane, and thank you for
11 joining.

12 Presentation - Diane Maloney

13 MS. MALONEY: Thanks so much, Rea. And I'd
14 like to first say thanks to CDER generally, and Rea
15 as well, for including CBER in this workshop today.
16 Sp I wanted to just give you a very high-level
17 introduction to CBER, Center for Biologics
18 Evaluation and Research, and the work that we do
19 involving patient engagement.

20 Oh, I did have a fun fact.

21 MS. BLAKEY: Please.

22 MS. MALONEY: I told Rea my fun fact is

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1 actually somewhat of a costly fact. I have three
2 daughters, and all three of them got married within
3 eight months of each other, but it was fun, and
4 memorable.

5 MS. BLAKEY: And costly.

6 MS. MALONEY: And they were all very special
7 and unique, as are my children.

8 CBER and patient engagement, we do need to
9 hear from patients. It's very important. I'll
10 tell you a little bit about the Center for
11 Biologics. This is a picture that was taken in
12 December of some of the folks in CBER. We are at
13 the far end of the campus in one of the newest
14 buildings, and we have actually quite a lovely
15 atrium. So there we are, at least a lot of us,
16 taking a picture of many of the employees in CBER.

17 I just wanted to let you know a message that
18 I think you've probably heard a lot today, that we
19 FDA and CBER really do listen to patients. We
20 recognize the important voice that you have and the
21 unique voice that you have; and that, really, it is
22 a critical one in the regulatory decisions that we

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1 make. And we very much value engaging with
2 patients and all that people do to contribute to,
3 in our center, the development of biological
4 products in particular.
5 Within CBER, we actually have a number of
6 activities that we do with regard to patient
7 engagement. One of the things is increasing
8 awareness within our center. We have a number of
9 groups that we've formed to pull people from all
10 the various offices that we have. We have a
11 patient engagement working group, and we have a
12 rare disease working group. All of our offices are
13 represented. We share information. We talk about
14 outreach opportunities and what's going on with the
15 other centers and the commissioner's office as
16 well, in patient engagement in general and rare
17 diseases as well. That would be within the center.
18 In addition, we work very closely -- I work
19 with all my colleagues here in the commissioner's
20 office, Center for Drugs, as well as the Center for
21 Devices, on cross-cutting patient engagement
22 issues, and then of course external work as well

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1 with patient groups.
2 Again, I think you all recognize that
3 patient-focused product development and drug
4 development is evolving over time, and it's been
5 going in since as early as the 1980s, maybe before
6 then I think with -- I was actually here in the
7 late '80s with the AIDS patients. I think we
8 learned a lot hearing from them and the value and
9 seeing things from all the various perspectives,
10 and then continuous as part of the Cures Act and
11 some of the provisions that I think people have
12 presented today.
13 I just wanted to talk a little bit so you
14 know -- we work, as I said, closely with CDER and,
15 CDRH as well, and the commissioner's office. A
16 number of patient groups are here not because they
17 are looking at a particular product but because
18 they care about a particular disease. And the
19 disease isn't necessarily -- there may be many
20 different therapies or diagnostics that would be
21 appropriate for that particular disease. And often
22 when a patient group might want to meet with the

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1 agency, it might be more appropriate to meet not
2 just with one center but to meet with another
3 center or all three medical product centers
4 together for that particular disease. So I just
5 wanted to underscore that.
6 Some of the products that we regulate within
7 the Center for Biologics are on this slide. We
8 regulate vaccines, including preventive vaccines,
9 childhood vaccines, as well as some therapeutic
10 vaccines. There are some cancer vaccines,
11 allergenic products. We regulate live
12 biotherapeutic products, or some people refer to
13 them as probiotics. We have many blood products,
14 for instance, for a lot of bleeding disorders.
15 We actually within our center regulate some
16 devices, so we regulate some devices that are used
17 to screen blood donors for infectious diseases.
18 You wouldn't want to take blood from someone who
19 might be infected with a disease, a virus, that
20 could be transmitted through blood. We also
21 regulate tissues, so for instance, skin and bone
22 and cornea, as well as cellular products,

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1 xenotransplantation products, and gene therapy. So
2 it's quite a range of products that we regulate.
3 Now I will give you a high level of some of
4 the types of meetings that we have had that have
5 involved patients. Salina has actually touched on
6 a lot of these. We have meetings where patients
7 have been involved for specific products. So they
8 might come in -- especially in the
9 instance -- Salina talked about they might be
10 special government employees, so they could have
11 access to confidential information. And they might
12 meet with one of our product offices at the
13 investigational new drug level, where the sponsor
14 is there as well. In addition, they might sit on
15 an advisory committee on specific issues that we're
16 dealing with, with regard to the particular
17 product, or as we're reviewing a biologic's license
18 application. So that would be the application for
19 a product approval.
20 In addition to product-specific meetings, we
21 sometimes have issue-specific meetings or
22 disease-specific meetings. For instance, we might

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1 have an advisory committee meeting on a particular
2 issue. For instance, one area we were dealing with
3 a couple years ago had to do with a risk assessment
4 we did with regard to variant CJ, Creutzfeldt-Jakob
5 disease, and what risk, if any, there was to
6 patients who received blood products. And we
7 engaged with some of the patients in terms of how
8 best to communicate that risk in a way that was
9 understandable and clear to folks.

10 We also engage with patients at a variety of
11 public meetings and workshops, some of which we
12 would sponsor, and then others that others sponsor
13 and invite us to. In addition, we will meet with
14 patient organizations, similar to John's meetings
15 that they hold, and again, which can be with our
16 center as well. We sometimes have meetings where
17 we meet, just our center, with various patient
18 groups.

19 You've heard Pujita talk about the
20 patient-focused drug development meetings. CBER
21 has been very involved in those as well. CBER led
22 the vast majority of them. We led three of them I

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1 think but participated in many more of the internal
2 ones. And in addition, we also have attended many
3 of the externally-led, patient-focused drug
4 development meetings and very much appreciate the
5 invitations to do that and all that we've learned
6 from all the patients.

7 Those are just examples of the patient
8 engagement that we have had, and this is just our
9 contact information on this slide should you want
10 it. Thank you very much.

11 MS. BLAKEY: Thank you very much. We can
12 live it up for a moment.

13 I just want to get a gauge because I want to
14 be mindful of the time, how many of you actually
15 have questions that you cannot leave here today
16 without asking of any of these panelists? Because
17 I can condense our discussion, being mindful of the
18 time.

19 (No response.)

20 MS. BLAKEY: No one absolutely, positively
21 has to ask a question before they leave here today?
22 You're thinking about it. You're processing it.

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1 Okay. Another question for you. How many
2 of you have considered having an externally-led
3 PFDD meeting?

4 (Hands raised.)

5 MS. BLAKEY: Okay, getting a little bit more
6 response there. That's good, important.

7 How many of you have interacted already with
8 the patient affairs staff; for example, the PECs?

9 (Hand raised.)

10 MS. BLAKEY: Okay, a few more there. We
11 like to know who's in the audience.

12 Anybody here a patient rep, has already
13 worked with OHCA as a patient rep?

14 (Hands raised.)

15 MS. BLAKEY: Okay, a couple. Anybody had
16 meetings already with CBER?

17 (A few hands raised.)

18 MS. BLAKEY: We're going to work on that for
19 you, Diane. We're going to get you a few more
20 folks.

21 One of the things that we discussed as a
22 group was what questions we thought might be key

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1 for you going forward knowing that we sort of work
2 in this space internally, but how we see things
3 evolving when it comes to patient engagement. And
4 I'm going to skip to my last big question, which
5 is, five years from now, ladies, what do you think
6 patient engagement will look like? Will it be
7 radically different? Will we be sort of in this
8 space that we're still in and hoping for something
9 new and adventurous? Or, unfortunately, do you
10 think we might be taking a few steps back if
11 there's some, I don't know, adventive technology?
12 While that thought has rolled around in your head
13 for the last week or so, what have you come up
14 with?

15 Salina, I'm going to pick you first.

16 MS. MILLER: I have quite an extensive wish
17 list, so I'm not going to go through them. I think
18 when we engage with patients, it's such a unique
19 conversation that the successes really -- the
20 conversation needs to change, and the conversations
21 are changing. Patients are much more engaged than
22 they ever have. I've been in OHCA for five years,

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1 and the complexities of the conversation are
2 changing. Patients are recognizing who we are more
3 and are able to ask really poignant questions. So
4 we have to be on top of our game and being a
5 resource for them.
6 I'd like to see that we are able to enhance
7 our current strong platform when it comes to
8 patient engagement with the program, particularly,
9 and that we're able to think of novel ways that the
10 patients can -- particularly the ones in the
11 program are able to engage with the agency, and
12 we're seeing that trend already. Adcons and
13 homework assignments with divisions are key, but
14 also thinking outside of that and having their
15 perspectives come in different ways I think is one
16 that I'd like to see over five years.
17 MS. BLAKEY: Thank you.
18 Pujita, you're actually involved in writing
19 some of the guidance for these things. What's on
20 your plate for the next five years?
21 MS. VAIDYA: If the past is any indication,
22 if you think back to five years ago, as I said, in

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1 2012 when we started thinking about how do we get
2 the patient's voice into this, how do we collect
3 this, we've come a very long way in the past five
4 years. There's been so much that has happened.
5 Now we know, we've learned that patients really
6 want to be active. They want to be at the table,
7 and really, a lot of folks have been given that
8 opportunity. As you hear all of us talk about, we
9 want more of you to come take initiatives. There
10 are several opportunities out there. There are
11 areas where you're experts, where we may not have
12 the expertise. So there's definitely a lot going
13 on.
14 Rea just mentioned the guidances. In the
15 slide that Diane put up in the 21st Century Cures,
16 we have a series of guidances that we're going to
17 be putting out in the next five years. So it's
18 really hoping that -- and this is to help guide the
19 methodological way of collecting this type of
20 patient input and for us to be able to take that
21 and incorporate that so that it can inform
22 regulatory decision-making and drug development; so

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1 not just what we do, but the whole development
2 process.
3 So in five years, that's when the plan is to
4 have all of the guidances out, and we hope that
5 we've given out all the information, that folks
6 have to take that and be able to collect robust
7 data and patient experience data, as we call it,
8 and either submit it to us -- in some cases we may
9 be the end user, but in a lot of cases it may be
10 other folks, the industry counterparts that we
11 have, or other folks who can take that data and do
12 something with it. I'm hopeful for the next five
13 years because I think our plan is to put a lot of
14 guidance out there, and hopefully that will be
15 informative for everyone. Thanks.
16 MS. BLAKEY: Diane, did you want to weigh in
17 on that?
18 MS. MALONEY: Sure. I'll add as well. We
19 certainly won't be moving backwards. I think that
20 you'll see more and more FDA folks that are having
21 direct contact with patients. I know just myself,
22 I've had a lot more and learned so much just in the

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1 last two years or so in terms of the involvement.
2 And I agree with Pujita. Congress now has asked us
3 to do some things, and we will do them. But I
4 think we were committed to doing a lot of engaging
5 with patients as well.
6 So I think it's a journey. We've begun it,
7 and I think it will continue. And in five years,
8 it will be interesting to look back to see what
9 we've achieved and then what more we have to do.
10 Thank you.
11 MS. BLAKEY: Andrea?
12 MS. FURIA-HELMS: I think there is an
13 opportunity for being a new office or a new staff.
14 The opportunities are actually quite endless.
15 You're starting from scratch and really
16 understanding what the needs of the patient
17 communities are, and that's what we're trying to
18 do. We're trying to reach out and understand what
19 their needs are and where can we enhance patient
20 engagement across the medical product centers.
21 Although opportunities are endless, resources
22 aren't always, but we're trying to do our best in

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1 incorporating as much of your voices as possible
2 where we can, and I think part of it comes from
3 collaborating with the other centers.
4 One of the things I do think that I hope to
5 see in the next five years is the evolving of the
6 patient experience data, the science around it. I
7 think it's starting, and it's really not ripe yet,
8 but I think it's developing. And I think with the
9 guidances that Pujita's office is working on and a
10 lot of this whole new science that's being worked
11 on outside of FDA, I think there may be opportunity
12 that in the future we can say that a listening
13 session or a patient-focused drug development
14 meeting actually informed a regulatory decision,
15 and we can actually correlate the two. So that's
16 something I'm hoping for.
17 Questions and Answers
18 MS. BLAKEY: Ditto. Second that.
19 We just have a couple minutes. If you have
20 questions, now would be the time. We do have a
21 couple of people who can walk around with a
22 microphone. Christine is there at the ready. If

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1 you've written anything and maybe you don't want to
2 be the person to read it, you could hand it over to
3 Christine.
4 Yes, please?
5 MS. KORKORIAN: I'm still not totally clear
6 on the difference between the listening sessions
7 and the patient representative program and what the
8 goals or objectives are of those two initiatives.
9 MS. MILLER: The patient representative
10 program, we have to do some recruitment for the
11 program to make them special government employees.
12 It is a four-year term, and they're able to serve
13 in a different capacity. So they are really on
14 standby at any point that we want to have a
15 conversation with them that may involve some
16 confidential information. There is reimbursement
17 and some compensation for certain activities. They
18 can also participate in a listening session, but I
19 believe the listening sessions are outside of that.
20 It could be the general public.
21 That's really the primary distinction that I
22 can think of, right?

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1 MS. FURIA-HELMS: Yes. The listening
2 sessions really are driven by review divisions
3 wanting and have an interest in understanding
4 typically a rare disease. They haven't had
5 experience with it, and they might have this need
6 to better understand it in their review work.
7 They are also quickly turned around. Just
8 recently, we got one done within four weeks, so
9 it's something that's a teleconference. We can
10 reach out to advocacy organizations to help
11 identify exactly the patients we need to hear from
12 and the caregivers, and then even subgroups within
13 that patient community, and have those
14 teleconferences with specific questions that are
15 coming from the review division so they can better
16 understand disease burden, quality-of-life issues,
17 and just how the disease impacts them on a daily
18 basis. And even, because it's typically around the
19 area of rare disease, how are they managing their
20 symptoms without any products on the market.
21 MS. KORKORIAN: That's always initiated by
22 [inaudible - off mic].

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1 MS. FURIA-HELMS: Correct.
2 MS. BLAKEY: If I might add, the listening
3 sessions in particular, that word is key because,
4 really, we're listening to hear what you have to
5 say, but typically we're not necessarily
6 responding. You'll recall Sadhna's talk earlier
7 about what FDA can and can't do. And there are
8 times when we want to glean information from you,
9 but we can't necessarily tell you why, or what it
10 is, or where some product might be in the review
11 process. So listening is key. It's typically more
12 of a little bit of a one-way type conversation,
13 though, we want the information so that we can
14 apply it in some form or fashion.
15 I do believe someone back here has a
16 question, and then, ma'am, you'll be next.
17 FEMALE AUDIENCE MEMBER: Our organization
18 would like to plan a PFDD meeting as part of our
19 annual patient conference, so I have two questions.
20 How much lead time do we need to plan this sort of
21 meeting, and do members of CDER travel, or do we
22 need to hold the meeting within the DC, Virginia,

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1 Maryland district?
2 MS. VAIDYA: Thank you for your question.
3 To answer your first question, we do have a letter
4 of intent process, and in the guidelines that we
5 have set forth for that, we do ask that at least a
6 one year's time headway would be nice. If you're
7 planning a meeting right now let's say for April
8 2019, or thinking about or considering something
9 there, we ask that you actually start thinking
10 about submitting your letter of intent around this
11 time, this time of year.
12 Typically, the planning itself, I would say
13 from the experience that we have, it takes at least
14 six months to plan one of these meetings to really
15 get it solid. So it's planning for that, and we
16 want to make sure that CDER, CBER, CDRH, all of our
17 colleagues are aware of it so that they have enough
18 time to actually plan to attend these meetings as
19 well.
20 So your question about traveling, one of the
21 other points that we have in our guidelines is that
22 it will be much easier for FDA folks to attend the

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1 meeting if it is in the DC, Maryland, Virginia
2 area. That is ideal. However, if you have a very
3 good webcast option or something, that will
4 definitely help. But to try to get folks to
5 actually be there in person, we do try to encourage
6 planning in this area. Thank you.
7 MS. BLAKEY: I apologize. I'm going to have
8 to make this the last question or comment just
9 because I promised I would be mindful of time.
10 Whoops. Okay. We'll have two.
11 You tell me, Christine. I'm sorry. I meant
12 the lady right here with the red jacket. I
13 apologize. If you really do want to ask a
14 question, we'll try to squeeze that in.
15 FEMALE AUDIENCE MEMBER: Similar to the
16 first question, I was a little confused on the
17 difference between the patient engagement
18 collaborative and the application process you're
19 currently going through with the 200 applications
20 and the patient representative program where people
21 have a separate application. What kind of
22 candidates are you looking for both of those

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1 programs, and how are the roles different?
2 MS. FURIA-HELMS: Sorry if I wasn't clear on
3 that. The patient engagement collaborative is a
4 forum to talk generally about patient engagement,
5 and understanding your experiences, and engaging
6 with FDA, and understanding our experiences so that
7 we can better enhance our engagements with patient
8 community stakeholders, so general discussions.
9 With the patient rep program, as Salina will
10 probably tell you, it's specific to a medical
11 product. They have to go through conflict of
12 interest to review that confidential information.
13 With the patient engagement collaborative members,
14 they're not screened. They're not special
15 government employees. Conflict of interest is
16 considered during the selection process but not
17 rigorously like becoming a special government
18 employee. So anyone can be as long as you meet the
19 criteria, which is similar to the patient rep
20 program. As long as you meet the criteria, you can
21 nominate yourself or be nominated by someone else.
22 MS. BLAKEY: If I could, just because we are

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1 short on time, and I apologize, ma'am, you have
2 your question still, we'll take it.
3 FEMALE AUDIENCE MEMBER: My question is
4 whether the general public can attend the advisory
5 committee meeting. If we can, what's the process
6 to apply to attend such a meeting? Thank you.
7 MS. MILLER: Generally, advisory committee
8 meetings are public. There's no necessary
9 registration per se. We've had patient groups that
10 have had registration for applications just to
11 bring them to the meeting, but for the most part,
12 the agency is open to the public.
13 MS. BLAKEY: So we hope you'll come. We
14 hope you'll all be there. Thank you all very much
15 for your attention. How about a round of applause
16 for our panel?
17 (Applause.)
18 MS. BLAKEY: Thank you, ladies. Very
19 informative. Thank you all. Appreciate it.
20 Audience Response Questions - Christopher Melton
21 MR. MELTON: Now it's audience response
22 questions again, so if everybody could please grab

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1 their clickers, I'll be going through the audience
2 response questions. I'll be reading four questions
3 for everyone.
4 Please evaluate the following sentence.
5 "Following the how to get your voice heard
6 discussion panel, I feel that I have the necessary
7 information and resources to request a meeting with
8 the FDA." Your choices are A, strongly agree; B,
9 somewhat agree; C, neutral; D, somewhat agree; and
10 then E, strong. So take a second and put your
11 answers, and we will tally the responses soon.
12 (Audience responds.)
13 MR. MELTON: We have A, 63 percent. All
14 right, great. Now we'll move forward over to
15 question number 2. "How long does a new drug
16 application take, also known as NDA, the approval
17 process typically take?" A, less than 6 months; B,
18 approximately 6 to 10 months; C, approximately 1 to
19 4 years; D, an average of 12 years; or E, none of
20 the above.
21 (Audience responds.)
22 MR. MELTON: The correct response is B,

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1 approximately 6 to 10 months, and we have
2 42 percent. So we've got that marked for next
3 year, and we'll know.
4 Question number 3, "The FDA can publicly
5 disclose the status of a drug product currently
6 under review." Answer true or false, A being true;
7 B being false. This is an easy one.
8 (Audience responds.)
9 MR. MELTON: Or maybe not. The correct
10 answer is B, false. Now we're going to transition
11 to question number 4. Drug manufacturers are
12 required to report adverse events from a drug to
13 the FDA, A being true; B being false.
14 (Audience responds.)
15 MR. MELTON: The correct answer is A, true.
16 We've got 9 percent that will get it the next time,
17 right? Thank you.
18 DR. WHYTE: Okay. That's not the right time
19 now, but we are in the home stretch. And I will
20 point out we have been very close to time. We've
21 spent a lot of time telling you the FDA
22 perspective, and myself and my colleagues thought

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1 it was very important for you to hear from others
2 and what their experience has been, the good and
3 the bad.
4 So I'm delighted to invite Alexandra Kruse
5 and Phyllis Foxworth to come to the podium. We
6 asked them to talk about their experience in terms
7 of interacting with the agency. Alexandra is the
8 research coordinator for the Platelet Disorder
9 Support Association, and Phyllis is the vice
10 president of the Advocacy, Depression, and Bipolar
11 Support Alliance.
12 Perhaps we'll start with Alexandra, and you
13 both come to the table -- really, the time is yours
14 to talk about your experience; we did not give any
15 prepared remarks to them -- and then allow them to
16 ask questions directly of you. But I really wanted
17 the time to be yours, and I appreciate you coming
18 and sharing your experience, the good and the bad.
19 Thank you.
20 Presentation - Alexandra Kruse
21 MS. KRUSE: Thank you to the FDA and
22 especially to PASE for inviting me here to speak

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1 today on behalf of the Platelet Disorder Support
2 Association. For 20 years, PDSA has been
3 empowering patients with immune thrombocytopenia,
4 or ITP, a rare autoimmune bleeding disorder that
5 affects 9 out of 100,000 people around the world.
6 Through education, advocacy, research, and support,
7 the FDA has really encouraged rare disease advocacy
8 organizations to make their voices heard, as
9 95 percent of rare diseases don't have an approved
10 treatment and there are no cures, making the work
11 that advocacy organizations do that much more
12 important and improving a patient's journey towards
13 better health.
14 Furthermore, many rare disease organizations
15 have an average staff of three people. Often they
16 are caregivers of patients or they are patients
17 themselves, making it difficult to prioritize
18 initiatives on behalf of their patient population.
19 PDSA has a staff of five full-time employees, and
20 I'm excited to share that engaging with the FDA has
21 been so much easier and more accessible thanks to
22 public workshops like these, in addition to

<p style="text-align: right;">Page 209</p> <p>1 collaboration with other advocacy organizations 2 that can help you learn best practices. This 3 workshop has done a really great job at sharing how 4 patient groups can work with the FDA, so Phyllis 5 and I are here to provide a bit of case studies and 6 to kind of hammer the point home.</p> <p>7 First I'd like to share with you a little 8 bit about PDSA's journey in engaging with the FDA. 9 PDSA was founded 20 years ago by ITP patient Joan 10 Young. At that time, there were few therapies 11 available to treat ITP, and the main treatment 12 choices were either really high doses of steroids 13 or surgical removal of the spleen, so neither a fun 14 option.</p> <p>15 Joan started the organization like many 16 other advocacy organizations by empowering ITP 17 patients through medical education and providing 18 support forums for patients to share their stories. 19 Ten years later -- so we're at 2008 -- Joan 20 testified before FDA's oncology drug approval 21 committee, or ODAC, a group of outside scientists, 22 clinicians, and laypeople charged with making</p>	<p style="text-align: right;">Page 211</p> <p>1 clinical trials and product development as well as 2 help to construct a holistic picture of what it's 3 like to live with a disease individually and as a 4 disease community, especially with regard to 5 quality-of-life data, which as we know sometimes is 6 the most important thing to patients. More 7 importantly, registries allow patients to share 8 their stories making them active participants in 9 research.</p> <p>10 To help further inform PDSA as an advocacy 11 group of what the FDA was looking for in regard to 12 patient engagement, I attended three public 13 workshops: Roadmap for Engaging with FDA CDER; 14 CDER's Rare Diseases Public Workshop; and 15 Patient-Focused Drug Development: Collecting 16 Comprehensive and Representative Input. Whether 17 today is your first workshop or your 15th, you know 18 that public workshops are a collaborative effort 19 between the agency and patient groups and provide a 20 plethora of ideas of ways in which patients can 21 work with the FDA. I wanted to express my 22 gratitude to the FDA for not only listening to but</p>
<p style="text-align: right;">Page 210</p> <p>1 recommendations to the FDA on various treatments. 2 This was our first interaction with the FDA, and 3 unfortunately it would be our only interaction 4 until eight years later.</p> <p>5 PDSA is really grateful to have a really 6 strong relationship with healthcare professionals, 7 medical institutions, researchers, the 8 pharmaceutical industry, and other patient advocacy 9 groups, but we have not been involved much in the 10 regulatory process since Joan's meeting. As one of 11 the four pillars of PDSA's mission is advocacy, we 12 knew that we needed to change, and we decided to 13 engage with the agency.</p> <p>14 It's important to note that in early 2016, 15 PDSA received a grant from the FDA and the National 16 Organization for Rare Disorders to begin a natural 17 history study patient registry to collect patient 18 experience data. Commissioner Gottlieb and others 19 at the FDA have stressed the importance of natural 20 history studies, as they're a golden opportunity to 21 provide data retrospectively and prospectively.</p> <p>22 Registries are great for recruitment and</p>	<p style="text-align: right;">Page 212</p> <p>1 actively including the patient voice and regulatory 2 decisions, and for allowing us to share our stories 3 with you and answer our questions.</p> <p>4 At the end of 2017, our executive director 5 emailed PASE to set up an ad hoc meeting to educate 6 the FDA on the ITP patient experience. Now, 7 actually you can go to 8 fda.gov/requestameetingondrugs – I've gone this 9 morning -- but back then, we received a meeting 10 request within a couple of hours, and we had a 11 meeting set up with the Office of Hematology and 12 Oncology Products in PASE, and I'll talk about the 13 details of our meeting in a bit.</p> <p>14 Looking ahead past 2018, we've learned 15 through these public workshops, and especially 16 today, that there are a number of ways to begin 17 help advance the regulatory process for ITP 18 patients to give them access to establish the new 19 drugs and improve the ITP treatment paradigm. The 20 list on the far right with the boxes is definitely 21 not exhaustive, but we plan on conducting an 22 externally-led, patient-focused drug development</p>

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1 meeting next year, submitting preliminary registry
2 data to the agency for use in clinical trials;
3 perhaps provide additional patient testimonies for
4 new ITP therapies if they're needed; and submit
5 comments on FDA draft guidances. All of these
6 activities help the FDA in providing more
7 experienced data, which ultimately helps the
8 patient.

9 Now I'm going to talk about our 2017 meeting
10 with OHOP and PASE, and what we did to plan our
11 meeting and some of the key things that I'd like
12 all of you as patient groups to take away from what
13 we learned. There are four key things that I would
14 say are important in planning a meeting between the
15 FDA and a patient group.

16 First, it's important to involve key
17 leaders. Our meeting in November included our
18 executive director, who spoke about PDSA's
19 initiatives to help ITP patients and our goals for
20 the meeting. A patient representative, Barbara
21 Pruitt, who is a fierce advocacy for improving the
22 lives of ITP patients, shared her 50-year journey

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1 of living with ITP; one of our medical advisors,
2 Dr. James Bussel from Weill Cornell Medical Center,
3 who discussed the unmet scientific need of ITP
4 physicians and researchers; and myself, who as
5 research coordinator shared patient experience data
6 from our registry.

7 Second, our goals were to educate the FDA on
8 the most significant symptoms of ITP, current
9 treatment side effects, burden of disease, and
10 impact of condition on quality of life; to ensure
11 that the ITP patient voice is included in providing
12 guidance and advancing science; and to serve as a
13 comprehensive resource on the patient experience
14 and provide input and guidance in new drug
15 development research moving forward.

16 Most importantly, we asked the FDA to
17 prioritize the unmet needs of our patients. The
18 ITP community needs more efficient diagnostic
19 tests. We need treatments that last and better
20 quality of life. We need increased awareness in
21 public and professional health communities and
22 comprehensive treatment centers to improve current

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1 outcomes, and we need increased research and
2 federal funding opportunities. These are lessons
3 we've learned from our patients, their caregivers,
4 our medical advisors, and clearly demonstrated to
5 the FDA that we realize what's missing in the ITP
6 paradigm, and identify for them the unmet need of
7 our patient community. Finally, the last thing we
8 learned is that you must be able to back up your
9 asks with quantitative or qualitative data, as was
10 mentioned multiple times throughout the workshop
11 today.

12 PDSA's registry with NORD and the FDA
13 attempts to fill some of the gaps and evidence in
14 the scientific need of our research community. The
15 registry establishes baseline information, logs
16 longitudinal disease progression, and identifies
17 patient-reported outcomes. Its goal is to
18 characterize and describe the ITP population as a
19 whole; assist the community with the development of
20 recommendations for standards of care; assist
21 researchers studying the pathophysiology of ITP and
22 interventional outcomes; and support the design of

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1 clinical trials for new treatments.

2 The impact of registries are monumental.
3 Providing patient experience data will in turn be
4 able to help regulators make informed decisions
5 about new therapies for ITP and inform trials.
6 Thank you to NORD and to the FDA for supporting the
7 rare disease program.

8 We were really encouraged during our
9 meeting, by the way, that the meeting was actually
10 a discussion and not necessarily a presentation
11 from either side. The agency's prioritization of
12 patient involvement ensures that feedback from
13 patients on endpoints and methodologies, as well as
14 benefits and risks, are integrated into the drug
15 approval and development process. This meeting was
16 beneficial both to PDSA and to the FDA in beginning
17 a fruitful collaboration and open line of
18 communication.

19 What are some of the take-aways? I think
20 there used to be this idea that patients and the
21 medical community and regulators used to be the
22 silos and didn't really work together, but I think

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1 it's really vital for everybody to work together to
2 improve how patients feel and function. So it's
3 really important for that collaboration to be
4 occurring, and the FDA really encourages that,
5 which in turn is really encouraging to our patient
6 community as well as to our medical advisors in the
7 scientific community.
8 As I mentioned, the FDA wants to include the
9 patient perspective, so when planning a meeting in
10 whatever form that might take, you need to help
11 them to help you. You need to know as a patient
12 advocacy organization what you bring to the table,
13 which is valuable experience information.
14 Another take-away is to have the right
15 people in the room and ask the right questions.
16 You should have an agenda prepared and make sure
17 you have a variety of disease experts convened to
18 share their experiences. And of course as we've
19 learned today, there are a number of ways that the
20 FDA can help you plan your meeting so you can help
21 them.
22 For us it was really encouraging to our ITP

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1 community that we are collaborating with the
2 agency. It really goes beyond facilitating
3 interaction. Working with the FDA raises awareness
4 and gets you one step closer to addressing the
5 unmet needs of your patient population. As I
6 mentioned earlier, patients are able to express
7 what matters most to them and take charge of their
8 own health, which is so important. Working with
9 the FDA empowers patients and helps them feel in
10 control of their healthcare experience.
11 Maybe most important, follow up with the
12 FDA, engage with them early, and engage with them
13 often. This really creates a strong bond between
14 advocacy organizations in the agency and keeps both
15 parties in the loop. This is really the next step
16 in patient advocacy, and it's really exciting.
17 Working with the agency allows regulators to listen
18 to patients regarding the benefits and harms of
19 treatments, as at times their chief complaints may
20 not be factored explicitly into drug development.
21 PDSA was really honored to be given the
22 opportunity to advance the science of patient input

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1 and provide guidance to the FDA. PDSA's focus
2 remains the clear and significant medical need of
3 our patient population, and we look forward to
4 collaborating with the FDA in the future. Thank
5 you for this opportunity.
6 (Applause.)
7 Presentation - Phyllis Foxworth
8 MS. FOXWORTH: Hi. I'm Phyllis Foxworth.
9 I'm with the Depression and Bipolar Support
10 Alliance. DBSA is the leading peer-directed
11 organization for individuals living with mood
12 disorders. We were founded over 30 years ago. I
13 like to tell people that it was well before there
14 was Facebook and the internet, but there were
15 several small pockets of support groups around the
16 country in major markets that were holding these
17 support groups. They somehow discovered each other
18 without Facebook or social media, and they came to
19 Chicago about 32 years ago and got together and
20 founded DBSA.
21 From there, we've grown to over 250
22 affiliates around the country that provide over 600

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1 support group meetings in their community. I'm
2 with the national organization, and our focus is on
3 providing education, hope, and inspiration for
4 individuals living with mood disorders, that they
5 can and should expect to lead quality, productive
6 lives, as well as participate in advocacy to make
7 that world happen. That takes us to where I became
8 involved with the FDA about three years ago.
9 I'm not going to go into much detail as I
10 often did, but kind of give you an overview of what
11 our campaign with the FDA has been all about. As I
12 said, we became engaged with the FDA about three
13 years ago. We responded to the docket that we
14 learned about today, where they had listed the
15 diseases and disorders that they were considering
16 for FDA-led, patient-focused drug development
17 meetings.
18 So we responded to that docket, and that
19 really forced us to start coalescing around the
20 idea of what is the unmet need and quite frankly,
21 that was the easy part of the whole process. There
22 are about 16 million people living with major

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1 depressive disorder in the United States; 21
2 million people live with mood disorders overall.
3 One-third to two-thirds of those people are not
4 getting any benefit from current medical,
5 therapeutic, and pharmacological interventions.
6 Furthermore, people living with depression
7 are at a high risk of suicide. People are dying
8 daily, and there is this idea -- I think I even
9 heard someone say this morning something about
10 depression, "Well, they've got all those compounds
11 out there." Well, the truth of the matter is,
12 two-thirds of the people are getting no benefit
13 from them. People who live with depression, major
14 depressive disorder, are at high risk of suicide.
15 Death by suicide is the 10th leading cause of death
16 in the United States.
17 The sad news is that there has not been any
18 breakthroughs in treating major depressive disorder
19 in over three decades. Thirty years ago, there
20 were some major breakthroughs with antidepressants
21 and antipsychotics, but there has been nothing
22 since then. And I keep going back to that fact

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1 that one-third to two-thirds of individuals who
2 have access to that medication are getting no
3 benefit.
4 In addition, those that are, are at very
5 serious risk of relapse, again raising the
6 possibility of suicide for them as well.
7 Additionally, people living with mood disorders die
8 25 years sooner than the average person, 25 years.
9 And that's not because of the suicide; that's
10 because of all the other physical conditions
11 associated with depression.
12 So we didn't have a difficult time
13 understanding what the unmet need was. There's
14 clearly an unmet need. We recognize that we need
15 to advance the science from 30 years ago, and
16 that's where we certainly want to collaborate with
17 the FDA on understanding where there are new
18 opportunities to look at new science around those
19 disorders. But we also recognize that for
20 patients, current clinical trials are primarily
21 focused on symptom relief, and that's not what
22 patients are interested in. With that hurdle, it

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1 becomes difficult for there to be new drug
2 development, so our collaborating with the FDA is
3 to try to move the needle on both the science and
4 to start looking at what are the outcomes that
5 patients want from treatment that are not symptom
6 based.
7 Going through over the campaign here, we
8 utilized the resources at our disposal. I will
9 share with you that we certainly didn't know what
10 we didn't know when we embarked on this journey.
11 It's been a great learning process for me. But we
12 were able to use resources at the FDA, particularly
13 PASE. They have been so helpful and valuable.
14 When we started out on this journey, we did
15 what they said not to do. We started dropping
16 emails, and we would have meetings with people.
17 And they would say, "Oh, you need to talk to
18 somebody else," so we would schedule a meeting with
19 somebody else. And we'd go to that meeting, and
20 they'd say, "Oh, you need to have a meeting with
21 somebody else." But I will say that at the end of
22 all those meetings, the person who said you need to

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1 have that meeting with somebody else always
2 followed up, and they would email me back, and they
3 would copy that person and say, "You need to be
4 meeting with these people from DBSA."
5 So eventually, that got us to PASE. I
6 remember having a meeting with Dr. Whyte and Rea.
7 They were in the room. And Dr. Whyte said, "Why
8 are you guys here?" And quite frankly, I didn't
9 know why we were here. I just knew that we had
10 this unmet need, and that I knew that there were
11 other patient advocacy organizations that were
12 using the FDA to help them find a solution to their
13 unmet need.
14 So I didn't have an ask when I went in, and
15 that's where PASE was so helpful, is that they were
16 really able to help us. They listened carefully to
17 our unmet need and helped us develop a path
18 forward.
19 One of the things that I did do after that
20 conversation with them was I wrote a white paper
21 that really helped me coalesce around the idea of
22 what is the unmet need and what is a pathway

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1 forward. I had a lot of mentors, people who were
2 at this meeting in years' past who were the pros.
3 And they were always willing to help me, and they
4 were always willing to share their ideas. I would
5 call them up and drop them an email, and they'd
6 say, "You're doing the right thing. You're on the
7 right path." So I would encourage you to use your
8 mentors out there.

9 Then we developed some very meaningful
10 input. As I said, when we had that first meeting
11 with PASE, Dr. Whyte said, "Why are you here? What
12 do you want?"

13 DR. WHYTE: [Inaudible - off mic].

14 MS. FOXWORTH: He was very friendly,
15 but -- he was very friendly. I do not mean that as
16 a criticism. It was really probing as to what do
17 you want; why are you here? And that's what we
18 needed to hear. And he suggested that we -- he
19 said in this organic meeting, "Hey, it sounds like
20 you guys need a scientific workshop." I took that
21 challenge. He laid down that guideline, and I took
22 that challenge. Within one year, we had a

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1 scientific workshop last November where we convened
2 all the major stakeholders, that being patients
3 themselves; caregivers; clinicians; our industry,
4 the people who are responsible for drug
5 development.

6 I remember Dr. Whyte kept saying that,
7 "Well, you need to be talking to the people who are
8 developing the drugs." The FDA was there. But we
9 began the journey. It was a full-day meeting. It
10 was very small, very intimate, of about 35 people,
11 academics who are responsible for creating those
12 tools to measure, where we started the conversation
13 about what is it that patients want and how do we
14 get to the place where we can start measuring what
15 patients want.

16 Based on that scientific workshop, I walked
17 out of there. Again, I continued to say that I put
18 myself in these positions where I don't know what I
19 don't know. And that's a message that I will leave
20 you with; it's don't be intimidated by that.
21 That's what's always propelled me forward is I
22 don't know what I don't know, but I know that

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1 mentors and people will help me find that answer,
2 and I'm not afraid of it.

3 That output from the scientific meeting
4 really helped us develop a strategy for the
5 patient-focused drug development meeting. We
6 submitted our LOI last November, shortly after the
7 scientific meeting, and we now have
8 scheduled -- our externally-led, patient-focused
9 drug development meeting is scheduled for
10 November 16th.

11 So we continue to be on this path. I just
12 want to share that it's a collaborative strategy.

13 As I said before, we knew what the unmet need was,
14 but we didn't know what to do about that. We also
15 knew that other patient advocacy organizations were
16 working with the FDA, but we didn't know what that
17 meant. And the collaborative effort that we've had
18 between the FDA and us has been invaluable.

19 They've been able to help us understand what our
20 ask is. They've been able to help us develop a
21 strategy for moving forward.

22 I just want to close with what is our

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1 strategy for moving forward. As I said, we opened
2 up that -- what we recognize is that, currently,
3 clinical trials for the past 30 years or longer
4 have been based on symptom mitigation, and we know
5 that's not what patients in our space are looking
6 for. But what I realize from that scientific
7 meeting was that we're really not that far apart,
8 that we have FDA language and we have academic
9 language that talks about homogeneous dimensions
10 and domains and validated skills, which mean
11 nothing to patients.

12 Patients have their own language, and that's
13 about what's working in my life and what's not
14 working. They have heterogeneous life
15 circumstances. If I wanted to scream how many
16 times I've heard at that scientific workshop,
17 "homogeneous, homogeneous, homogeneous," but I
18 realize that we really aren't that far apart, that
19 we have more similarities than we think. It's just
20 that we're all speaking the different language.

21 So that's where we're going with our
22 patient-focused drug development meeting. We are

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1 looking to spend some time in some focus groups
2 with our patients to understand what it is that's
3 important in their life; what are they looking for
4 within treatment outcomes. We are developing
5 panels that will be able to share the burden
6 perspective with the FDA. We will then be able to
7 share some of the qualitative and quantitative
8 surveys that we're doing over the next six months
9 with the FDA.

10 Most importantly is that I have a monthly
11 meeting with the FDA to help me, and I did not know
12 that was going to happen. I thought I was on my
13 own. I thought I was going to have to just pull
14 together this patient-focused drug development
15 meeting, again, not knowing what I don't know. And
16 when they accepted the LOI, they reached out and
17 they said now is our time for our monthly meetings,
18 and that has been so invaluable.

19 So that's the mantra that I will leave you
20 with. It's okay that you don't know what you don't
21 know; that the FDA is here to help.
22 (Applause.)

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1 Questions and Answers

2 DR. WHYTE: I think we have time for a
3 couple of questions, and we'll be wrapping it up
4 very soon. I will say while you come to the mic,
5 my big point to people has always been make an ask;
6 what's your ask? And I think that's part of the
7 challenge, that folks often get so excited just to
8 come in and tell their story. It's also important,
9 what are you asking us to do. And that kind of was
10 my point, like why are you here?

11 MR. ACCETTURA: Carl Accettura. I'm with
12 PharmsRx Therapeutics. I came today because I saw
13 Phyllis was on the agenda and I wanted to get to
14 understand what DBSA was doing. And I was more
15 delighted because I've made connections with
16 rare-disease-side people. This has been a great
17 meeting, so I thank FDA for holding this.

18 My one question for Phyllis was why did it
19 take all the way to November? Because we heard
20 earlier maybe six months to put together a
21 patient-focused drug development meeting. Was
22 there anything unusual that occurred?

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1 MS. FOXWORTH: We submitted our LOI last
2 November, and it was reviewed, and we received word
3 in March that it had been accepted. So between
4 March and November is about -- I can do my math.

5 MR. ACCETTURA: Well, why did it take until
6 March then to be accepted? Is that part of the --

7 MS. FOXWORTH: It goes through the review
8 process.

9 MR. ACCETTURA: So it's really closer to
10 12 months than 6 months?

11 DR. WHYTE: I think part of it is on our end
12 as well, that internally there is a bunch of folks
13 that we want to be involved in it. Our focus
14 is -- I know everyone, often time frames are
15 different, but it's also expectations where we can
16 have discussions on. These are hard to do well,
17 and what we want is the interested parties to come
18 together and really think through the process. And
19 then we want to be able to respond to what the
20 groups are thinking, and sometimes those interests
21 are different, and that's a good thing, but then it
22 takes time to work it out. I know everyone is

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1 always on a fast time track, and that's okay. So I
2 think part of it is on our end as well.

3 MR. ACCETTURA: Yes. We're working on
4 treatment-resistant depression, so that really
5 becomes a very small subset of the patients. And
6 Phyllis and I were talking, and everyone kind of
7 assumes that depression is taken care of, but it
8 isn't at all. So this opportunity to have a
9 patient-focused drug development meeting around
10 that point is very important.

11 MS. FOXWORTH: And I just want to add that
12 we received a word, which I think was very timely.
13 I submitted the LOI November 30, and then somewhere
14 the 1st of March, we received notice that it had
15 been accepted. And I need all that time to
16 prepare. I don't want to just slap something
17 together that's not of value to the patients nor
18 the FDA. I really need that time to pull together
19 a quality meeting.

20 DR. WHYTE: Any other questions? I know
21 folks are getting tired.
22 (No response.)

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1 DR. WHYTE: Well, I want to thank both of
2 you for coming and sharing your perspective, and
3 thanks for your kind words. It's an iterative
4 process. We want to get better, and hearing from
5 everyone helps us to do that.
6 I want to thank all of you for coming today.
7 I know it can be challenging to get here. We've
8 spent many hours here, and I hope it's been
9 valuable to you. I've had the fortune of being up
10 here, and being visible, and getting to interact
11 with you, but as you can see, there are a host of
12 folks that have been involved.
13 I want to thank my folks and colleagues from
14 the Division of Learning, Chad and Derek [ph]. I
15 want to thank our friends at OCOM and DDI, Zac;
16 Raj; and Sharon; and certainly all the folks on our
17 team, Noah; Rea; Chris; Sadhna; Malena [ph]; Scott;
18 Jungaha; Derek; Diane; Mary; Hala; Rhonda; Shawn;
19 Dave; David; Christine; and Chris. You never
20 expect all these folks are necessary to make this
21 type of meeting happen, but it is, and I want to
22 recognize their hard work as well.

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1 We have a couple of final questions, and I'm
2 going to let Noah Goetzel -- as he says, like
3 pretzel -- do the final audience response questions
4 because, again, Noah has done an enormous amount of
5 work bringing this together along with Rea and the
6 rest of the team.
7 Final Poll Questions - Noah Goetzel
8 MR. GOETZEL: Thank you very much,
9 Dr. Whyte.
10 I'm back, everyone. So in the morning -- I
11 have results for you. The first question that I
12 asked, that one hasn't changed. Still 80 percent
13 of you have been here before.
14 For understanding the function of CDER, for
15 that one, 20 percent of you said you guys are not
16 at all confident in understanding CDER's functions;
17 57 percent said you're somewhat confident; and
18 22 percent said very confident. So I'm going to go
19 ahead and ask that question again. Pick up your
20 voting little gadget things, the clickers, and A
21 for very confident; B for somewhat confident; and C
22 for not at all confident.

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1 Go ahead and submit your votes. Thanks.
2 (Audience responds.)
3 MR. GOETZEL: All right. We have our
4 results. We had a big jump. Twenty-two percent,
5 very confident, went up to 66 percent, and a few
6 of you say you're somewhat confident, and amazingly
7 zero percent say you're now not confident
8 whatsoever. So everybody's at least a little bit
9 confident in understanding what CDER does, and
10 that's good news.
11 On to the next question. In the morning,
12 the question was how confident are you in your
13 ability to navigate through engaging with CDER. In
14 the morning, we had 44 percent said not at all
15 confident; 53 percent said somewhat confident; and
16 2 percent, one person, said they were very
17 confident.
18 So now the polls are open. You can vote
19 again, your confidence level with navigating
20 through and engaging with CDER, choice A is very
21 confident; B, somewhat; and C, not at all
22 confident.

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1 (Audience responds.)
2 MR. GOETZEL: All right. Now we have
3 53 percent, which is an increase in 7 percent
4 saying that they are very confident in engaging
5 with CDER, navigating through and engaging with
6 CDER; 41 percent somewhat; and 6 percent are not at
7 all confident.
8 We've got one more question for you before
9 the final words of wisdom by Dr. Whyte, and then
10 we'll be all set. This last question is how would
11 you rate your overall satisfaction with the
12 information presented today during our CDER and You
13 Public Workshop? A, very satisfied; B, somewhat
14 satisfied; C, neutral; D, somewhat dissatisfied;
15 and finally E, very dissatisfied.
16 Go ahead and vote with your clicker the last
17 time for the day.
18 (Audience responds.)
19 MR. GOETZEL: Okay. That's great news. We
20 have 68 percent who said they were very satisfied
21 and 29 percent who said they were somewhat
22 satisfied; 3 percent are neutral; and nobody said

1 that they are dissatisfied with today's
2 presentation. So that's great to hear. Thank you
3 guys very much.

4 Closing Remarks - John Whyte

5 DR. WHYTE: Well, thank you, Noah, and thank
6 you all for sticking with us. I guess my final
7 words of wisdom would be that we're open for
8 business. We want to hear from you. Check out
9 fda.gov/requestameetingondrugs. Hopefully, it
10 won't crash, and we look forward to engaging with
11 all of you. Safe travels this afternoon. Thank
12 you.

13 (Applause.)

14 (Whereupon, at 3:07 p.m., the meeting was
15 adjourned.)

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