

*FDA - Roadmap for Engaging with CDER  
Public Workshop*

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*May 12, 2017*

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*A Matter of Record  
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1            P R O C E E D I N G S  
2            (9:10 a.m.)  
3            Introductions and Opening Remarks  
4            DR. WHYTE: Good morning, everyone. We're  
5 going to start in about a minute, so if folks can  
6 have a seat. There are still seats in the front.  
7 I know no one ever wants to sit in the front, but I  
8 promise it'll be okay if you sit in the front.  
9            I'm John Whyte. I'm the director of  
10 Professional Affairs and Stakeholder Engagement  
11 here at the Center for Drugs at the Food and Drug  
12 Administration, so welcome.  
13            Just so you know, there is a race going on  
14 later today, the White Oak Classic, so you're kind  
15 of trapped here because, soon, certain roads will  
16 be closed. I'm joking. You will be able to get  
17 out. But everything will be so interesting, you  
18 will want to stay.  
19            Today is our second roadmap for engaging  
20 with the center. And it's really a desire to help  
21 folks understand how to engage with the Food and  
22 Drug Administration on issues of drugs. It can be

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1 a very confusing place. We often talk about the  
2 FDA regulates 25 cents of every dollar. There are  
3 thousands of employees here on this campus and  
4 around the country, as well as around the world.  
5 So it can be challenging when you have a question  
6 about drug approval or drug safety. Where do you  
7 go? How do you talk to people? How do you find  
8 out who to talk to?  
9            So today really is that desire to start a  
10 conversation. Some of you are already quite  
11 familiar with the agency and our regulatory  
12 processes, and others are very new and have some  
13 misconceptions about the FDA.  
14            Just so you know, all of you have gotten  
15 this folder and there's a bunch of materials in  
16 here, including an organizational chart, which is  
17 just the center, just the Center for Drugs, and  
18 that can be challenging. Again, who do you talk  
19 to, and when do you talk to, and what can you talk  
20 about, and what can't you talk about?  
21            So hopefully you're going to learn a little  
22 bit about that today. And again, this isn't meant

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1 to be the only point in time that we're going to  
2 have engagement, but really the start of a dialogue  
3 and the start of a conversation.  
4            As I said, there are many folks on the  
5 webcast, so if you have any questions, we want to  
6 have a very interactive discussion. Please come to  
7 the mic so the folks that are watching online can  
8 hear it as well.  
9            We are recording today's proceedings for  
10 archival purposes, so you can always go back. So I  
11 ask as a courtesy that you silence your phones and  
12 put them on vibrate, so not to disturb your  
13 colleagues or the speakers.  
14            The full agenda is there, and what is going  
15 to be really exciting is we are going to have a  
16 Jeopardy later today. There won't be any prizes  
17 except your bragging rights that you won FDA  
18 Jeopardy, so start thinking about your team.  
19            So we're going to get started because we  
20 like to try to stay on time. And it's my pleasure  
21 at this point in time to introduce Dr. Doug  
22 Throckmorton, who's the deputy center director for

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1 regulatory programs.  
2            What we've done is we've asked everyone to  
3 give us a fun fact, try to humanize these  
4 government employees that you interact with.  
5 Dr. Throckmorton, I always thought his fun fact was  
6 that he was from Nebraska, because how many of us  
7 know people from Nebraska? He's my first Nebraskan  
8 that I've met.  
9            But his first job was detasseling corn,  
10 which is not to be confused with shucking corn. So  
11 does anyone know what detasseling corn is? I've  
12 tried to include a picture. Essentially, it's  
13 removing the wheat-looking part of the cornstalk  
14 from the plant by hand, which is very intense work.  
15            That's the kind of person that Doug  
16 Throckmorton is, a very intense worker here. And I  
17 have the privilege of working with Dr. Throckmorton  
18 on almost a daily basis. He has been one of the  
19 biggest supporters here at the center and at the  
20 agency in creating the group that I'm in charge of,  
21 Professional Affairs and Stakeholder Engagement.  
22            He is a strong proponent of true dialogue

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1 with patients, and patient groups, and health  
2 professionals, and is always thinking of ways of  
3 how do we include patient input into our regulatory  
4 decision-making. So he truly is a champion of all  
5 of you that want to work with the center and how do  
6 we do that more effectively. Dr. Doug  
7 Throckmorton?  
8 (Applause.)  
9 Welcome – Douglas Throckmorton  
10 DR. THROCKMORTON: Wow. This guy sounds  
11 pretty good. Thank you, John, very much.  
12 I will say I agree. I am a real champion of  
13 the work that you guys are doing. I'm delighted  
14 you guys are here today. I'm delighted you guys  
15 are going to spend some time.  
16 I hope you learn a lot and apply what you  
17 learn to forward all the work we're doing together,  
18 because I think John's right. We've got to be  
19 working together. As I'll get to, I've been at the  
20 agency long enough to see a time when that was not  
21 the understanding. And I think, under  
22 Dr. Woodcock's leadership, we've charted a much

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1 better course.  
2 So I know two things about the importance of  
3 external stakeholder engagement. First, it's  
4 important for me to do my job for Dr. Woodcock, for  
5 the center to do its job for the Food and Drug  
6 Administration, and for the Food and Drug  
7 Administration to do its job to meet its mission to  
8 protect, and promote, and make available safe and  
9 effective medicines for the American public. So it  
10 is an integral part of everything we do in order  
11 for us to succeed.  
12 Second, I know how hard it is, and that's an  
13 important aspect of what John and his team are  
14 trying to help you with here today, something I  
15 hope you're able to use in the challenges that you  
16 all face.  
17 Let me talk about importance just a little  
18 bit. As I said, I started in 1997, started as a  
19 reviewer in cardiovascular medicine. When I  
20 started, the engagement that we had I would say  
21 extended no further than the professional  
22 societies.

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1 So the idea of talking to a patient advocacy  
2 group -- there were not as many patient advocacy  
3 groups available, true, but the idea of, as a  
4 culture, engaging with the patient advocacy groups  
5 was really foreign. It happened. It happened  
6 occasionally. There were strong groups out there.  
7 It was not in the DNA of what we did as a center.  
8 I would say fast-forward to the early 2000s,  
9 when we were confronted by two things, one a  
10 recognition that we needed to reinvigorate medical  
11 products development, to make it safer, more  
12 effective, more efficient; and second, that we  
13 needed to do a better job of communicating the  
14 things that we were doing and the things that we  
15 understood.  
16 I think, at that point, Dr. Woodcock looked  
17 around and understood that, without any question, a  
18 critical part of accomplishing those two things was  
19 a greater engagement with the outside world. That  
20 meant reaching outside of the walls of the agency,  
21 talking to the external stakeholders, understanding  
22 the needs better than we did so that we could do

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1 our job better than we were.  
2 I believe that vision was exactly right. I  
3 think that vision has driven a culture change in  
4 the last 10 years-plus within the center and within  
5 the agency as well. We get it. We understand that  
6 engagement is more than just a good thing to do.  
7 It's absolutely essential.  
8 As a part and parcel of that, we've built  
9 places in the agency, places within my center,  
10 focused on external engagement, focused on making  
11 sure that happens.  
12 John's group is obviously one of the  
13 highlights, the central parts of the work that the  
14 center is doing. I'm glad that his group reports  
15 to me. It has made enormous strides over the years  
16 that it has been part of our organization. But  
17 there are many other groups, and I'm sure you guys  
18 have been engaging with them as well.  
19 The Office of Strategic Programs has done  
20 incredible work on our patient-focused drug  
21 development, the meetings that I hope many of you  
22 have been able to participate in.

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1 OHCA, Office of Health Affairs and Community  
2 Engagement, at the agency level has been named  
3 various things over many years, but is probably the  
4 longest-lived advocacy interaction group within the  
5 agency and continues to play a really important  
6 part. I chaired a two-day meeting on opioids with  
7 external stakeholders earlier in the week, and the  
8 OHCA participation in that meeting was absolutely  
9 essential.

10 But there may be some groups you may not  
11 think of as engaging in external stakeholder  
12 engagement as much also. The rare diseases group,  
13 I would point out. They're in the back of the room  
14 if you wonder what the definition of a rare disease  
15 is. They have candy back there, too, so definitely  
16 worth a visit.

17 The pediatrics group -- and I think Lynne  
18 Yao and her group may be talking later on in the  
19 morning. These groups have always, I believe,  
20 understood the importance of advocacy and  
21 engagement in important places within the center  
22 and the agency also.

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1 The second piece I wanted to say is I get  
2 how hard this is. FDA, like every federal  
3 organization I've ever been in or aware of, is  
4 complex and different from every other federal  
5 agency that I've ever been aware of.

6 So the organization at the FDA bears little  
7 resemblance, except in very large ways, to the  
8 organization at CMS, or VA, or whatever. So trying  
9 to identify who to call, how to identify a  
10 decision-maker, the right form to submit, whatever  
11 that is, is daunting under the best of  
12 circumstances, and it's challenging, especially  
13 when you get to the federal level.

14 I'm delighted that you guys are going to be  
15 getting an overview of the agency. I think we have  
16 worked very hard to try to demystify the agency.  
17 Our Office of Communications has a group set up  
18 specifically to help answer those kinds of  
19 questions.

20 I hope you reach out to them. I should have  
21 included them in my list of advocacy groups, too,  
22 because I think their leadership clearly

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1 understands and has put into place ways to engage  
2 the outside community.

3 I hope that, as a part of that overview  
4 process, you come to understand, one, that we want  
5 to help. Our interest is in making external  
6 advocacy and engagement possible and apply it to  
7 the drug development process as quickly and as  
8 efficiently as possible.

9 The second thing I hope you understand is  
10 that there are things that we do that we can't  
11 always talk about. So when things come up, and  
12 there are challenges, and you're wondering whether  
13 we're listening, yes, we're listening.

14 If we're not always responding, ask, get  
15 clarification about whether that's something that's  
16 grounded in a misunderstanding, grounded in a need  
17 to have a conversation; or whether it's grounded in  
18 something that we're not able to talk with you as  
19 fully about, just to clear up that miscommunication  
20 so that you don't misunderstand.

21 We want to help, we want to engage, and we  
22 want to be part of the conversation. But

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1 sometimes, we're just simply not able to do that as  
2 much as we'd all like to.

3 With that, John, I'm going to turn this back  
4 over to you. Thank you for your kind remarks. I  
5 miss Nebraska. It's a great place. You all ought  
6 to come visit sometime. Thank you very much.

7 (Applause.)

8 DR. WHYTE: So all of you should have this  
9 little keypad because we're going to do some  
10 audience response questions, which are separate  
11 from Jeopardy. So hopefully you all have one of  
12 these. If not at your table, hold up your hand,  
13 and we'll get some to you.

14 Part of the goal is not just to meet myself  
15 or to meet Dr. Throckmorton, but to meet many  
16 members of our team. That's part of the goal  
17 today. So you'll meet folks, and know them, and  
18 get to dialogue with them.

19 So I'm going to introduce my colleague,  
20 Chris Melton. His fun fact -- I don't know if it's  
21 that fun, other than he's not a doctor, but he is  
22 an avid golfer and told me that his handicap is 10.

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1 So I guess that is pretty good, and he has played  
2 golf on two islands.  
3 So I don't determine people's fun fact.  
4 They tell me what it is, and I just read it. So  
5 with that, I'll turn it over to Chris Melton.  
6 (Applause.)  
7 Audience Response Questions  
8 Christopher Melton  
9 MR. MELTON: Good morning, everyone. My  
10 name is Chris Melton. I'm a health communications  
11 specialist with Professional Affairs and  
12 Stakeholder Engagement. And in my role as a health  
13 communications specialist, I like to promote a  
14 culture of two-way engagement between the Center  
15 for Drug Evaluation and Research and stakeholders  
16 such as yourselves.  
17 Now, as I go into the audience response  
18 questions, we'll have three of those to go over,  
19 and I would ask that everyone please grab their  
20 clickers that they have handy. Also, on the Web,  
21 they'll be able to respond, but they will not be  
22 showing on the screen in here today.

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1 So for our first question, is this your  
2 first time at an FDA meeting? Select A for yes or  
3 select B for no. And as the questions come in,  
4 we'll see them tally up.  
5 (Audience answers.)  
6 MR. MELTON: So it looks like we have a mix  
7 of rookies and some veterans here. We definitely  
8 want to welcome everyone for your first time here,  
9 and we look forward to your attendance throughout  
10 today.  
11 Now, we're moving on to question number 2.  
12 How confident are you in your understanding the  
13 functions of CDER? So select A for not at all  
14 confident, or select B for somewhat confident, or  
15 C, very confident.  
16 (Audience answers.)  
17 MR. MELTON: We'll have the results up here  
18 on the screen. We have 60 percent somewhat, 27 not  
19 at all, and then 13 very confident.  
20 Now, we will move on to our final question,  
21 number 3, how confident are you in your building to  
22 navigate and engage with CDER, within the FDA?

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1 A, not at all confident; B, somewhat confident; or  
2 C, very confident?  
3 (Audience answers.)  
4 MR. MELTON: Then our results will be coming  
5 up. Well, thank you, everyone, for your response.  
6 And now, I would like to turn it over to Dr. Whyte.  
7 DR. WHYTE: Thank you. So we can see we  
8 have a lot of work to do to try to educate you.  
9 And just so you know, because you might think folks  
10 at FDA are very serious, we did a dry run of this  
11 with our team, and all of the answers were not at  
12 all confident, "I don't know, this is my first-time  
13 meeting." So I should have shown those results.  
14 So we do have a lot of jokesters here.  
15 At this point in time, we're going to have a  
16 discussion about the drug approval process at FDA.  
17 And I'm delighted that my colleague, Dr. Milena  
18 Lolic, will be presenting how does an NDA work at  
19 the FDA, because many times, patient groups, and  
20 advocacy groups, and sometimes physician  
21 groups -- most of the time, when they're  
22 interacting with us, they're upset about that there

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1 is no drug development in something like lupus, or  
2 they're upset that they're concerned whether or not  
3 a new drug is going to be approved. Sometimes it's  
4 also drug safety issues as well. But I'm being  
5 honest. Most of the time, it's about approval.  
6 Milena's going to walk us through how this  
7 process works and let you know what the FDA does do  
8 and what it doesn't do. So we don't do clinical  
9 trials. We don't make drugs or distribute drugs.  
10 And I will say, as the folks at the Division of  
11 Drug Information at OCOM knows, whenever people  
12 call about that they've lost a drug, it's always  
13 something of an opioid nature. It's never Lipitor  
14 or aspirin.  
15 So we don't make drugs, and we don't send  
16 drugs to you if you lose them. So we'll learn  
17 about the new drug approval process. And Milena  
18 shared with me that she recently bought a piano,  
19 and she now is learning how to play the piano. And  
20 like many doctors, high achievers, she told me  
21 she's now going to be working on an opera soon and  
22 composing an opera.

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1 So that's good to know, hopefully while she  
2 still does her day job and works on drug trial  
3 snapshots, which I'll just give a pitch, also is in  
4 the back. Again, on the back table, there are a  
5 bunch of resources for you, including drug safety  
6 programs, new drug approvals, which I encourage you  
7 to look at, as well as the Drug Trial Snapshots  
8 program, which Milena leads here at the center.  
9 (Applause.)  
10 Presentation – Milena Lolic  
11 DR. LOLIC: Thank you, John. We'll see  
12 about that opera stuff a little later.  
13 Good morning, everybody. In the next  
14 20 minutes or so, I will share with you my six  
15 years of experience in the drug approval process.  
16 It tends to look like this, a lot of paperwork  
17 coming to the desk of the reviewer. And thankful  
18 to development in electronics, we are receiving  
19 most applications electronically now. But it's  
20 still a lot of pages to be reviewed.  
21 I will start with a brief overview of the  
22 drug development and talk about what happens when

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1 divisions receive NDAs, new drug applications, and  
2 what happens after the approval. There will be a  
3 two-minute fast-speed cartoon summarizing about 10  
4 to 15 years of drug development. So let's see how  
5 will that work.  
6 (Video played.)  
7 DR. LOLIC: So let's simplify this. Drug  
8 development is a very long and quite uncertain  
9 process. The FDA gets involved in the drug  
10 development process sometimes at the end of the  
11 pre-IND phase with a pre-IND meeting that is about  
12 to happen, describing the future plan for drug  
13 development.  
14 The second phase, the IND phase, is the most  
15 interactive with patients, patient advocacy groups,  
16 and the sponsor of the IND, and that is where all  
17 the clinical trials leading to hopefully NDA  
18 submission will be conducted.  
19 Phase 4 on your right side is undetermined  
20 duration, and it will last as long as the NDA is  
21 active. Of the four phases of drug development,  
22 NDA review is the shortest, about one year,

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1 although that's not how it feels when you review  
2 it.  
3 I want to clarify some confusion about the  
4 terminology that's not always easy to follow. On  
5 your left side, there are different type of  
6 designations, and on the right, the types of NDA  
7 reviews, which are determined at NDA arrival or  
8 just shortly before it. And then to make this a  
9 little more confusing, we have expedited programs  
10 marked with asterisks here.  
11 All four represent the effort to address an  
12 unmet medical need in the treatment of a serious  
13 condition.  
14 Being placed in one of these expedited  
15 programs means that FDA will expedite development  
16 and the review, not changing the approval  
17 standards, just streamlining the process.  
18 Accelerated approval, which is at the bottom  
19 of this slide, is actually a path that allows for  
20 earlier approval of drugs that will, again, treat a  
21 serious medical condition and fill an unmet medical  
22 need, but this approval will be based on a

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1 surrogate endpoint.  
2 The clinical trials confirming the clinical  
3 endpoint will be on the way at the time the drug is  
4 approved. This may be the shortest review,  
5 sometimes about four or four and a half months  
6 long.  
7 This is the NDA review timeline. For  
8 standard review, it takes about one year from the  
9 arrival of the NDA to issuing the action letter.  
10 There is a shorter way of approving drugs, priority  
11 review. This one takes about eight months.  
12 In the first month or so, the reviewers take  
13 time to make sure that the application is complete  
14 and reviewable. A majority of the time of course  
15 is spent looking at the data and reanalyzing them.  
16 Very frequently during this phase, the FDA will  
17 then direct the applicant, asking for clarification  
18 of the data or asking that they be reanalyzed in  
19 some different way.  
20 There are also a couple of meetings  
21 scattered throughout this review process that are  
22 used to communicate with the applicant how the

<p style="text-align: right;">Page 25</p> <p>1 review is progressing. 2 Perhaps the most frequent interaction 3 occurred in the last third of the review during 4 labeling negotiations. These can sometimes be 5 completed literally 5:00 to 5:00 on Friday 6 afternoon. 7 This whole process is confidential. There 8 is no public sharing of the findings or 9 communications. So how do we actually do that? 10 How do we review the conduct? 11 It is not uncommon that the NDA has 50,000 12 or 100,000 pages, and we look through all of them. 13 Each discipline, clinical, statistics, chemistry, 14 toxicology, takes its section, looks through it, 15 and a team, which is comprised of about 3 to 5 16 people, will occasionally ask the company for 17 additional information. They will analyze and look 18 to get the same result as the company that 19 submitted it. And they will very frequently 20 discuss the findings among themselves and the 21 members of the team. 22 There is also frequent interaction with the</p>	<p style="text-align: right;">Page 27</p> <p>1 recommendation, although it happens more frequently 2 than not. 3 So the answer to that question is 4 communicated to the applicant in the action letter 5 as the approval, or complete response, or actually 6 non-approval. The reason for calling it complete 7 response is because it describes the deficiencies 8 that we've found and way to address it, should the 9 applicant decide to come back. 10 One or the other answer may come during the 11 regular review clock, or sometimes it will follow 12 within three months of that clock, or even longer. 13 And that happens if during the review, either FDA 14 requests and receives a lot of new data or the 15 applicant decides to submit. If that cannot be 16 reviewed within the allocated time, the NDA clock 17 will be extended. 18 So everybody welcomes the approval. As you 19 can imagine this very long walk, when it's over, a 20 new, safe and effective drug is available. When 21 that happens, FDA actually approves everything that 22 you may associate with the drug: its name,</p>
<p style="text-align: right;">Page 26</p> <p>1 other review members because the interpretation of 2 each group and discipline heavily relies on 3 understanding where the whole process is going. 4 And in the meantime, numerous consultations and 5 interactions occur during the review at the whole 6 FDA level. 7 There are multiple groups, such as patient- 8 reported outcome groups, QT review teams, multiple 9 groups dealing with pediatric development that need 10 to be consulted in order for this review to be 11 completed. 12 So at the end of all of this work, we 13 actually need to answer only one question. Does 14 the benefit of the drug outweigh its risk? 15 Sometimes FDA does it on its own and sometimes with 16 the help of an expert. The most transparent way of 17 expert inclusion is the advisory committee, which 18 happens a couple of months before the anticipated 19 date of action. 20 The decision to call whether the benefit 21 outweighs the risk relies on FDA solely. There is 22 no requirement for FDA to accept advisory committee</p>	<p style="text-align: right;">Page 28</p> <p>1 manufacturing facilities, labeling, and very 2 shortly after the approval, the promotional 3 materials that you will see on TV or in journals. 4 So what happens after the approval? There 5 is actually just more data coming after the 6 approval. We may ask for more data as the 7 condition of approval. If you remember the 8 accelerated approval that we said is pretty fast, 9 but based on surrogate endpoints, one of the 10 conditions of that approval is that we see the 11 clinical data, and there is a time on that when we 12 want to see them. 13 We also ask, for example, that pediatric 14 trials be done within a certain time frame. For 15 some companies, they may actually volunteer to do 16 that, so we will have either a postmarketing 17 requirement or commitment. 18 Sometimes, the company wants to expand the 19 development program, so there will be new data 20 coming for the same drug, but perhaps a new 21 population or the new indication. And for the 22 newly marketed drug, there is a fairly large number</p>



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1 of safety data that is collected immediately  
2 following the approval and continues during the  
3 life of the NDA.  
4 We also monitor our work on NDAs. This  
5 slide shows three last years of NDA and BLA  
6 approvals based on the type of review. As you can  
7 see, we average about 100 to 110 per year. We look  
8 at the time that we spent reviewing them. And as  
9 you can see here, again, for the last three years,  
10 we can proudly say that about half of all the  
11 approvals occur at about the eight-month mark.  
12 [Indiscernible]? We think it is. But we  
13 also look, how do we stand in comparison to the  
14 rest of the world? And this is the comparison  
15 among regulatory agencies in approvals of new  
16 entities, the newest of the drugs. Every year, FDA  
17 was first to approve more than 50 percent of the  
18 new drugs, more than any other authority.  
19 Now, I would like to go through publicly  
20 available information once the drug is approved.  
21 Several of the drugs will have a press release  
22 within a couple of hours of approval. In general,

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1 this information is available for the drugs that we  
2 anticipate will be of a great public interest.  
3 All the FDA reviews -- and there can be  
4 thousands of pages -- are public and available on  
5 drugs at FDA. Some of the text will still be  
6 redacted because there is still proprietary  
7 information contained in our reviews.  
8 For the last two years and for some type of  
9 the new approved drugs called new molecular  
10 entities, what we have available for public are  
11 drug trial snapshots, and they're available within  
12 30 days of approval.  
13 So how do you access drugs at FDA? Google  
14 it, and this is what you will see once you type in  
15 a couple of letters of the drug you are interested  
16 in. As you scroll down, you will have the list of  
17 all the reviews. Again, there can be thousands of  
18 pages, so if you want to read, pace yourself, quite  
19 a heavy read and very scientific.  
20 A somewhat shorter and much more friendlier  
21 version to read are drug trials snapshots, and this  
22 is the first page that you will see once you Google

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1 drug trial snapshots. Once you scroll down, you  
2 will find the list of, at this point, 90-plus  
3 snapshots that have been published in the last two  
4 years. The database is searchable by drug name,  
5 active ingredient, and date of approval. On the  
6 right side, there is abbreviated indication, the  
7 disease for which the drug was approved. On the  
8 far right is a link to prescribing information.  
9 The main topic in the drug trial snapshots  
10 is the demographics, is the answer to the question,  
11 who participated in clinical trials. So this is  
12 one example. As you can see, and that you will see  
13 on the first page of the approved drug, the  
14 demographics break down on race.  
15 So in this case, you see people of five  
16 different races participated in the trial, about  
17 70 percent of our participants were men, and about  
18 half of all participants were younger than 65 years  
19 of age.  
20 So while this information is the key of each  
21 snapshot, you will also find in them a description  
22 of the trial design, all of the results of drug

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1 efficacy and safety, and observed differences in  
2 efficacy and safety among certain demographic  
3 subgroups.  
4 I would like to close with a comparison of  
5 these three different types of information that are  
6 available about NDA approval that are sorted out  
7 based upon a couple of interesting information  
8 pieces that you may find in them. And obviously,  
9 the reviews will be the most comprehensive one, but  
10 you will notice they are missing consumer-friendly  
11 information.  
12 Prescribing information, obviously intended  
13 for professional, will occasionally have a patient  
14 insert or a med guide that will cover some parts of  
15 consumer-friendly information. However, the  
16 snapshots, which will not be as comprehensive as  
17 the other two, which do not have, for example, the  
18 rationale for approval or the demographics of the  
19 whole development program, will definitely be  
20 consumer friendly, easy to read, and provide you  
21 with that information of who actually were the  
22 people that made the core of the database used for

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1 the approval of the new drugs.  
2 I'd like to thank you, and I will welcome  
3 your feedback.  
4 (Applause.)  
5 DR. WHYTE: So you know, all the slides are  
6 going to be available on the website as well. So  
7 those folks that are listening online will be able  
8 to find all the slides.  
9 Now, a couple of folks have asked me about  
10 the Wi-Fi password. I hope you're all being  
11 riveted by this and you're not trying to Google  
12 things online, but in case you need the Wi-Fi, it's  
13 the FDA public access -- no, FDA Public is the  
14 network that you would log onto, and the password  
15 is publicaccess, P-U-B-L-I-C-A-C-C-E-S-S, all lower  
16 caps, all lowercase, no spaces.  
17 That's because I've been eating candy and  
18 now have a sugar rush. Dr. Throckmorton mentioned  
19 there's candy in the back for the Rare Disease  
20 Program, so I encourage you to get some if you need  
21 your candy fix.  
22 So there are lots of ways to engage with the

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1 FDA and to engage with CDER, the Center for Drugs,  
2 and we're talking about this, that you can request  
3 meetings, you can send in e-mails, you can send in  
4 materials. And a lot of times, we'll talk about  
5 the docket. And those folks that are familiar with  
6 regulatory processes know that often when we're  
7 trying to solicit comments, a docket is open and  
8 people can send in their comments, and the comments  
9 are taken very seriously and are addressed.  
10 So it's my pleasure at this time to  
11 introduce John Wright, not to be confused with John  
12 Whyte -- a lot of people thought I was giving this  
13 talk and I misspelled my name, but I'm not.  
14 John is from the Division of Dockets  
15 Management in the commissioner's office, and he's  
16 going to talk about how do we rock the docket. And  
17 his fun fact is he is a woodworker and musician who  
18 enjoys building and playing his own electric bass  
19 guitar. And his son is quick to let him know what  
20 grooves and what doesn't.  
21 That dates us a little, doesn't it? Is that  
22 Earth, Wind, and Fire, "Let's Groove Tonight"? All

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1 right, John Wright.  
2 (Applause.)  
3 Presentation -- John Wright  
4 MR. WRIGHT: Good morning. Thank you, John.  
5 And, yes, my four-year-old does have fun with  
6 things. I like to make noise sometimes, and he's  
7 quick to remind me that if it doesn't sound like PJ  
8 Masks or some other wonderful show, it's not quite  
9 as fun.  
10 So what do we do at Dockets Management? We  
11 have taken on a role in the past many years that  
12 involves a lot of public contact. The public tries  
13 to reach the FDA in a number of ways, and Dockets  
14 Management is one of those avenues that allows  
15 people to ask us, to make regulations, change  
16 regulations, and things of that nature.  
17 We have, let's say, about 20 people in our  
18 office. It's not a large organization. However,  
19 we handle hundreds of thousands of contacts with  
20 the public every day. Now, we work for the Office  
21 of the Commissioner. Many people are under the  
22 impression that Dockets Management works for CDER

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1 because CDER is very large. And don't get me  
2 wrong. We do a great deal of our work for CDER.  
3 However, we serve the entire FDA, which means we  
4 have 15,000 clients, the 20 of us or so, 15,000  
5 internal, and external, private industry,  
6 individuals, and things of that nature.  
7 So we're fairly busy, and we actually handle  
8 drugs to laser beams. The FDA, I believe, manages  
9 or regulates almost one-quarter of every dollar  
10 spent in the United States. So you can imagine  
11 that we touch a lot of interesting things.  
12 Now, we have three teams that handle  
13 somewhat discrete tasks, although there is a lot of  
14 overlap. The team I'm on is the Administrative  
15 Proceedings and Management Team. Our supervisor is  
16 sitting over here, Dynna Bigby.  
17 What we do is we process Federal Register  
18 entries, which means if the agency wishes to tell  
19 the public or industry something and they want to  
20 publish it in the Federal Register, they'll come to  
21 us. And once they've begun drafting, they'll have  
22 us open up a docket number.

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1 That docket will then hold all of the  
2 associated documents that go with that  
3 announcement. That includes many, many, many  
4 public comments in some cases to those dockets.  
5 Now, a petition to the government is one of  
6 those things that -- of course, those of you who  
7 recall civics know that is one of the rights of  
8 organizations and citizens, to petition their  
9 government for redress, or questions, or that sort  
10 of thing, and Dockets Management is the part of the  
11 FDA that makes that a reality.  
12 We have certain rules and regulations, of  
13 course, that state how these petitions need to look  
14 and what you need to include in them. We are  
15 extremely responsive to individuals and industry  
16 wishing to do this.  
17 I have spent untold hours on the phone, or  
18 via Jabber, or any other technological methods,  
19 spoken with citizens, and walked them through this  
20 process, because oftentimes, the people attempting  
21 to address our agency and our government are  
22 individual citizens. At some point, they may be

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1 desperate. They may not have a lot of avenues. So  
2 they approach us, and we will talk them through the  
3 process and ensure that they are heard.  
4 That's one of the key things about Dockets  
5 Management. We are extremely responsive to the  
6 public. We are not the red tape that some people  
7 complain about the government being.  
8 We also handle comment management. Now,  
9 what that means is when there is a docket or a  
10 citizen petition opened, or a regulation that's  
11 pending, the FDA wants to have some input from the  
12 public. What do you think this regulation is going  
13 to do about your industry, your company, or your  
14 interests?  
15 Now, occasionally, the public will comment  
16 electronically. Industry may also comment, and  
17 some of these comments can be quite extensive. For  
18 example, they include things, studies, thousands  
19 upon thousands of pages long, to a simple opinion,  
20 "I don't think this is a good idea." They can be  
21 just about anything.  
22 When they arrive at Dockets, what we'll do

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1 is we'll collect them and collate them, and make  
2 sure that the decision-makers have a good idea of  
3 what the public and the industry believes is  
4 important about any pending regulations or matters  
5 they're interested in.  
6 Also, we do records, and administrative  
7 decisions, and things like that. Dockets  
8 Management, as a part of the Office of the  
9 Commissioner and under the Offices of the Executive  
10 Secretary, carries records of every administrative  
11 decision made by the agency, going way back, all  
12 the way to the 1950s.  
13 Now, what that means is if the government  
14 has made a decision about it, it involves food or  
15 drugs, and that decision was based upon a  
16 regulation promulgated before the decision was  
17 made, it means it's likely an administrative  
18 decision. It doesn't involve a great deal of  
19 research. It just involves looking at the  
20 regulations.  
21 If that is the case, Dockets Management has  
22 the records. We know what happened. We know how

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1 to find it. So what will frequently happen is you  
2 may have a situation in your organization or your  
3 industry where you want to, say, make a new  
4 product. And you want to say, "FDA, have you done  
5 anything like this before? Have you made any  
6 decisions? And if so, what were they based upon?"  
7 You can do research, and you can find out,  
8 and you can say, "Dockets Management, the FDA made  
9 this decision 30 years ago. I want everything you  
10 have," and you can put in a FOIA request or you can  
11 come and visit us, and we will get you all of those  
12 records. Very little of what we hold is  
13 restricted, so you can have just about everything  
14 that we have.  
15 So as you see the rule of thumb here, if you  
16 see it in the Federal Register and it has a docket  
17 number, we probably have a copy. Please reach out  
18 to us if you'd like to read it. Many people come  
19 to us when it's far too late and they're  
20 frustrated. By that point, they're like, help, and  
21 so we can help. We've got the records.  
22 You'll notice I say most records requests

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1 are handled very quickly. Under the FOIA Act, we  
2 have 20 days to respond. Those of you with  
3 experience getting information from the government  
4 understand that it most likely takes a lot longer  
5 than that. I'm happy to report to you that, in  
6 Dockets, it usually takes a lot less than 20 days.  
7 Now, I did talk about citizen petitions.  
8 One of the things that is very common and that is a  
9 regular occurrence with respect to CDER, and one of  
10 the things we do at CDER, are abbreviated drug  
11 applications, over-the-counter drugs.  
12 These things are usually decided on an  
13 administrative basis. They don't involve that you  
14 submit compounds, et cetera, et cetera to  
15 scientists to get analyzed. These decisions can be  
16 made based upon the regulations and rules at hand.  
17 And when that happens, it comes through us.  
18 Our role is purely administrative. We are  
19 not going to get your petition and tell you, "We  
20 think this will work," or, "No. This can't  
21 possibly work." We will never do that. What we  
22 will do is we'll say, "You know, it's missing a

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1 piece. This is what you need to add. You need to  
2 say something about the environment," things like  
3 that. We'll tell you what has to be in the  
4 petition. In fact, in most cases, we'll tell you  
5 exactly what it needs to say.  
6 So always, just call us if you have any  
7 questions. We will guide you through it.  
8 These are the regulations that cover  
9 submissions to Dockets Management. These are most  
10 of them, 10.20 and 10.30. These cover general  
11 submissions as well as citizen petitions, and there  
12 are many associated regulations the more specific  
13 your submissions get. However, by the time you  
14 need to make any submission, you're encouraged just  
15 to call us, and we will tell you what applies and  
16 how to make sure you comply with it.  
17 As I said, there are some content  
18 requirements, and I mentioned, say, for example,  
19 the economic impact on a citizen petition. Many  
20 people will look at the petition requirements and  
21 go, "Oh no. I don't know how my petition is going  
22 to impact the economy," and if you call me, I'll

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1 quickly tell you not to worry. All you need to do  
2 is put a sentence in there, saying, "I'll tell the  
3 Commissioner if the Commissioner asks," and then  
4 you're done. So it's not that bad. And it's  
5 important just to call us if you have any  
6 questions.  
7 Now, we did talk about comment management,  
8 and the one thing I want to stress is that comments  
9 do take a little while to get posted. Some people  
10 will comment, and that day, that afternoon, they'll  
11 call me and they'll say, "John, I didn't see my  
12 comment on the internet. Are you censoring?" And  
13 I'll say, "No. We don't have the manpower to  
14 actually censor," and we don't. We're just a  
15 little slow.  
16 We get 100,000 of these, and there are maybe  
17 five or six people doing this at a time, so it  
18 occasionally takes a little while. It's not a  
19 conspiracy. So please don't be afraid to comment.  
20 Every single one is read.  
21 Help. We hear this one a lot. Where do you  
22 go if you need help? Here's the most important

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1 thing. Pull out your cameras, get the recording  
2 because you can have our phone number. This is not  
3 at all typical of the government. But here we are.  
4 Here's our phone number and our e-mail addresses.  
5 I encourage you to speak with us whenever you have  
6 any questions.  
7 There is also a web address there for a  
8 SharePoint site. That site is a fantastic little  
9 snapshot of what Dockets Management does. Dynna  
10 put together that snapshot some time ago, and it  
11 has come in very, very handy. Whenever people have  
12 questions, we can just send them over there and  
13 tell them to share it.  
14 So if you'd like, you can check out that  
15 website. If you have any problems, or questions,  
16 or comments, please don't hesitate to contact us.  
17 Those are our direct office phone numbers, and we  
18 do endeavor to get back to everybody within 24  
19 hours or less.  
20 Do you have any questions? I may have  
21 answers.  
22 (No response.)

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1 MR. WRIGHT: None? Okay. Well, Happy  
2 Friday, everybody, and it was wonderful speaking to  
3 you.  
4 (Applause.)  
5 Questions and Answers  
6 DR. WHYTE: I think we're going to see if  
7 folks have any questions on the last couple  
8 speakers. And I learned a lot, John. I didn't  
9 know we use Jabber, so I'll have to look that up,  
10 as well as I could come visit you to go find  
11 comments. I'll have to figure out where you are.  
12 But I thought the issue of making comments  
13 is something that folks that are especially new to  
14 engagement with the agency don't think about. And  
15 it's really something that you want to consider as  
16 one of the ways to interact with the agency,  
17 because as John referenced, they are read, and they  
18 are acted upon. And that's one opportunity to  
19 engage.  
20 You want to think of numerous tools and  
21 resources that you can use to get your point  
22 across. So it really is a very, very important

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1 tool. And many folks at the agency aren't always  
2 aware of it and understand it, so it's an important  
3 point.  
4 I do want to remind folks that if you want  
5 lunch -- and I hope you want lunch -- we cannot  
6 provide lunch for you. But you can purchase lunch  
7 at the kiosk right outside where you registered.  
8 And you should do that during the break that we're  
9 about to take because access to the cafeteria is  
10 often restricted, so it's something to think about  
11 if you want to buy lunch. Remember, I told you  
12 there is a race going on, so there are some road  
13 closures that are starting very soon for a couple  
14 of hours.  
15 So if folks have any questions, please come  
16 to the mic. Any questions?  
17 While someone is coming to the mic -- or she  
18 may be going to the bathroom -- remember, we're  
19 going to play Jeopardy, and that's going to be fun.  
20 So you're going to think about teams.  
21 I think we're going to have four teams. Is  
22 that right? I'm looking at folks. Four teams. So

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1 there are going to be four teams, and you can pick  
2 four or five people to be on your team. So make  
3 some friends, come with new people because, after  
4 the break, we're going to want sign-up, so who are  
5 the teams going to be.  
6 So question? Hi.  
7 MS. SANTIAGO: Hi. I'm Kristen Santiago  
8 with the cancer support community. And I was just  
9 curious, for the drug trial snapshots, are those  
10 only for approved products? And then how is it  
11 chosen which ones are up there and how long do they  
12 stay up there for?  
13 DR. LOLIC: Thank you for your question. As  
14 of now, drug trial snapshots are only done for new  
15 molecular entities, meaning a new molecule for the  
16 first time approved in the United States,  
17 regardless of the indication.  
18 Once they are published, they're available  
19 until, hopefully in the near future, we expand it  
20 to perhaps adding efficacy supplements or some new  
21 data on the initial approval. But as of now, new  
22 molecular entities within 30 days of approval, and

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1 they remain on the website to be seen.  
2 DR. WHYTE: Question in the back?  
3 FEMALE AUDIENCE MEMBER: I didn't hear the  
4 question.  
5 DR. WHYTE: Sure. So the question was about  
6 the drug trial snapshots, and were they for every  
7 drug, and how long will they stay on.  
8 Milena mentioned they're for all new  
9 molecular entities, which are new molecules. So  
10 it's not for all drugs that are approved. And it's  
11 only for drugs that are approved. It's not for any  
12 information relating to drugs that are not  
13 approved.  
14 Once it is online -- and our goal -- and  
15 Milena has been excellent in doing this -- is,  
16 within 30 days of approval, we try to get that  
17 information online. And you can sign up to get a  
18 notification that a new one has been posted.  
19 We really do encourage you to look at those.  
20 Dr. Woodcock has been a champion of transparency,  
21 of who's enrolled in a clinical trial, particularly  
22 based on sex, race, and age, and are there any

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1 differences based on that demographic information.  
2       It's one more piece of information. It's  
3 not meant, as Milena talked about, to replace the  
4 drug label, but it is important information for  
5 patient groups as they are thinking about advocacy,  
6 safety, and efficacy, and we are very receptive to  
7 comments.  
8       I think something you'll find that  
9 Dr. Woodcock is really trying to create at the  
10 center is to have this true two-way engagement,  
11 which is separate from communication. So  
12 historically, as Dr. Throckmorton had talked about,  
13 it's really been pushing information out. When we  
14 want you to know something, we push the information  
15 out to you.  
16       But how do we bring information back to the  
17 center, back to our officials to understand what  
18 patients are thinking, what is clinically  
19 meaningful to patients? We're going to hear about  
20 that in a little while, but really wanted to  
21 emphasize that. And that's why we want to have a  
22 lot of dialogue today. We want you to meet folks,

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1 meet members of CDER, meet members of our team.  
2       So if there are any more questions, we're  
3 happy to entertain them.  
4       MALE AUDIENCE MEMBER: One quick question,  
5 and it's for John Wright, and it has to do  
6 with -- I just want to kind of clarify.  
7       So if I wanted to ask for access to specific  
8 information in the Federal Register, I'm not going  
9 to necessarily just contact you and say, "Can you  
10 give me everything on drug X?" Instead, I would  
11 say, "I see this in the Federal Register. Can you  
12 give me what you have on that?"  
13       Is that kind of how it works?  
14       MR. WRIGHT: It depends on the drug that  
15 you're asking about. Typically, Dockets Management  
16 will have the records on every approval that is not  
17 a new drug approval. In other words, if the  
18 approval of that compound, device, drug, laser  
19 beam, is based upon the regulations and it's not  
20 novel, we will have the records.  
21       If it's novel, it's a new drug, it's a new  
22 chemical, or something like that, then those

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1 records will belong at the center where it's  
2 originally approved.  
3       The exception to that are discussions that  
4 happen in advisory committees. Different advisory  
5 committees will discuss different drugs, compounds,  
6 devices, things of that nature, and we do maintain  
7 advisory committee records and many of the  
8 materials that are submitted to the advisory  
9 committees for discussion.  
10       In those cases, we can usually get those  
11 records or we can refer you to the people,  
12 organizations that hold them. But in pretty much  
13 every case, if we don't have it, we're going to  
14 tell you how to get it. So we're still a good  
15 resource.  
16       MALE AUDIENCE MEMBER: Thank you.  
17       MR. WRIGHT: You're welcome.  
18       DR. WHYTE: Okay. Anything else? All  
19 right. It is roughly almost -- sure. Got in at  
20 the last minute. Hopefully that mic will work.  
21       FEMALE AUDIENCE MEMBER: So I have a couple  
22 of questions representing my table --

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1       DR. WHYTE: A couple? Okay.  
2       FEMALE AUDIENCE MEMBER -- so I'll try to  
3 consolidate. So four dockets, mainly, so two  
4 questions.  
5       When you're talking about pushing  
6 information out, when a docket is created or  
7 opportunities for comments come up, is it out of  
8 your office that this happens? What are the ways  
9 that the information is pushed out? Is it just  
10 through the Federal Register?  
11       I know we've seen it in the patient  
12 newsletter, and there's an FDA guidance documents  
13 website, but are there other avenues where we would  
14 see the information other than just going to the  
15 dockets page or to the Federal Register? That's  
16 question one.  
17       The second question is, when there are  
18 updates, when extensions are given to comments, I  
19 know for me it's sometimes difficult to learn when  
20 those extensions have happened, and what that new  
21 date is, and where that information can be more  
22 easily accessible, and quickly, because the Federal

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1 Register is very slow in updating that information.  
2 MR. WRIGHT: Thank you very much for your  
3 questions. Excellent questions. The first one,  
4 how do we let the public know things, is all of  
5 those.  
6 Let's take CDER for example. CDER has a  
7 very good website. They have a lot of information  
8 available there. That's going to be one location.  
9 Typically, they will also have subsites for any  
10 particular programs that are happening related to a  
11 specific issue.  
12 Now, the role of dockets in public  
13 information is very, very specific in that we  
14 manage the database that is reflected in  
15 regulations.gov. So if you go to regulations.gov  
16 to look things up, what you're seeing is the  
17 product of Dockets Management. So everything in  
18 our database is reflected on regulations.gov, and  
19 that is how most of our information gets to the  
20 public.  
21 The Federal Register often will have  
22 information contemporaneous with us. It'll all

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1 for this, but some of the most critical is we  
2 cannot confer competitive advantage to anybody. We  
3 wouldn't know how, and we wouldn't want to get in  
4 trouble. So we're very careful about that. We  
5 release things when they're supposed to be out. So  
6 there's not necessarily an intelligence advantage  
7 to anything we release other than older records.  
8 Does that answer your question adequately?  
9 FEMALE AUDIENCE MEMBER: Yes.  
10 DR. WHYTE: I think it is a good point. And  
11 something that Dr. Woodcock wants us to think about  
12 is how do you find out about things if you're not  
13 already in the know. In many ways, we always talk  
14 about the Federal Register notice and, prior to me  
15 coming to government, I did not know what the  
16 Federal Register notice was or how it works.  
17 So how do you even find out that there is a  
18 request for information if you're not part of that  
19 loop, so to speak? And I'd be very  
20 interested -- and I know my team would as  
21 well -- in figuring out ways how do we do that.  
22 And we've explored ways. Would we create a central

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1 happen at the same time. Oftentimes, we won't know  
2 until we get a Federal Register feed. That said,  
3 however, you can always call us and find out.  
4 Also, if you are watching a particular  
5 approval go through the works, we are not actually  
6 going to be able to provide any information until a  
7 decision has been made or a public status has been  
8 issued. When that occurs, it will go on  
9 regulations.gov, and we will get the information  
10 after the fact.  
11 But those are the primary avenues. We don't  
12 actually issue things like press releases out of  
13 dockets. We just make sure that the information we  
14 do put out is pretty consistent in there. I  
15 recommend that most people actually bookmark  
16 regulations.gov. When they have a docket of  
17 interest, go to regulations.gov, find it, and  
18 bookmark it because, when it does have changes,  
19 like your second question about updates, those  
20 updates, we put in regulations.gov as we get them.  
21 We also can't tell you before that update is  
22 made until it's made. There are many, many reasons

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1 site somewhere on CDER that might be of particular  
2 interest to patients during the time that we're  
3 allowed to do it?  
4 So that's a fair point because as part of  
5 engagement, it's really about partnerships. And  
6 there is a recognition, especially in the center  
7 director's office, that everyone doesn't come to  
8 our website for information and that the website is  
9 very hard to navigate. That's just the reality of  
10 it.  
11 So how do we work with partners, and who are  
12 those partners? And how do we effectively engage  
13 with them? And this is still very new to the  
14 center. So we want to hear from you. And other  
15 folks have expressed it when there are meetings.  
16 Could there be a central site for all the patient-  
17 focused drug development meetings, whether they're  
18 internal or external?  
19 We're still trying to think through those  
20 processes, but would be very interested if you have  
21 ideas to tell us how to do that, recognizing that  
22 no one size fits all, but if we truly want to

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1 engage, we don't want to just preach to the choir,  
2 so to speak, to those groups that already know how  
3 to manage it well. We want to educate those folks  
4 who have a perspective, and have an opinion, and  
5 don't have a large regulatory staff, or don't have  
6 a big team that can figure all this stuff out.  
7 So that's part of today's meeting as well,  
8 to educate us about how we're going to find out  
9 about things. So the docket is a great way to  
10 communicate. But if you don't know about it and  
11 you can't figure it out, how does that help get  
12 your voice heard? So those are things we want to  
13 hear about.  
14 Other questions?  
15 (No response.)  
16 DR. WHYTE: I saw a hand. Okay. So I'll  
17 try it again.  
18 So it is now 10:15. How about we take a  
19 15-minute break, order lunch if you like, create  
20 your Jeopardy team, and we'll reconvene a little  
21 early, and maybe we'll get out early today. We'll  
22 reconvene at 10:30. Thank you.

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1 (Whereupon, at 10:14 a.m., a recess was  
2 taken.)  
3 DR. WHYTE: We can come back in. We're  
4 going to get started. We're starting a little  
5 late, but I know people wanted to order lunch, so I  
6 encourage you to come back in. And hopefully,  
7 you've ordered lunch and you've started to think  
8 about your Jeopardy team.  
9 Now, we're going to talk about -- the  
10 government likes to measure things. And one of the  
11 things, as we think about patient engagement and  
12 measuring what's clinically meaningful to patients,  
13 is really trying to think through, how do we  
14 measure how patients feel and function.  
15 All of them talk about, and Dr. Woodcock  
16 does as well, that when we work with patient groups  
17 and engage with patients, we really need to  
18 understand what is clinically meaningful to  
19 patients.  
20 We may choose a measure that is a 6-minute  
21 walk test. And you may say, "Well, you know what,  
22 Dr. Whyte? That's not important," even though

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1 that's objective, and that's reproducible, and  
2 there's some question about all of that, but what  
3 I'm really interested in is upper strength mobility  
4 because I want to be able to change myself. I want  
5 to be able to feed myself.  
6 We may have a measure in migraine that it's  
7 complete resolution of headaches, and you may say,  
8 from learning, from talking to all of you that you  
9 know what? I don't have to have complete  
10 resolution of my headache, but I need to be able to  
11 get to a certain level of functioning.  
12 That's important for us to hear as we think  
13 about changing what are those endpoints. And the  
14 only way we can effectively do that is to engage  
15 with patients and talk to patients. And that is a  
16 process that continues to iterate.  
17 So at this point, I'm going to introduce  
18 Michelle Campbell. And her fun fact is, she  
19 completed a bucket-list item recently and saw the  
20 Northern Lights in Norway earlier this year.  
21 So how many of you have been to Norway? How  
22 many have been to Nebraska? We have a very metro

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1 D.C. area I think here, but it's my pleasure to  
2 introduce Michelle.  
3 (Applause.)  
4 Presentation – Michelle Campbell, PhD  
5 DR. CAMPBELL: Good morning, everyone. My  
6 name is, as John said, Michelle Campbell, and I am  
7 part of the clinical outcome assessment staff, and  
8 we are based in the Office of New Drugs.  
9 This is the group that we look at outcome  
10 assessments that are used in clinical trials, and  
11 we also manage something called a Clinical Outcome  
12 Assessment Drug Development Tool Qualification  
13 Program.  
14 We're a group of multidisciplinary  
15 scientists, physicians, and pharmacists that are  
16 looking at outcome assessments and really looking  
17 to see is it measuring what's important to patients  
18 and how is it, and is it appropriate to be used.  
19 And I'm going to talk to you about what we do, and  
20 how we look at measurements, and what we need  
21 today.  
22 Here's my proof that I did go see the



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1 Northern Lights in Norway, and as always, our  
2 standard disclaimer statements.  
3 We're really in this new area of patient  
4 empowerment. About two years ago in the same room,  
5 Dr. Woodcock made a statement that says that  
6 patients are their experts. They are experts on  
7 their diseases and what's important to them, and  
8 that we really need to listen to our patients, and  
9 talk to them, and let them educate us, and help us  
10 in determining what's important to them.  
11 So this has been a real good push that we're  
12 seeing the last couple years of how we involve  
13 patients. Today, we see the increasing role of  
14 patient groups. You see vast uses of communication  
15 through social media, and we're seeing a lot of  
16 multi-stakeholder collaborations. And this could  
17 be through patient advocacy groups, with industry,  
18 with academia, or with other groups coming  
19 together, and working together, and trying to  
20 evaluate what's important to patients.  
21 The science of patient input is a high  
22 priority for us, so we are very much interested on

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1 how we can capture what's important to patients.  
2 We know that it takes a village, that  
3 patients, not only are experts, but they're not  
4 necessarily an expert in clinical trial design, or  
5 instrument developments, or another term for an  
6 instrument might be a survey.  
7 So they may not be experts in that, but they  
8 do play a key role. So what we need to do is that  
9 we need to pull all those pieces together to form  
10 that village and help create something that will  
11 work.  
12 Some of you may be aware of FDA's  
13 Patient-Focused Drug Development initiative. And  
14 this is where patients are able to inform us on  
15 what's important to them. What this allows -- we  
16 call it PFDD -- is a more systematic way of  
17 gathering the patient perspective.  
18 My colleague, Pujita Vaidya, will be  
19 presenting later, and will be speaking a little bit  
20 about the patient-focused drug development, but  
21 this first was initiated under the Prescription  
22 Drug User Fee Act V. And during that time, the FDA

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1 said they would grant 20 meetings in various  
2 disease areas. And we can say that we actually  
3 will be having 24 by the end of this fiscal year.  
4 You can see what's been covered, a whole  
5 range. Some of these have occurred with our other  
6 center, CBER, which is in biologics. Actually,  
7 last Friday, we had one on autism here in this  
8 room.  
9 So why are these meetings important? First,  
10 we get to hear from patients directly. These  
11 meetings bring together various CDER stakeholders  
12 and people from the Office of New Drugs, so  
13 reviewers from prospective disease in therapeutic  
14 areas. And it really helps us learn what's  
15 important to patients.  
16 It also helps maybe identify areas of unmet  
17 needs and gaps and helps us identify what might be  
18 some potential outcomes to explore.  
19 There is some external interest now, and  
20 we're seeing more interest in what we're calling  
21 externally-led PFDD meetings because we know  
22 there's 300,000 diseases. We just can't hit them

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1 all. So there's a big push to see we can have  
2 these externally-led PFDD meetings, and I know  
3 Pujita will be highlighting this later on this  
4 afternoon, or this morning, I should say. But this  
5 is really a way for us to continue to learn about  
6 new disease areas and what's important to patients.  
7 One highlight that comes out of our PFDD  
8 meetings held here at the agency is a report called  
9 the Voice of the Patient, and it summarizes what  
10 was spoken at these PFDD meetings.  
11 These are really critical reports that we  
12 receive back from these meetings. We use these.  
13 So in reviewing a specific disease area and we know  
14 there's been a PFDD meeting -- I know I personally  
15 have -- we'll go back and sometimes read the  
16 reports to refresh our memories to really make sure  
17 that what we're seeing and what we're reviewing is  
18 really accurately reflecting what's important to  
19 patients. So we are utilizing these reports.  
20 We need to be able to bridge from patient  
21 input to patient-focused clinical trial endpoints,  
22 and that's where our group comes in at the FDA to

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1 help with that.

2 We wanted to find something called clinical  
3 benefit. And what that is, it's a positively  
4 clinically meaningful effect of an intervention.  
5 So how does it positively affect how a patient  
6 feels, functions, or survives?

7 Survival I think we all agree that's simple  
8 to determine, but feels and functions is a little  
9 bit different. So we need to understand from our  
10 patient input how to select the appropriate  
11 clinical outcome assessment to achieve this.

12 What we're going to be looking at is either  
13 did we decrease maybe symptom severity in a  
14 patient, in our population -- and what we're  
15 looking for is how can we measure this clinical  
16 benefit. We want to be able to describe this in  
17 labeling terms that outcome of interest measured,  
18 and we want to make sure that this isn't  
19 misleading.

20 So we really want to make sure that we're  
21 accurately capturing what is important to patients,  
22 and it's really capturing what the mechanism of the

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1 drug is really doing.

2 There are four types of clinical outcome  
3 assessments that we focus on in our group. The  
4 first are probably the most common type. They're  
5 called patient-reported outcomes, and it comes  
6 directly from patients. So patients, as you were  
7 all patients, think about yourself, and you know  
8 your signs and symptoms and when you may be  
9 feeling, coming down -- just say, right now it's  
10 allergy season. If you grew up in Maryland or live  
11 in Maryland, we're all feeling this.

12 So we probably all know when we think, oh,  
13 is this allergies, or is this something else? We  
14 can self-report, and that is the best way if we can  
15 actually accurate self-report, a patient can.

16 We have clinician-reported outcomes, and  
17 this is, as they say, where we're using clinicians  
18 to report outcomes of symptoms from patients and  
19 from patient experiences, because we understand  
20 there are some diseases where patients may not be  
21 able to accurately self-report, and we need to  
22 still rely on our clinicians.

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1 We have observer-reported outcomes. We see  
2 this often in patients, again, who may not be able  
3 to self-report, so maybe in our pediatric  
4 populations. So we're looking at observable  
5 behaviors or symptoms that we can observe, so that  
6 a parent can see and report.

7 Then we have our performance outcome  
8 measures, which would be your 6-minute walk as an  
9 example. And a lot of times, people lump all of  
10 those clinical outcome assessments and just use the  
11 term PROs. But really, we are looking at four very  
12 different things.

13 A PRO is a measurement-based report that  
14 comes directly from the patients. These are some  
15 examples such as pain intensity, seizure episodes,  
16 asthma symptoms, rescue medication use. It's an  
17 umbrella term as I said. PROs span the gamut from  
18 simple instruments such as a single-pain  
19 assessment, what is my worst pain in the last  
20 24 hours, to perhaps complex health-related,  
21 quality-of-life measures, or broader things.

22 At the FDA -- and you'll probably be hearing

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1 this a couple times today -- we have to uphold laws  
2 and regulations. And within these regulations and  
3 standards for assessments, like patient  
4 questionnaires, patient-reported outcomes, clinical  
5 outcome assessments, they require methods of  
6 assessments of subjects' response to what we call  
7 well-defined and reliable.

8 Thus, we want to describe findings from  
9 these assessments in labeling those statements that  
10 are not potentially false or misleading. So not  
11 only do we recommend drug sponsors and patient  
12 groups to engage with patients to develop these  
13 clinical outcome assessments using qualitative  
14 research -- focus group interviews, concept  
15 solicitation, one-on-one talks -- we also recommend  
16 that they perform appropriate quantitative research  
17 or statistical testing of these instruments that  
18 also helps us define and look at is this instrument  
19 well-defined and reliable.

20 Together, with both talking with patients  
21 through qualitative research and statistical  
22 testing through quantitative work, it tells us

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1 whether patients can understand and respond to the  
2 intent of these questionnaires.  
3 That's really important because what we want  
4 to know is that not only do we understand the  
5 questions, and not only are they important to  
6 patients, but can you understand. Do the response  
7 options make sense? Do they really capture what a  
8 patient feels every day?  
9 So this is really important because, in the  
10 end, as John mentioned, we want to know if it's  
11 meaningful. So we need to make sure that even  
12 instructions and directions on an instrument make  
13 sense, that a patient will be able to complete over  
14 the course of a clinical trial.  
15 These instruments and questionnaires provide  
16 an estimate of what is meaningful change or  
17 meaningful improvement. That's why it's really  
18 important to get your patients involved early to  
19 determine how to interpret meaningful change in  
20 improvement in the questionnaire.  
21 That's a key word, is how do we interpret  
22 the results from these questionnaires, and, two, is

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1 it meaningful? We encourage early and often  
2 communications with our industry sponsors to come  
3 and talk to us about development of clinical  
4 outcome assessments, so we can help provide  
5 guidance and advice, I should say, on what they may  
6 need and things to consider.  
7 As always, we do have a guidance available.  
8 In 2009, the agency published a guidance on how to  
9 interpret these regulations for PRO measures and  
10 intended to provide advice for clinical benefit.  
11 Many of these principles described in this guidance  
12 also fits in those other clinical outcome  
13 assessments such as observer-reported outcomes and  
14 clinician-reported outcomes.  
15 What this does is this provides an optimal  
16 approach for patient-reported outcome developments.  
17 But we do note that in promoting increased patient-  
18 focused drug development, we need to exert some  
19 flexibility to meet the challenges of drug  
20 development.  
21 It's important to recognize that these  
22 recommendations contained in the guidance represent

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1 one approach, but other approaches may be  
2 considered. And that's why we encourage early  
3 communication with the agency to talk about that,  
4 because we do recognize in some of our disease  
5 areas and drug development areas that we do need  
6 flexibility, and one example would be in some of  
7 our rare disease areas.  
8 So why is all of this important? Why do we  
9 care? Because what we really want is we want to go  
10 from a clinical outcome assessment to a clinical  
11 trial endpoint. Your assessment is not necessarily  
12 your endpoint, but it's going to help explain that  
13 endpoint.  
14 So what we do is we make sure that that  
15 clinical outcome assessment is being used in the  
16 correct population of the attendant, maybe  
17 treatment population, or we call the context abuse.  
18 What group are we really studying? What is the  
19 concept of interest or what exactly are we trying  
20 to measure? Is it symptom severity? Is it  
21 frequency of events?  
22 That's our interest. We want to make sure

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1 that we're capturing that correctly with our  
2 outcome assessment.  
3 Finally, can we see a clinical benefit? Is  
4 the instrument sensitive enough to detect change?  
5 We want to make sure that we're able to see if  
6 there was improvement from a drug, that we were  
7 able to capture that correctly. And ultimately, if  
8 we have all of those in place, we can hopefully be  
9 able to form what an endpoint would be in a  
10 clinical trial.  
11 We face a challenge. We know that PROs are  
12 important in some diseases and that PROs may be the  
13 only direct way to assess a clinical benefit. So  
14 well-developed and fit-for-purpose instruments,  
15 however, may not exist for many diseases. So in  
16 some cases, well-developed outcome assessments may  
17 exist, but PROs are needed to provide the patient  
18 perspective to understand if, say, a small change  
19 of walking ability, as measured in a clinic, really  
20 makes a difference in patients' lives every day.  
21 I think that's really important, that we  
22 want to make sure that that change we see is

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1 important to patients and impacts their daily  
2 lives.  
3       So how do we handle this challenge of not  
4 having exactly what we need, but we know we need to  
5 develop a clinical outcome assessment? This is  
6 what we call our roadmap, ironically going with our  
7 title of our workshop today. We like our roadmaps  
8 here.  
9       But this is actually something that -- it's  
10 a lot to digest at this moment, so please don't  
11 take it all in. It is available on our website.  
12 But it's a roadmap to patient-focused outcome  
13 measurement, an approach, an optimal approach,  
14 really, and trying to develop and select an  
15 appropriate outcome assessment.  
16       So what is really important is when you're  
17 look at this roadmap, you see three columns. What  
18 we encourage is that people start from the  
19 beginning. The first column is understanding the  
20 disease or condition. And that's when we're going  
21 to really talk to our patients, talk to our  
22 clinical experts who may help establish that.

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1       So during this time, we're going to  
2 understand what is the natural history of the  
3 disease; what is the population; is there  
4 subpopulations within it; is there different  
5 severity levels; do these severity levels look  
6 different among that patient population; what are  
7 current treatment options; is there a treatment  
8 option.  
9       Then getting the caregiver, patients,  
10 clinician perspectives: what would be clinical  
11 benefit to them? What is the impact of the disease  
12 on their daily lives? So this is the opportunity  
13 through this qualitative work to have these  
14 discussions.  
15       As we move on in this roadmap, we wanted to  
16 identify, from learning from our patients, what is  
17 really an important concept that we may be able to  
18 measure that a drug may be able to mark a clinical  
19 benefit in. So we'll determine that.  
20       Then you want to define, again, that  
21 population you want to study, and then ultimately  
22 select what is the appropriate way to measure that.

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1 So is it something in pediatrics where we may have  
2 to look at something that's observable and use an  
3 observer-reported outcome, or is it something we  
4 can get direct patient response from?  
5       Then finally we have how do we select the  
6 appropriate measure. So sometimes we may be able  
7 to go to an existing instrument and just make minor  
8 modifications, and do that, or sometimes we have to  
9 start from scratch. So this lays out ways to  
10 approach that.  
11       We don't want this to be seen as a hurdle or  
12 barriers to instrument development and clinical  
13 outcomes assessment development, but it just really  
14 is that roadmap and maybe a framework to think  
15 about when approaching an appropriate selection of  
16 the desired outcome measure.  
17       This is just a quick example we showed one  
18 time for idiopathic pulmonary fibrosis to just kind  
19 of show the things and ideas to consider, so  
20 understanding the disease, what does that  
21 population demographics look like starting from  
22 that first column? Is there any therapeutic

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1 availability for treatments? What are the key  
2 symptoms?  
3       Then going through and just trying to find  
4 that, and just give a sense. This is just an  
5 example of one that you could use to help you in a  
6 disease area. And I think we've realized over  
7 time, as we talk about our roadmap, putting an  
8 example together of a disease kind of shows how one  
9 may be able to use them.  
10       We know that patients' input ultimately  
11 helps us, and it helps us here at the agency. It  
12 helps us determine what to measure, what is  
13 measured to provide evidence of that clinical  
14 benefit; how best to measure the concepts in a  
15 study; and what is meaningful improvement.  
16       Often when we are talking about instrument  
17 development and talking with our sponsors, we often  
18 say, well, what's important to patients? Go back  
19 and ask the patients. What was said in your  
20 qualitative work? We want patients to be thought  
21 about and asked early on what would be that  
22 meaningful change.

<p style="text-align: right;">Page 77</p> <p>1 Some ways that stakeholders can work with 2 the agency, to work with the agency and try to seek 3 advice on clinical outcome assessments, 4 development, and review, there are actually three 5 pathways. The first is to that traditional 6 IND/NDA/BLA pathway, and that is handled within 7 those programs specifically. 8 The second is through our drug development, 9 clinical outcome assessment qualification pathway. 10 And this is outside of the individual drug 11 development program. This is a voluntary program 12 that is meant to work in areas of unmet need for 13 development of clinical outcome assessments in a 14 pre-competitive fashion. 15 So we're looking at development of novel 16 instruments, perhaps. And the real goal of 17 qualification -- and it's important to emphasize 18 that a qualified instrument does not need to be 19 used in an individual drug development 20 program -- is that a qualified instrument, if an 21 instrument is qualified, can be used in multiple 22 drug development programs based on that specific</p>	<p style="text-align: right;">Page 79</p> <p>1 they participate. People from the Office of New 2 Drugs participate. 3 So different groups participate, and talk 4 about, and listen to ideas that patient advocacy 5 groups may have, other outside stakeholders may 6 have, and just kind of get in some early thinking 7 of this. Again, these are informal meetings, 8 they're non-binding, and they are outside the scope 9 of an individual drug development program. 10 So some just closing thoughts to think 11 about, the FDA encourages the development and 12 implementation of patient-focused clinical outcome 13 assessments in clinical trials to support drug 14 approvals and labeling claims. 15 As a reminder, and we cannot emphasize 16 enough, really, early patient input is critical in 17 the road of that development. And actually, in the 18 areas of unmet need, if we can get early 19 engagements and be done in a pre-competitive space 20 early, it's also beneficial. 21 The identification tools is just one aspect 22 of patient-focused drug development. The values of</p>
<p style="text-align: right;">Page 78</p> <p>1 population and targeted area of interest that 2 they're measuring. 3 So we like to say, based on its context of 4 use or population, and based on that concept of 5 interest or that targeted aspect we're measuring, 6 this instrument we feel can be used and is 7 sensitive to measure change, and we can use it in 8 multiple drug development programs. 9 So this is a growing program, and we work 10 with a variety of submitters from individual 11 academics to large consortia. And again, this is 12 voluntary and in the pre-competitive space. 13 The third way is through our critical path 14 innovation meetings program that has occurred 15 recently. Again, this is outside of individual 16 drug development programs, so these meetings are 17 really meant to be for early novel technologies, 18 methodologies that people may want to explore. 19 It's a non-binding meeting, so some high- 20 level thinking and inputs from various stakeholders 21 within CDER. Some of our colleagues here, who 22 you've been hearing from presenting, and from PASE,</p>	<p style="text-align: right;">Page 80</p> <p>1 patients' needs to drive the selection of these 2 outcome assessments is remembering who the ultimate 3 end user is, which is our patients. 4 We are continuing to learn best ways to 5 engage patients in drug development. And again, we 6 do encourage early communication, so to reach out 7 to us and have these early discussions and helping. 8 With that, I thank you. 9 (Applause.) 10 Questions and Answers 11 DR. WHYTE: Given the importance of this 12 topic, we wanted to make sure -- because you're 13 giving a lot of good information -- and again, the 14 slides will be available -- if folks had any 15 particular questions about this, Michelle has some 16 time to answer some questions now. 17 So if you have a question, please come to 18 the mic. There's one in the back, somebody that 19 works here. 20 Go ahead. Can you come to the mic? See, 21 even at FDA, we all don't know everything, so don't 22 feel bad.</p>

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1 FEMALE AUDIENCE MEMBER: I learned a lot.  
2 Thank you, Michelle.  
3 DR. CAMPBELL: You're welcome.  
4 FEMALE AUDIENCE MEMBER: My question was, I  
5 don't know if it's allowed, but I'm wondering if  
6 it's possible to share an example of, say, one  
7 example where the patient-reported outcome was  
8 useful in development, and why it worked out so  
9 well for the development plan, and maybe another  
10 example on how it led the whole development plan  
11 astray.  
12 DR. CAMPBELL: I probably can't get into the  
13 second part of that question, but I can give some  
14 examples that we have actually publicly talked  
15 about where patient-reported outcomes have made it  
16 to labeling and help support a labeling claim.  
17 One is Kybella. That did go to an advisory  
18 committee meeting. And that group worked closely  
19 with the clinical outcome assessment staff through  
20 their drug development program pathway in helping  
21 to develop what was needed to measure that endpoint  
22 of interest.

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1 So that is an example. And there was an AC  
2 meeting. So as we learned from Dockets Management,  
3 you can go back and actually see and learn about  
4 that. I do know that information is available  
5 because it did go to AC. But that's an example.  
6 There's an example that's talked about in  
7 oncology a lot with the drug Jakafi, had some  
8 labeling that was used, and that's an example they  
9 use a lot in oncology because there's some  
10 challenges in oncology and the use of clinical  
11 outcome assessments, just the nature of how their  
12 trial designs are.  
13 So those are two examples that we often hear  
14 about and can be used. So there are examples where  
15 there are successes. And I think there's probably  
16 a lot more successes than we know. And if you  
17 really think about it, a patient daily diary in  
18 essence is a patient-reported outcome, so it may  
19 not be specifically saying that it was used in a  
20 clinical outcome assessment, but one was probably  
21 used to meet what an endpoint was.  
22 Next question?

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1 MS. DUFF: Hi. Thanks. My name is Jocelyn  
2 Duff. I am here from a nonprofit organization  
3 called Cure CMT4J. This is a disease. It's an  
4 ultra-rare. It affects about 22 people worldwide,  
5 and my 11-year-old daughter is affected by this.  
6 It's very much like ALS. We just had our diagnosis  
7 about a year and a half ago.  
8 We started our foundation. We're in the  
9 very early process of this. So a lot of what we're  
10 talking about here today feels to me eons away.  
11 But I was intrigued by your comment in your slide  
12 with the critical path innovation meetings pathway  
13 and just wanting to hear you speak a little bit  
14 more about that if you could and who best to  
15 contact.  
16 DR. CAMPBELL: Sure.  
17 MS. DUFF: Right now, we're in preclinical  
18 trials and every day is a critical day with this  
19 disease. And so we're trying to really get all of  
20 our ducks in a row and make sure we're thinking  
21 about everything as we go forward towards a  
22 clinical trial.

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1 DR. CAMPBELL: Sure, not a problem. So the  
2 critical path innovation meetings are housed out of  
3 the Office of Translational Science. And actually  
4 I think you could probably Google critical path  
5 innovation meetings FDA, because I Google  
6 everything when I need to find something on the FDA  
7 site myself. But I know they have a really good  
8 website.  
9 So what they do is they lay out what they  
10 are, and they actually have the requester to submit  
11 to have a meeting. So a person explains what they  
12 are, kind of revamps what I said, that these are  
13 usually high level and novel.  
14 There's a request. And there's actually an  
15 e-mail address associated with that website. I  
16 feel like it's cpimrequest@fda, but don't quote me  
17 on that, but it's along the lines of that. But  
18 that is available. It's on their site.  
19 In the form that someone who's interested  
20 would submit, you'd list information, but you talk  
21 about maybe what your questions are to the agency,  
22 want to cover, maybe a little history of the

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1 disease, and then you submit your request.  
2 It is my understanding that the person, the  
3 project manager for that, reaches out and contacts.  
4 And what happens when those meetings happen is that  
5 the submitter really sets that agenda of the  
6 questions you want to ask the agency and presents  
7 slides, and really does a very informal  
8 presentation of the disease or depending on  
9 what -- so if it's a disease, for example, and you  
10 have questions about trial development, having that  
11 presented.  
12 These can be held in person or via  
13 teleconference. If they're in person, they're here  
14 on our campus here, but if not, we have groups that  
15 obviously cannot get to this area, and that we do  
16 have them via the Web.  
17 But there is a page that is available. Like  
18 I said, Google is our friend here, and I would  
19 encourage just looking for that. But they lay out  
20 exactly what you need, and the form is pretty  
21 clear. And they do have an e-mail address, and  
22 they're very good at responding to questions and

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1 the comments, and helping people navigate that  
2 system.  
3 Yes?  
4 MS. WHITING: Hi, my name is Grace Whiting.  
5 I'm with the National Alliance for Caregiving. And  
6 I wanted to know if you could touch a little bit  
7 more on observer-reported outcomes and what you  
8 view as the role of the family caregiver, whether  
9 it's a person who's a blood relative, or friend, or  
10 neighbor who's caring for someone, not just in  
11 pediatric and cognitively impaired patients, but in  
12 other populations as well.  
13 DR. CAMPBELL: Right. For an observer-  
14 reported outcome, we want it to be something,  
15 either behaviors or symptoms, that an outside  
16 observer other than the patient can report. An  
17 example we give is -- I know you said no children,  
18 but this is an example I think we can all  
19 understand is, is my child in pain?  
20 Pain is a really hard concept to measure,  
21 even if I was reporting it myself. So that is a  
22 really hard question if we ask an outside person to

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1 say is this child in pain.  
2 So that's an example of why we would say  
3 it's really hard to ask that question. What we  
4 might want to say is, are there behaviors that  
5 maybe a child makes or a person that may be  
6 associated. So that's why you want to learn these  
7 behaviors and things you can observe from the  
8 patient, so you'd be able to accurately report. So  
9 that would be a way in that development.  
10 We do rely on our caregivers or outside  
11 people -- depending on the trial again -- it's  
12 going to be very dependent on the specific disease  
13 of interest, and the course of the disease, and who  
14 may be the best primary reporter. You may have  
15 things where you have school-aged children, and  
16 actually the teacher may be the better reporter or  
17 something like that.  
18 So you have to really select, and that  
19 roadmap helps you determine who's actually the best  
20 reporter of those observable symptoms that someone  
21 may display. So there are areas where we  
22 definitely know that our caregivers are people who

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1 help assist to play an important role.  
2 It's always important, I think, having been  
3 on the other side, been in academia, so I was a  
4 researcher and having the same reporter every time.  
5 Designating who would be the primary reporter  
6 decreases some measurement error we'd be looking at  
7 to make sure we get something accurate. But we do  
8 discuss and try to identify who could be that best  
9 person, and again, it's going to be disease  
10 specific, I think.  
11 DR. WHYTE: Maybe one quick question. Sure.  
12 MS. WEST: Hi. I'm Melissa West. I'm with  
13 the Kidney Health Initiative, and it's a follow-up  
14 on that, which is -- and you mentioned symptoms.  
15 One in our community in particular is depression,  
16 and yet in some of our clinical settings, we have  
17 care teams who are observing, but obviously they're  
18 not the one reporting depression.  
19 Has depression ever been considered  
20 underneath an observer-reported outcome?  
21 DR. CAMPBELL: That's an interesting  
22 question, and let me find the best way to try to

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1 answer your question if I can. I would say, if  
2 we're looking at depression alone, I think it often  
3 is a mix between probably patients just knowing  
4 what the symptoms are and perhaps an observer or  
5 caregiver, so it could be a combination.  
6 So we do recognize that in some disease  
7 areas, it could be a multitude of input you're  
8 getting. So the more actual things you're getting  
9 kind of tells a better story. We have seen where  
10 you're getting multiple input available from  
11 different perspectives, not only the patient, but  
12 maybe a caregiver or clinician. Well, thank you  
13 much.  
14 DR. WHYTE: Thank you.  
15 So I'm delighted to introduce Mary Ghods,  
16 who is a pharmacist in PASE. And her fun fact is  
17 she is an impressionist oil painter. So I'll be  
18 looking forward to seeing those oil paintings next  
19 week. Mary is going to use those audience response  
20 questions, so you want to come up to the mic, Mary?  
21 Audience Response Questions - Mary Ghods  
22 MS. GHODS: Thank you, Dr. Whyte, for the

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1 introduction. I'm still a beginner, so no requests  
2 please.  
3 So now we have our second set of polling  
4 questions for the audience, so if you have your  
5 clickers handy, please, we'll begin. There will be  
6 four questions in this session.  
7 Our first question is who develops and test  
8 drug and biological products before they reach the  
9 public? Is it, A, FDA; B, physicians and  
10 healthcare systems; C, pharmaceutical companies; or  
11 D, all of the above?  
12 (Audience answers.)  
13 MS. GHODS: I think we have it locked in,  
14 and we'll show the responses. Well, the correct  
15 answer is, C, pharmaceutical companies. So maybe  
16 we could answer some questions on that if you have  
17 any questions on that later. Thank you.  
18 We'll move on to our second question. Among  
19 the world's preeminent regulatory organizations,  
20 which approves new drugs the fastest? Is it A,  
21 European Medicines Agency; B, is it the U.S. FDA;  
22 C, Health Canada; D, Japan's Pharmaceutical and

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1 Medical Device Agency; or E, Australia's  
2 Therapeutic Goods Administration?  
3 (Audience answers.)  
4 MS. GHODS: So as a hint, it may be where  
5 you are now.  
6 Very good, 86 percent of you got the correct  
7 answer, U.S. Food and Drug Administration. Thank  
8 you for your attention.  
9 All right. Our third question, what  
10 initiative did the FDA launch in 2013 to gain  
11 patient perspectives on specific diseases and their  
12 treatments through a series of patient meetings to  
13 better inform the drug review process?  
14 Is it, A, the Clear Path Initiative; B, the  
15 Safe Use Initiative; C, No Clinical Trial Left  
16 Behind Act; or D, patient-focused drug development,  
17 also known as PFDD?  
18 (Audience answers.)  
19 MS. GHODS: Ninety-five percent said  
20 patient-focused drug development, which is the  
21 correct answer. Very good. Thank you.  
22 Our last question is a true-false. Generic

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1 drugs are as safe and effective as the brand-name  
2 drugs. A, true; B, false?  
3 (Audience answers.)  
4 MS. GHODS: Very good, 89 percent responded  
5 with the right answer, true, generic drugs are as  
6 safe and effective as the name-brand drugs. Thank  
7 you very much for your time and attention.  
8 (Applause.)  
9 DR. WHYTE: I'm sure it was the Canadians  
10 here voting Health Canada as the quickest. So at  
11 this point, I'm delighted to introduce my good  
12 friend, Larry Bauer, from the Rare Diseases  
13 Program, who's going to talk about supporting rare  
14 disease drug development and CDER's Rare Diseases  
15 Program.  
16 We can pull Larry's picture up, because this  
17 is his fun fact. He once attended a music festival  
18 in the middle of the Sahara Desert, slept in  
19 nomads' tents, rode a camel, and was bit in a foot  
20 by a scorpion as part of the experience. And it  
21 was not on a recent United Airlines flight, so  
22 that's good to hear.



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1 (Laughter.)  
2 DR. WHYTE: But much of our work here really  
3 is in rare diseases when we hear from patient  
4 groups, and that makes sense because it's that  
5 sense of urgency and that need. And you have a  
6 great quote back there about how we often learn in  
7 medicine that we're taught not to think about  
8 zebras, which are unusual presentations of disease.  
9 But for millions of people every year, they are a  
10 zebra, and we need to really address how we  
11 effectively engage with those patients.  
12 So I'm waiting for Larry to come up. Maybe  
13 it's left to me. There are some links, Qs and As,  
14 and there we go. I could pretend that we got your  
15 picture on the -- but that's not.  
16 Larry is really one of the best champions  
17 here, and then there are several members of his  
18 team as well. And I think you'll enjoy hearing  
19 what he has to say. So Larry Bauer?  
20 (Applause.)  
21 Presentation – Larry Bauer  
22 MR. BAUER: Good morning, everyone. Thank

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1 you, John, and thanks to our colleagues in PASE for  
2 inviting me to participate in the conference today.  
3 As John mentioned, a lot of the work here at  
4 the FDA and a lot of the work you're doing is  
5 related to rare diseases. And at the break, I met  
6 several of you, and quite a few of you are already  
7 working in the rare disease space.  
8 So I'd like to tell you a little bit today  
9 about how at the FDA, and specifically within CDER,  
10 how do we support rare disease drug development.  
11 I have the typical disclosures. Just to go  
12 over the outline quickly, I'm going to talk a  
13 little bit and give you an overview of rare  
14 diseases and orphan drugs, talk about orphan drug  
15 development, talk about some of the special  
16 challenges that we see in rare pediatric diseases.  
17 Then I'd like to talk specifically about the  
18 Rare Diseases Program within CDER, which I am a  
19 part of, and then another topic I know of interest  
20 to people is the rare pediatric disease priority  
21 review vouchers.  
22 So what is a rare disease? Probably most of

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1 you know, it's defined by the Orphan Drug Act that  
2 was enacted in 1983 to help encourage drug  
3 development for rare diseases by incentivizing  
4 them. The Act defines a rare disease within the  
5 United States that affects less than 200,000  
6 people. These tend to be challenging drugs to  
7 develop because of the small numbers of patients  
8 that are eligible to enroll in clinical trials.  
9 They're a highly diverse group of orders.  
10 They affect almost every body system, and I know  
11 NIH especially has worked to identify the different  
12 diseases, and they've found over 7,000 rare  
13 diseases. Most are serious and most have unmet  
14 medical needs.  
15 So each disease individually is rare, but  
16 when you collectively put together all the people  
17 affected in the United States, it's around  
18 30 million people. So it's a significant public  
19 health issue in this country.  
20 Just a little bit about the Orphan Drug Act,  
21 as I said, it was enacted in 1983. And before it  
22 was passed, there were only about 10 drugs that had

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1 been approved for orphan diseases. And since then,  
2 we've approved over 500, well over 500 drugs.  
3 So just a little bit about orphan drug  
4 development, in many ways, orphan drug development  
5 is not that different than developing a drug for a  
6 common disease. When you want to study a drug in  
7 human beings, you still have to have a clinical  
8 investigation.  
9 These investigations are conducted under an  
10 IND, which is an investigational new drug  
11 application. What that is, when a company develops  
12 a new product and they'd like to test it in human  
13 beings, they have to submit a data package to the  
14 FDA with things about the animal testing that's  
15 been done to show that we have some idea that this  
16 is probably going to be safe to give to people,  
17 something about the drug quality, how is it  
18 developed, how do you know that the drug is a  
19 stable drug so it will always be the same drug  
20 given.  
21 Once the FDA receives the IND application,  
22 we have about 30 days -- not about, exactly 30 days

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1 to review it. And after 30 days, whether you hear  
2 from us or not -- if you don't hear from us, you  
3 can go ahead and use it, but otherwise, if there's  
4 anything that's questionable, we'll put the IND on  
5 hold until the issue is resolved.

6 An important note is that the Orphan Drug  
7 Act does not define a separate regulatory standard  
8 for rare diseases versus common diseases. The same  
9 level of effectiveness and safety has to be  
10 demonstrated for us to approve the drug.

11 Orphan drugs, the gold standard is two  
12 adequate and well-controlled trials with the drug,  
13 but oftentimes, for rare diseases, the populations  
14 are very small, so we sometimes accept one adequate  
15 and well-controlled trial with supporting evidence.

16 The FDA's required by law to exercise its  
17 scientific judgment to determine how much data and  
18 information it will take to ensure the safety and  
19 effectiveness, and we try to be as flexible as  
20 possible for rare diseases because we know of the  
21 challenges involved.

22 Now, most rare diseases, many of them,

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1 affect children. There are special issues in  
2 developing drugs for children, but especially for  
3 children with rare diseases. Many rare diseases  
4 have phenotypic diversity within a disorder, which  
5 means that the disease presents differently in  
6 different populations.

7 This sometimes is due to genetic subsets,  
8 that there's slightly a genetic slight difference  
9 that causes different forms of the disease to  
10 manifest. We're often lacking validated endpoints,  
11 outcome measures, biomarkers. They just haven't  
12 been developed yet. And oftentimes, there's no  
13 drug precedent.

14 So for many rare diseases, no drug has ever  
15 been developed, so the first time it comes to the  
16 FDA, that's the first time we're seeing something  
17 for this disease.

18 Also, when you're developing drugs for  
19 children, there are many ethical considerations for  
20 enrolling children in clinical trials. We have  
21 special concerns about protecting the safety and  
22 the innocence of children, and yet we want to

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1 develop safe and effective drugs for children, so  
2 you have to do clinical testing.

3 A couple of things, pediatric research  
4 studies should pose no more than minimal risk, and  
5 the risks need to be justified by the anticipated  
6 benefit. Another thing is that, especially when  
7 studying very small children, we need to rely on  
8 parents to consent and for the parents to  
9 understand what the risks are involved, and then  
10 they have to make a decision for their child. But  
11 then we also want the children to offer assent,  
12 which means just their verbalization or somehow  
13 communicating that they're willing to participate  
14 in the study.

15 Now I'd like to focus a little bit more on  
16 the Rare Diseases Program. This was a program  
17 started in CDER's Office of New Drugs. There was a  
18 need for a program to really focus on the issues  
19 related to rare diseases. It was formed in 2010,  
20 and our mission statement is that we try to  
21 facilitate, support, and accelerate the development  
22 of drug and biologic products for the treatment of

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1 patients with rare disorders.

2 A question we get a lot is what is the  
3 difference between the Office of Orphan Products  
4 Development and the Rare Diseases Program. These  
5 are the two kind of big rare disease groups at the  
6 FDA.

7 The Office of Orphan Products Development,  
8 or OOPD, they administer the Orphan Drug Act. So  
9 they work with orphan designations, orphan  
10 exclusivity, and they also have a grants program  
11 both for orphan grants as well as they just started  
12 recently a natural history grants program. They  
13 also work on rare pediatric devices and  
14 humanitarian use device program. Another thing,  
15 they work with rare disease stakeholders.

16 The Rare Disease Program, in contrast,  
17 really are not involved in orphan designation or  
18 the grants, but we communicate within CDER within  
19 the review divisions. We focus on complex  
20 regulatory requirements for INDs, NDAs, and BLAs.  
21 And we work to develop policies and procedures,  
22 including guidances related to rare disease drug

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1 development.

2 A couple areas where we overlap is that both

3 groups coordinate across the FDA centers and

4 offices. We have formed something here at the FDA

5 called a Rare Disease Council that has

6 representation from all the different centers and

7 different groups involved in rare diseases.

8 We work with outside stakeholders. Both

9 groups try to enhance the rare disease information

10 on the FDA website, and we meet together to talk

11 about that and develop the information, and we meet

12 together to work on policy issues.

13 This is the current staff in the Rare

14 Diseases Program. At our table in the back of the

15 room, you can meet the associate director for rare

16 diseases, Jonathan Goldsmith. Then there's five of

17 us, five additional employees that have different

18 roles and responsibilities within the group, and we

19 hope that this program continues to grow.

20 Some of the projects, I'd like to talk to

21 you about some of the things that we're doing

22 within CDER. We have several guidances under

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1 development related to rare disease drug

2 development. Those will be forthcoming. You'll

3 hear more about those as they get published.

4 We work with senior staff here at the FDA

5 regarding rare disease projects and policies. We

6 work on the Rare Pediatric Disease Priority Review

7 Voucher Program and administer that within CDER,

8 and I'll have some slides later that go into a

9 little more depth about that program.

10 Another important thing is that the

11 foundation for rare disease drug development is

12 good science. So we try to do what we can to

13 support the development of a good scientific

14 foundation for rare disease drug development.

15 We've developed a database here where we track the

16 rare disease drugs and a lot of different

17 information about each drug. We also work on peer-

18 reviewed publications.

19 We try to work collaboratively with our

20 stakeholder groups in the community. We work

21 closely with NIH. We participate in the annual

22 Rare Disease Day that happens every February,

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1 usually on the 28th of February, except for leap

2 year. Every five years, we get February 29th, the

3 rarest day in the calendar.

4 We participate as panelists in the patient-

5 focused drug development meetings that you've heard

6 about. And we have face-to-face meetings with

7 patient advocacy groups, often collaborating with

8 PASE, and with our colleagues in OHCA, and

9 sometimes the orphan drug group.

10 We give presentations to stakeholder groups

11 when requested. One of our major stakeholder

12 groups we work with is the National Organization

13 for Rare Disorders, and we always help them plan

14 their big annual meeting that happens in October.

15 I believe it's October 16th and 17th this year.

16 It'll be happening in Washington, D.C. We respond

17 to many, many queries from both internal and

18 external stakeholders.

19 Rare diseases are complicated, so we get

20 questions from the review divisions. We get

21 questions from people developing drugs. And

22 sometimes, we don't have the answers, but we are

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1 more than willing to try to steer you in the right

2 direction or connect you with the right people at

3 FDA because we know how challenging it is to

4 navigate the system here. Also, we're a member of

5 the FDASIA Section 1137, which had to do with

6 patient participation in medical product

7 discussion.

8 Another important thing we try to do is to

9 promote consistency in innovation and review. We

10 hear a lot from industry that they think the

11 different review divisions have different ways of

12 reviewing drugs, so we do whatever we can to attend

13 the meetings for rare disease drug development, and

14 to be part of those meetings, and to try to ensure

15 that there's as much consistency as possible.

16 We've also developed a rare disease drug

17 training course for the review staff here, so once

18 a year -- it's actually happening next week -- we

19 have a full day of training for all the CDER review

20 staff. And then we also have presentations to

21 numerous professional societies.

22 One of our most recent projects is that

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1 we've developed an European Medicines Agency and  
2 FDA rare disease cluster. So this group meets once  
3 a month. It's a telecon that happens with  
4 colleagues in Europe, colleagues here at the FDA,  
5 and we discuss topics of global interest in rare  
6 diseases.

7 Sometimes these are higher-level topics and  
8 sometimes they're very specific to a specific drug.  
9 We have a memorandum of understanding that we can  
10 share confidential information between Europe and  
11 us. So we talk, how are you thinking about this,  
12 how are you thinking about this endpoint, or where  
13 are you at in the approval process, and we try to  
14 better understand each side of the ocean's thinking  
15 about a certain topic.

16 This slide just shows a little bit about  
17 predicting the future for rare disease drug  
18 development. Prior to sending in a new drug  
19 application or a biologics licensing application,  
20 people can apply for an orphan designation. An  
21 orphan designation, you just have to show that this  
22 is for a disease that's a rare disease and that

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1 there's a plausible reason that this probably will  
2 work for the rare disease.

3 So this graph shows, from 1983 up through  
4 2016, you can see there's three data points, '83 to  
5 2001, 2002 to 2008, and 2009 to 2016. And the blue  
6 arrows define where those three periods are.

7 We've gone from the first period of 59 drugs  
8 being designated as orphan to this most recent  
9 period of 2009 to 2016. It's gone up to 248 orphan  
10 designations. So this shows that there's a lot of  
11 interest in rare disease drug development, and this  
12 is where a lot of the work is happening.

13 The last topic I wanted to talk about was  
14 the Rare Pediatric Disease Priority Review Voucher  
15 program. This was established in 2012 with the FDA  
16 Safety and Innovation Act, and it provides an  
17 incentive to encourage the development of drugs in  
18 biologics for the prevention or treatment of rare  
19 pediatric diseases.

20 So once the drug is approved at the FDA, the  
21 sponsor of a rare pediatric drug, they can be  
22 eligible to get a voucher. This voucher is

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1 redeemable for another review down the road, but  
2 that review can get a priority review, which means  
3 it will be reviewed in six months instead of the  
4 standard 10 months, but it can be for a common  
5 disease.

6 So drugs for common diseases get a standard  
7 review of 10 months, but if you have one of these  
8 vouchers, you can cash in the voucher. And it  
9 could be a new drug for diabetes or for  
10 hypertension. But you'll get a six-month review.  
11 So this is of a lot of interest to industry.

12 To get one of these vouchers, it has to be  
13 for a rare pediatric disease. The definition was  
14 changed fairly recently. It's for a serious or  
15 life-threatening disease in which the serious or  
16 life-threatening manifestations primarily affect  
17 individuals from birth to 18. And greater than 50  
18 percent of the disease-affected population has to  
19 be pediatric. It has to be a rare disease, so it  
20 has to affect less than 200,000 people. And you  
21 have to have done clinical studies where you  
22 actually studied the drug in children.

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1 The candidate drug or biologic product that  
2 you're developing has to be a new drug. It cannot  
3 have been approved before. This is to innovate new  
4 drug development. And you can't seek an adult  
5 indication for a non-rare disease or a different  
6 disease from the rare pediatric disease at the same  
7 time. And when you submit it to the FDA, it has to  
8 be eligible for a priority review itself. So that  
9 means that we have to deem that this is for serious  
10 disease with unmet need, and we're going to give it  
11 a six-month review.

12 So far, the program's been, I think, fairly  
13 successful. Ten vouchers have been awarded to  
14 date. One of the aspects of the program is that  
15 you can sell the vouchers. So this has been  
16 another motivator for industry, and they've sold  
17 for up to \$350 million, so it's a lot of money  
18 we're talking about. So far, three of the vouchers  
19 that have been awarded have been redeemed for  
20 priority reviews for other drugs.

21 We have a guidance, once again, like  
22 Michelle showed you. There's a Rare Pediatric

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1 Disease Priority Review Voucher guidance that has  
2 more information. And if you have any questions  
3 about this program, once again, we'd be more than  
4 happy to answer questions.  
5 So I thank you for your attention. There's  
6 my e-mail address. And like I said, anyone from  
7 our program at any time, we'd be more than happy to  
8 communicate with you. So thank you.  
9 (Applause.)  
10 Questions and Answers  
11 MR. BAUER: Are there any questions? Hello,  
12 Jen.  
13 FEMALE AUDIENCE MEMBER: Good to see you  
14 again, Larry. My question is, can you comment on  
15 the Rare Disease Council, how this evolved, who  
16 serves on the council, mission and goals?  
17 MR. BAUER: Sure. Yes. So the Rare Disease  
18 Council, I don't think you hear much about outside  
19 the agency. But what happened was, when the Rare  
20 Disease Program began, we found that we were having  
21 individual meetings, like our program would meet  
22 with CBER, the staff at CBER that were working on

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1 rare diseases. We'd have a t-con, what are you  
2 doing. Then we'd have a monthly meeting with the  
3 Office of Orphan Products Development. Then we'd  
4 talk to OHCA. We'd talk to all these different  
5 groups. Then we thought, why aren't we just  
6 meeting together once a month?  
7 So the membership, we have representation  
8 from CDER, CBER, CDRH, from PASE, from the Patient  
9 Affairs and Stakeholder Engagement, from OHCA, the  
10 Office of Health and Constituent Affairs. We have  
11 group membership from the Office of Legislation. I  
12 think that's most of the people, yes.  
13 We meet once a month, and we develop an  
14 agenda about what's current. Each group reports  
15 off on what approvals they've had recently or any  
16 meetings of interest coming up. And then we talk  
17 about topics that are of broad interest to the rare  
18 disease groups here.  
19 MR. WHITE: Good morning, Larry.  
20 MR. BAUER: Good morning.  
21 MR. WHITE: My name is David White. I'm a  
22 patient advocate with the Kidney Health Initiative.

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1 I'm kind of new to this, so if this is a dumb  
2 question, I apologize. But you mentioned the need  
3 for ongoing assent with the -- being different for  
4 the -- is it different for the pediatric population  
5 than the adult population?  
6 MR. BAUER: I think assent -- in the adult  
7 population, when an adult signs a consent form that  
8 they are willing to participate in study, their  
9 consent contains their assent. You understand that  
10 if an adult, who has their adult consciousness, if  
11 they are agreeing to participate in a study, at the  
12 same time they're assenting to it.  
13 A child maybe has never been really fully  
14 asked, do you understand the study, do you  
15 understand the risks. They might just be too small  
16 to understand that, but they also have the ability  
17 to say I'm willing to do this, whatever it is.  
18 You have to kind of explain to a child in  
19 terms that they can understand, and they have to on  
20 some level be willing to go ahead and participate  
21 in the study. Children have a right to say I  
22 absolutely don't want to do this, this is too much,

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1 this is too painful. Thank you very much.  
2 (Applause.)  
3 DR. WHYTE: Again, the Rare Disease program  
4 has a table in the back, and they're the ones with  
5 the candy, so please go see them.  
6 At this time, I'm delighted to welcome Noah  
7 Goetzel from our team, who is an ORISE fellow, who  
8 is going to have some audience response questions.  
9 And Noah, you might be familiar, he does a podcast  
10 for the Washington Wizards.  
11 So how are the Wizards doing? Is it over?  
12 I don't know.  
13 Audience Response Questions  
14 Noah Goetzel  
15 MR. GOETZEL: Good morning, everybody. How  
16 are you doing? Thanks for the warm welcome, John.  
17 The Wizards are still playing. They're fighting  
18 for their play-off lives tonight, and they've got a  
19 big game before us.  
20 Larry didn't tell you before he started, but  
21 there is a test afterwards. And I'm going to ask  
22 an audience response question related to the

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1 material he just covered.  
2 First question, what is the Rare Disease  
3 Program able to do? There are a couple of options.  
4 The Rare Disease Program at the FDA can do which of  
5 the following? Provide training to medical  
6 reviewers on rare disease drug development; B,  
7 collaborate with NIH, National Institute of Health,  
8 to accelerate drug development; C, Rare Disease  
9 Program works interactively with rare disease  
10 stakeholder organizations; or D, works to speed  
11 review and approval of drugs to treat rare  
12 diseases? Last option is E, all of the above.  
13 I'll give you guys a couple of seconds to  
14 chime in your responses.  
15 (Audience answers.)  
16 MR. GOETZEL: Smart group we have here.  
17 Ninety percent said all of the above. That's the  
18 correct answer. All of those are roles of FDA's  
19 Rare Disease Program.  
20 Next question, which of the following  
21 factors does not go into consideration when the FDA  
22 is considering which drugs to approve? Biological

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1 marks is A; B, patient-reported outcomes;  
2 C, company stock prices; or, D, clinical outcomes.  
3 I hope you guys get this one.  
4 (Laughter.)  
5 (Audience answers.)  
6 MR. GOETZEL: You got it, company stock  
7 prices not a factor for drug approvals.  
8 Next question, if a drug shortage strikes,  
9 the FDA can do which of the following, manufacture  
10 more drugs to meet the demand; import drugs from  
11 foreign countries; force a manufacturer to produce  
12 more drugs; or D, none of the above?  
13 (Audience answers.)  
14 MR. GOETZEL: Let's see what we got for the  
15 results. So the answer is B, import drugs from  
16 foreign countries. About a quarter of you guys got  
17 that one.  
18 Now we're on to our final question of this  
19 audience response answer. If you're prescribed  
20 certain prescription medications, it is legal to  
21 buy them online, true or false? A is true; B is  
22 false.

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1 (Audience answers.)  
2 MR. GOETZEL: It's about 50/50 in your  
3 results. The answer is true. If you're procedure  
4 those medications, it is indeed legal to buy them  
5 online. Thank you so much, and I'm going to turn  
6 it back over to Dr. Whyte.  
7 (Applause.)  
8 DR. WHYTE: I want to give Noah a lot of  
9 credit. Noah's only been here for about three  
10 months and really has taken the lead, and writing  
11 all those questions.  
12 So see how much you can learn just from a  
13 short period of time? Here he is, a young guy who  
14 has chosen to come to government to work, and has  
15 come to the FDA, so yes. Let's give him a round of  
16 applause, and it really is doing a terrific job  
17 here, and we're lucky to have him.  
18 (Applause.)  
19 DR. WHYTE: So I'm delighted to welcome to  
20 the stage Rea Blakey. I've been fortunate to have  
21 worked with Rea in a variety of roles probably over  
22 the last, I'll say, 15 years. And I'm delighted

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1 that she's joined me here at the FDA.  
2 Now, you may remember Rea was a  
3 long-standing reporter on a local station,  
4 Channel 7, here in the Washington, D.C. area, and  
5 then was at CNN, and worked with me at Discovery  
6 Health Channel as well as Discovery Channel.  
7 Her fun fact is, while she was a medical  
8 correspondent at CNN, Rea's name -- and people  
9 always get her name wrong as she says -- it's  
10 R-E-A -- was used as the answer to a New York Times  
11 crossword puzzle clue.  
12 So I'm delighted to introduce Rea Blakey,  
13 who's going to moderate a panel, and really  
14 deserves a lot of credit to her and her team for  
15 really pulling the day together. Rea has done a  
16 superb job. So thank you, Rea.  
17 (Applause.)  
18 Panel Discussion – Rea Blakey  
19 MS. BLAKEY: Hi. Good morning, all. I'm  
20 going to ask the panelists to step up, please, so  
21 we can all be together at once.  
22 Is everyone enjoying themselves, learning a

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1 lot? That's most important, learning a lot.  
2 No? No one's learning anything.  
3 (Laughter.)  
4 MS. BLAKEY: Is the mic on? It's because I  
5 have this weird sound to my voice. I'm having an  
6 allergy reaction over the last couple of days. And  
7 you've probably seen a commercial about someone  
8 called The Muddler. That's me today.  
9 So forgive the quality of my voice, but I'm  
10 sure that you will enjoy the content from our  
11 panelists. I am really thrilled that they've all  
12 joined us today because these are people we  
13 interact with at Professional Affairs and  
14 Stakeholder Engagement on a regular basis.  
15 Quite honestly, if we weren't a whole  
16 community, we wouldn't get nearly as much done.  
17 Sometimes, occasionally, we step over top of one  
18 another, but we pretty quickly sort it out, and  
19 we're very fortunate to have a collaborative effort  
20 that exists here.  
21 So I want to just extend my personal thanks  
22 to each of you for participating even though you

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1 haven't heard any questions yet. And I did promise  
2 them that I wanted this to be a very interactive  
3 session. And by that, I mean you can't just sit  
4 there. That's what interactive means.  
5 So I might throw in a pop quiz question for  
6 the audience. I might ask a speaker to address  
7 something that maybe they weren't prepared to do,  
8 but only if the audience doesn't participate, so  
9 it's really on you as to how much pressure is  
10 placed on them. Got it? Then we'll know if you're  
11 truly friendly. Oooh, it could be tough.  
12 All right. Let me ask a question. How many  
13 of you would like to have your voices heard? Show  
14 of hands, please.  
15 (Show of hands.)  
16 MS. BLAKEY: There are some people who are  
17 not raising their hands. So that intrigues me.  
18 But for those of you who would like to have your  
19 voices heard, you have come to the right session.  
20 This is exactly what this panel is about. And a  
21 lot of it has to do with the fact that we're the  
22 people oftentimes on the front line of engagement

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1 when it comes to CDER and the FDA.  
2 So without further ado, I do want to  
3 introduce the panel. And let me just say that  
4 there is that constant disclaimer that you've heard  
5 before. This goes for all the panelists, that the  
6 opinions expressed are personal, do not  
7 specifically represent the FDA.  
8 Given that, let's start with Dr. Lynne Yao,  
9 who is farthest from me. She's the director of the  
10 Division of Pediatrics and Maternal Health. She  
11 and her staff led CDER's efforts toward informed  
12 use of medicines in children and women. And I know  
13 that that's of great interest to all of us, but  
14 they're a specific sort of in-house consultant  
15 group that we use here. So it's really important  
16 to have Lynne and her team participate.  
17 Also, you did a public workshop maybe last  
18 year. Maybe you could tell us a little bit about  
19 that as part of your comments.  
20 Next to Lynne, we have Pujita Vaidya, who is  
21 the acting director of the decision support and  
22 analysis team. That's part of the Office of

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1 Strategic Programs. We collaborate a lot at PASE  
2 with OSP, and one project in particular we're  
3 really happy about, we'd love to tell you about  
4 today, but you'll have to come back and check our  
5 website because we don't really have all of our  
6 information available. But that's just a little  
7 tease to make you come back.  
8 Pujita's going to talk a lot today about  
9 externally-led patient-focused drug development  
10 meetings. And I know that's an interesting topic  
11 for a lot of you.  
12 Next to Pujita is Chris Melton, who is my  
13 colleague. You heard Chris introduced earlier  
14 today. He is a health communications specialist.  
15 And he's going to represent the perspective of  
16 PASE, what we're doing in our office and how we  
17 engage with you as stakeholders.  
18 Closest to me, Andrea Furia-Helms, who is  
19 with the Office of Health Constituent Affairs. I'm  
20 going to use a little pop quiz question here,  
21 Andrea. I hope you're all right with that.  
22 Her office actually also received recently

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1 an award for, let's see, patient representative  
2 training workshop that they had put on. So they're  
3 very deeply embedded in patient engagement here at  
4 FDA.  
5 But the pop quiz question, which is for the  
6 audience, has to do with a particular drug  
7 development issue. It's a drug, in fact, that's  
8 used to treat HIV and AIDS. It was first  
9 synthesized as a potential anti-leukemia drug, but  
10 it didn't work. However, it was found to be active  
11 against a retrovirus, which led government  
12 researchers to consider it as an HIV fighter. The  
13 drug was approved in 1987.  
14 Who can tell me the name of the drug?  
15 No, Larry, you can't.  
16 Anyway, you can just yell it out, who  
17 doesn't work at FDA.  
18 MALE AUDIENCE MEMBER: AZT.  
19 MS. BLAKEY: AZT. Thank you.  
20 There are going to be more pop quizzes for  
21 you folks because I need a little bit more energy  
22 from you. And that brings me to this interesting

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1 little tidbit. Your office really came about  
2 almost as a result of all of that activity during  
3 the early '80s.  
4 Andrea, take it away.  
5 Presentation – Andrea Furia-Helms  
6 MS. FURIA-HELMS: Good morning, everyone.  
7 Thank you for coming today. Thank you, Rea, and  
8 thank you for PASE's inviting OHCA, the Office of  
9 Health and Constituent Affairs here today.  
10 I want to start today with just a little bit  
11 of overview about our office. Our office is  
12 located in the Office of the Commissioner, and we  
13 have been around for, as Rea had mentioned, quite  
14 some time.  
15 We started in the late 1980s in response to  
16 the HIV-AIDS patient advocates protest outside of  
17 the FDA headquarters at that time. And they were  
18 concerned because FDA was taking a little bit  
19 longer than they anticipated for reviewing and  
20 approving new therapies for them. And at that  
21 time, that's when FDA realized we need an office to  
22 work with patient advocates, and really talk to

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1 them regularly, and include them in the process.  
2 So our office is an office of patient  
3 engagement and assistance. We assist you all in  
4 navigating FDA across the medical product centers.  
5 We work with devices, drugs, and biologics. So if  
6 you have an issue that you don't know where to go,  
7 you come to us, and we help navigate for you. We  
8 help you connect with the appropriate people. We  
9 help you get meetings and to meet with the  
10 appropriate people to address your concerns and get  
11 your voices heard internally.  
12 We are basically advocates for you all. As  
13 you are advocates for your patient communities, we  
14 are advocates for you internally, and we work to  
15 include your voices in regulatory processes. We  
16 look at different activities and meetings that we  
17 feel that the patient voices could be useful, and  
18 we work to get those voices heard for you.  
19 This is just to show some milestones of  
20 patient engagement over the years at FDA, as I  
21 mentioned it starting in the late '80s. Things to  
22 note is the FDA Patient Representative Program,

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1 which I'll be talking to you mostly about today.  
2 That started in 1991 when the first patient  
3 representative served on an anti-viral advisory  
4 committee for an HIV-AIDS drug.  
5 Then that's when the cancer advocacy  
6 community said, hey, we require a voice, too. We  
7 want a voice at the table as well. So we really  
8 opened it up to all serious and life-threatening  
9 diseases at that point. And we fought for patients  
10 to have a vote on advisory committees in the mid-  
11 1990s.  
12 In the early stages of the Patient  
13 Representative Program, the patient representatives  
14 were not voting, and they weren't allowed to review  
15 the confidential information. But our office  
16 fought for that, so now patient representatives  
17 have an equal vote as the scientific members.  
18 In recent years, we've expanded patient  
19 engagement as you can see, not only a broader  
20 inter-office with the FDA patient network, which  
21 I'll touch upon later, but also, as Pujita will be  
22 speaking about, the patient-focused drug



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1 development, and then other center-specific  
2 activities that have been occurring.  
3       So as I mentioned, the Patient  
4 Representative Program began in the 1990s. Really,  
5 the goal is to have the patients have an active  
6 role in the advisory committee process and the  
7 review division meetings. So there are certain  
8 meetings that occur early in the drug development  
9 process that patients can have a voice in as well,  
10 and the Patient Representative Program also  
11 provides that voice as well.  
12       So the patient voice is a representative in  
13 these important decision-making meetings for  
14 regulatory issues. And I think it's important to  
15 note that having a patient at the table humanizes  
16 the process. It reminds us that these are folks  
17 that are the end users of the products, and that's  
18 what we have to keep in mind.  
19       So who are the patient representatives?  
20 They're patients that have experience with the  
21 disease or condition, primary caregivers to  
22 patients such as spouses, family members, even

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1 friends. And they're usually members of patient  
2 advocacy communities and are involved in patient  
3 advocacy groups.  
4       Our patient representatives have to become  
5 special government employees. That's a temporary  
6 government employee status. So we're regular  
7 government employees, and this is sort of a  
8 temporary status, but they do go through conflict  
9 of interest screening, just as we do as regular  
10 government employees. Currently, we have over 200  
11 patients and caregivers serving in the program, and  
12 they represent over 300 diseases and conditions.  
13       We have a recruitment process, and we  
14 recruit based on need. We know that advocates want  
15 to advocate. They want to act. They want to do  
16 things. They want to make an impact. So we want  
17 to make sure that the patient representatives that  
18 we recruit will have an opportunity to serve within  
19 their four-year appointment.  
20       It's usually that we recruit because there  
21 is a product in development, and we need a patient  
22 voice and a patient perspective in that particular

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1 product, or there's a product application in house  
2 for FDA to review. And once they're on board, we  
3 immediately start training.  
4       There's preparation and training involved in  
5 terms of an FDA 101, where we provide a high-level  
6 overview of our regulatory processes, our  
7 organizational structure, and really to address  
8 some misconceptions and misinformation about FDA  
9 and what already is and is not.  
10       We have regular webinars and also an  
11 annual patient representative workshop, which we  
12 have every July. And that brings in the newly  
13 recruited patient representatives to learn about  
14 the medical product development life cycles,  
15 conflict of interest. Because advocates are out  
16 there advocating during their activities, being a  
17 special government employee, some of the activities  
18 can conflict them out of serving, so we have to  
19 provide specific training on that.  
20       Mentoring by senior patient representatives,  
21 the newly recruited sometimes are a little  
22 intimidated before their first meeting with FDA and

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1 the sponsor, so we connect them with the senior  
2 patient representatives to sort of ease their mind  
3 about how to prepare, what to expect. And that's  
4 been very helpful to them.  
5       What this training does not only prepares  
6 them in serving, but it also furthers an  
7 understanding an appreciation about FDA's  
8 regulatory processes. And they go back to their  
9 patient communities and they provide education as  
10 well. As I mentioned, there may be some  
11 misconceptions and misinformation out there about  
12 FDA's regulatory authority for example.  
13       So that education and training that we  
14 provide them also helps them provide that  
15 information to their community.  
16       So we have a legal basis for continuing and  
17 broadening our patient input in recent years. The  
18 FDA safety and Innovation Act of 2012,  
19 Section 1137, which Larry had mentioned earlier,  
20 patient participation and medical product  
21 discussions, is the legal basis for us to find ways  
22 to include the patient voice earlier in the

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1 development process.

2 What has been done so far since that has

3 been signed into law is we created a cross-agency

4 workgroup to discuss how to implement this. And we

5 decided we should open a docket in hear from our

6 stakeholders, from you all. How should we

7 implement it? What are your recommendations and

8 suggestions?

9 So from that, we pulled all the comments

10 together, and there's a stakeholder view summary

11 report on our website. We have ongoing activities,

12 as you all know and you're probably involved in.

13 There are centers that are implementing their own

14 activities, and we continue to do our activities as

15 well in OHCA.

16 But from that cross-agency workgroup that

17 was initially formed, now we've evolved into a

18 patient counsel. So now, because there are so many

19 activities and so much going on across the centers,

20 we're working together to better inform each other,

21 and to leverage off each other when we have patient

22 engagement activities, and really to know what's up

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1 and coming.

2 So from FDASIA 1137 and from that

3 stakeholder views report, one of the suggestions

4 that we heard you, and we listened, and now we're

5 taking action, we're developing the Patient

6 Engagement Collaborative, and we're working with

7 the Clinical Trials Transformation Initiative on

8 this.

9 This is going to be an external group of

10 stakeholders such as yourselves that can

11 participate in regular meetings with FDA to talk

12 about how can we enhance patient engagement at FDA.

13 It seems to have been an explosion over

14 recent years about patient engagement, which has

15 been fantastic, but we sort of want to make sure

16 we're going in the right direction and that maybe

17 there's some things we could be doing better.

18 So currently, that's in development, and we

19 are going to issue a Federal Register notice for a

20 call for nominations, hopefully soon. There's been

21 a little bit of a hold with the transition in

22 administration, but once that comes out, I

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1 encourage you to apply if you're interested. If

2 you have any questions, I'm happy to answer them.

3 But that's all I have.

4 MS. BLAKEY: Wonderful. Thank you, Andrea.

5 All right. Is our audience still with us?

6 I think it's time for another pop quiz. Put your

7 thinking caps on. This particular drug is used to

8 treat estrogen-positive breast cancer, which

9 accounts for 50 to 70 percent of cases. It may

10 also prevent the development of breast cancer in

11 high-risk patients.

12 It was originally intended as an anti-

13 fertility drug when it was synthesized, but it

14 turned out that it stimulated ovulation instead of

15 suppressing it.

16 Who has a guess at what this drug is called?

17 Tamoxifen. Perfect, wonderful. Okay. I have one

18 person who is definitely with me in sync. Thank

19 you so much.

20 Just for that, I'm going to try another one,

21 and I bet more of you can get this one. This

22 particular drug first appeared in the market in

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1 1979 as a breakthrough for high blood pressure,

2 however, it increased body hair growth for

3 80 percent of patients.

4 You don't have to wait if you know the

5 answer. The drug is?

6 AUDIENCE MEMBER: Rogaine.

7 MS. BLAKEY: Thank you. Wonderful.

8 Congratulations. Fantastic.

9 All right. I got them warmed up, Chris.

10 Now it's your turn to talk about what we do in

11 Professional Affairs and Stakeholder Engagement

12 that would be of interest to this audience.

13 Presentation – Christopher Melton

14 MR. MELTON: Rea, thank you for the

15 introduction.

16 What's important in what we do with

17 Professional Affairs and Stakeholder Engagement, we

18 are a conduit to start two-way engagement. And I

19 know you've heard a lot of acronyms, and

20 Dr. Throckmorton in the beginning speak as far as a

21 culture change within PASE. We are here to be a

22 conduit for two-way engagement. So if there are

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1 any questions that you have regarding who would I  
2 speak with, you would come here with us in PASE.  
3 Also, we have at least five top issues that  
4 we've been working on, one of them being patient  
5 advocacy groups and stakeholder meetings. In 2016,  
6 we have had over 104 meetings, and most of those  
7 have been with external stakeholders, and that was  
8 a 30 percent increase over 2015.  
9 But the basic point, what I would like to  
10 get across to the audience, is that the Rock the  
11 Docket, that's a good key initiative to start the  
12 process because, as you've heard and will hear  
13 throughout the day, you'll hear Federal Register  
14 notice, docket, this is a way to start the  
15 communication. And once you have that starting  
16 point, then from there it can continue to grow.  
17 And again collaboration and us being able to have  
18 open communication will really work the best for us  
19 to continue on. And that's it for me.  
20 MS. BLAKEY: Which is fine, because we want  
21 to leave plenty of time for questions and answers.  
22 So that was a very lovely introduction. We move

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1 down to Pujita, who wants to talk a little bit more  
2 about the externally-led PFDDs, among other things.  
3 Presentation – Pujita Vaidya  
4 MS. VAIDYA: Hi, everyone. I'm Pujita  
5 Vaidya, as Rea mentioned. And I'm in the Office of  
6 Strategic Programs in FDA's Center for Drug  
7 Evaluation and Research.  
8 Today, I'll be talking to you about the  
9 Patient-Focused Drug Development initiative  
10 overall. This is an initiative that I've been a  
11 part of for about five years now, so from the very  
12 beginning, I've been involved in this work. So  
13 it's pretty near and dear to me, I would say.  
14 I just want to put a disclaimer. I know  
15 Michelle has introduced some of this stuff, so some  
16 of the slides may be similar. I'll try to switch  
17 it up a little bit and just give a quick overview,  
18 and then mainly focus on the externally-led  
19 patient-focused opportunity here.  
20 So as we've heard from a lot of folks today,  
21 people living with the condition have a direct  
22 stake in the outcomes of drug development, and they

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1 have a unique ability to contribute input and can  
2 inform drug development and evaluation.  
3 So FDA recognized that there is a need for a  
4 more systematic way to collect and gather this  
5 patient perspective that can inform drug  
6 development overall. So what we came up with in  
7 PDUFA V, which is the fifth authorization of the  
8 Prescription Drug User Fee Act, is the  
9 Patient-Focused Drug Development initiative under  
10 which we are conducting 24 meetings, which are  
11 specific to certain disease areas.  
12 So here, you can see the list of different  
13 diseases that we have focused on, and we have two  
14 remaining for this fiscal year, which will close up  
15 PDUFA V.  
16 At these meetings, I would say, overall, the  
17 disease area is here. You can see diseases are  
18 chronic, symptomatic. There are several rare  
19 diseases as well in our list here.  
20 Typically, at these meetings, when you  
21 attend the patient-focused meetings, you'll get  
22 about, I would say, anywhere -- we've ranged from

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1 30 to about 80 to 90 patients or patient  
2 representatives that attend the meeting, overall  
3 attendees, so other folks, I would say. But in  
4 total, we would say about 100 to anywhere, 150  
5 total participants. And then we have similar  
6 numbers on the webcast as well at these meetings.  
7 The meetings that we have are focused on two  
8 main topic areas. So the main discussion is  
9 focused on gathering patient perspectives on  
10 patient symptoms and its impact on daily life, and  
11 also patients' perspectives on current approaches  
12 to managing their condition.  
13 So the types of questions we ask are, which  
14 substance has the most significant impact on your  
15 life, how does it affect the ability for you to do  
16 specific activities, how well do your current  
17 treatment regimens treat the most significant  
18 symptoms, what are some of the things that you look  
19 for in an ideal treatment, and we also delve into  
20 discussion about, in some cases, what factors do  
21 you take into account when making decisions about  
22 treatments.

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1 So these are the types of questions that we  
2 cover and the discussion that we have in a large  
3 group-facilitated discussion.  
4 I would say one of the main things that we  
5 have realized is that active outreach is the key to  
6 success, and that's where patients, stakeholders,  
7 and advocacy groups play a very important role.  
8 We have seen in several cases, in  
9 preparation for these meetings, that advocacy  
10 groups have taken initiative to coordinate efforts,  
11 whether it's helping with outreach through social  
12 media, through the contacts that you all have,  
13 because we actually here at the FDA, we don't have  
14 the direct contact with the patient themselves. So  
15 you're the ones who hold the key to that database,  
16 let's say.  
17 Along with that, some have organized for  
18 these meetings. Some have organized patients,  
19 transportation, buses to actually bring patients  
20 and patient representatives to the White Oak  
21 campus. As you've probably realized today, it's  
22 not easy to come here and get to this location. So

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1 they have organized that. They have organized pre-  
2 meeting get-togethers, sometimes even webinars to  
3 prep folks for these meetings.  
4 One of the main things, as we've learned, I  
5 would say, is these meetings really strengthen the  
6 understanding of the disease and treatment burden.  
7 As Michelle mentioned earlier, each meeting results  
8 in a voice of the patient report that faithfully  
9 captures the patient input from the various  
10 information streams.  
11 So through the webcast, what we hear at the  
12 meetings, through the docket, as you've heard  
13 about, where a lot of people are able to submit  
14 their comments after the meeting as well, that  
15 input can support FDA staff and benefit-risk  
16 assessment and also in thinking about clinical  
17 outcomes assessments as Michelle mentioned.  
18 Another thing that we think is -- the  
19 patient input collective can value drug development  
20 more broadly as well. So in cases, it can help  
21 identify areas of unmet need in the patient  
22 population, help identify or develop tools and

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1 assess benefit of potential therapies, and also  
2 help raise awareness and channel engagement within  
3 the patient community overall and educate.  
4 Now, I'll talk to you about the externally-  
5 led patient-focused drug development opportunity  
6 that we have. There was a growing interest,  
7 external interest in expanding the efforts to  
8 gather patient input in support of drug development  
9 and evaluation.  
10 About two years ago, we started welcoming  
11 patient organizations to identify and organize  
12 their own patient-focused collaborations. These  
13 meetings are truly your meetings. FDA, I would  
14 say, in the part of the planning part, we don't  
15 have a lot of input, and we leave that all up to  
16 you. And any resulting products from these  
17 meetings, we also say -- let's say, any reports,  
18 surveys of actual meetings. Those are not FDA-  
19 endorsed or sponsored. So these truly will be your  
20 meetings that you are conducting to gather this  
21 information.  
22 We have realized that the success of an

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1 externally-led patient-focused meeting really  
2 requires a joint and aligned effort by multiple  
3 advocacy groups associated with the disease areas  
4 because in some disease areas, as you all know,  
5 there are several groups that are involved for one  
6 particular disease. So it's nice for everyone to  
7 come together and look at opportunities to conduct  
8 these types of meetings.  
9 Now, I'd like to go over some considerations  
10 and things to think about as you're planning a  
11 meeting. What we realized here and from our own  
12 meetings, and what we would like to share, is that  
13 the key participants and the voices that we want to  
14 hear at these meetings are from patients, patient  
15 representatives, meaning caregivers or parents who  
16 are directly affected by this, and then patient  
17 advocates as well. Those are the key -- it's  
18 really a platform to hear their perspectives.  
19 The target audience, in addition to them, I  
20 would say, who are mostly in listening mode, would  
21 be your regulator, the regulatory, federal agencies  
22 like the FDA folks, medical product developers, so

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1 drug developers, device developers that are there.  
2 They're important to have in the room  
3 because they're the ones who will go -- and from  
4 what they hear in the meeting -- let's say,  
5 something about endpoints. If we're hearing  
6 something from patients about you're really not  
7 focusing on the core symptoms that I think is most  
8 meaningful to me, they're the ones who can go and  
9 start thinking about it further, researchers and  
10 healthcare professionals.  
11 What we've tried to do is from the 22  
12 meetings that we've conducted so far, we want that  
13 to kind of help serve as a model in identifying  
14 targets in disease areas to have a meeting in the  
15 main topics that I mentioned earlier, focusing in  
16 on those two topics, exploring this structure and  
17 format of using a facilitator-led large group  
18 discussion, having an interactive webcast and other  
19 discussion aids like polling tools like we're using  
20 today.  
21 Meeting deliverables are always very helpful  
22 because if for some reason let's say you have

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1 folks, you have drug developers, you have folks  
2 from the FDA staff who are for some reason unable  
3 to attend the meeting, it's good to have a web  
4 recording available, or a transcript, or a summary  
5 report for them to refer back to later.  
6 One thing I do want to mention is that these  
7 meetings do not have to be a stand-alone meeting.  
8 So we really encourage you to consider taking the  
9 style, and understanding the style, and  
10 incorporating it into other opportunities. A lot  
11 of groups have annual conferences. They also have  
12 maybe sometimes a scientific workshop.  
13 There may be an opportunity to actually add  
14 a session, a two-hour session maybe, to that to  
15 kind of gather the patient perspectives there. So  
16 it doesn't necessarily always have to be a half-day  
17 meeting or a full-day meeting.  
18 We do have a letter of intent process where  
19 we ask that you submit a letter of intent to the  
20 Office of Strategic Programs. It is really just so  
21 that we know that this meeting is taking place so  
22 that we can serve as a helpful resource to you.

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1 Since we are the ones who have been leading this  
2 effort for the past five years, four and a half  
3 years now, we have learned a lot, and we are able  
4 to guide you through the process.  
5 We understand, like I said, that since we're  
6 a team of five that leads this, and we're the ones  
7 who conduct the meetings along with the other  
8 projects and initiatives that we work on, we really  
9 understand that it takes a lot of effort. But it  
10 does not need to be resource intensive.  
11 So you may not necessarily always need to  
12 have a meeting planner or a scientific writer for  
13 these meetings. That's where we want to try to  
14 help to at least serve as a resource so that we can  
15 guide you through your planning.  
16 As I mentioned earlier, active community  
17 outreach is key to ensure a representative group of  
18 patient perspectives are actually in the room. So  
19 that's very important. And at the end of the day,  
20 I think the main thing is we want to be respectful  
21 of the time of patients, and caregivers, and  
22 patient advocates, and groups out there.

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1 Here is just some more information. We have  
2 all of our stuff on our FDA website. The  
3 externally-led page has guidelines on the letter of  
4 intent process. If you have any questions, please  
5 e-mail us to our patient-focused box. Thank you.  
6 MS. BLAKEY: Thank you, Pujita.  
7 Dr. Yao, I'm going to give you the last word  
8 on the panel for now, and then I would encourage  
9 those of you in the audience who have questions to  
10 not only formulate them quickly, but to come toward  
11 a microphone or raise your hand so that we can  
12 incorporate those questions as part of the  
13 discussion. I don't want us to run out of time.  
14 Dr. Yao, you want to talk a little bit about  
15 what goes on in your office?  
16 Presentation – Lynne Yao  
17 DR. YAO: I'm going to talk very briefly,  
18 which for those of you who know me is a real  
19 struggle. But Rea has the stick. She can just  
20 show it to me, and I'll know I need to get cut off.  
21 I really want to be brief because we really  
22 are here this morning to hear about questions that

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1 you might have about how you get your voice heard.  
2 I'll just give you a couple of examples, and then I  
3 want to hear from you. We all want to hear from  
4 you.  
5 The first is this image that I was given of  
6 a cartoon of a castle with a big wall around it,  
7 and a moat, and alligators, and you see someone  
8 lobbing with a catapult something over into the  
9 castle.  
10 That's the view that many people used to  
11 have of FDA, and some of you may have right now,  
12 that there's this gated-off castle where it's  
13 impossible to penetrate. And if I want to get  
14 something heard or I want to have my voice heard,  
15 I've got to throw something over the wall and see  
16 if ever something gets thrown back over.  
17 What you've heard this morning, I think, is  
18 not just that we are interested in throwing things  
19 back over all the wall, but indeed, we've lowered  
20 the gate. We've taken our first tentative steps  
21 out there to meet you, and we want you to come on  
22 in. Okay?

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1 All of the initiatives that you've heard are  
2 efforts to do that. Some of them are very formal.  
3 Some of them are less formal. But all of them are  
4 intended so that you can get your voice heard. And  
5 we are very, very interested in the Office of New  
6 Drugs and the Center for Drug Evaluation and  
7 Research to hear your voice.  
8 The only other thing that I want to say is  
9 that patients matter. Patients matter. If it  
10 weren't for patients and families, we would not  
11 exist. My background is in pediatrics, and I want  
12 to leave you the one story that has to do with a  
13 question that arose about the difference between  
14 assent and consent that I heard.  
15 I had a patient when I was an intern who had  
16 a very unfortunate aggressive form of leukemia,  
17 acute myelogenous leukemia. And Jonathan was going  
18 through treatments. His parents were very  
19 concerned. He was an only child, only five years  
20 old. And because of this great program  
21 called -- what's that program?  
22 See, now I'm going to forget now -- where

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1 kids get -- Make A Wish. It was the Make A Wish  
2 Foundation. Jonathan and his parents enrolled.  
3 And it was their deep desire for Jonathan to meet  
4 his grandparents in Korea because he had never  
5 gotten a chance to meet.  
6 So his parents had coached him, and coached  
7 him, and coached him because they were going to get  
8 interviewed about what Jonathan's wish would be.  
9 So they said, "Jonathan, what do you want to do?"  
10 And he said to his mom and dad, "I want to go to  
11 Korea to see my grandmother." Great.  
12 So they interviewed the family together, and  
13 the family said, "Well, we really want to go to  
14 Korea to meet Jonathan's grandmother because he  
15 never got a chance to meet her." Okay.  
16 So then what they do is interview the child  
17 by himself. So when they got Jonathan into the  
18 room and they said, "Jonathan, what do you really  
19 want to do if you had anything you could do?" And  
20 he said, "I want to go to Disneyland!" And the  
21 family went to Disneyland.  
22 (Laughter.)

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1 DR. YAO: So the difference between  
2 consent -- and this, again, illustrates why the  
3 patient voice is so important.  
4 We know, certainly in children, in the care  
5 of children, that there are a lot of things that  
6 get involved when you have a serious disease, when  
7 you have a chronic disease, when you have a disease  
8 that requires therapy, and maybe there's no therapy  
9 involved.  
10 The parents are desperate to find a cure or  
11 treatment for the child. And maybe the only thing  
12 the child really wants is to go to Disneyland. So  
13 what we really want to do is get at the heart of  
14 the matter, hear the voices, hear the voices of  
15 patients, of children, of parents, and develop  
16 programs that address all of those needs.  
17 Questions and Answers  
18 MS. BLAKEY: Perfect, perfect.  
19 Now we'd like to hear your voices.  
20 Questions, please? Don't be bashful. Someone is  
21 approaching. Yes. And it's okay if there's a  
22 small line. I think we can probably take three or

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1 four depending on the length of the responses and  
2 so forth. Yes, ma'am?  
3 GINA: Hi. I feel like I'm on the old Phil  
4 Donahue show. My name is Gina. I'm the executive  
5 director for the Alport Syndrome Foundation. I  
6 have a couple of questions about the externally-led  
7 meetings, as we are hoping to hold one next year.  
8 You mentioned that several advocacy groups would be  
9 necessary. If there's only one advocacy group that  
10 really covers a disease state, I'm presuming it's  
11 okay if we do this.  
12 MS. VAIDYA: Yes, of course. I think the  
13 point I was trying to get at is if there are  
14 several groups out there, for you to join forces.  
15 GINA: Earlier in the day, it was mentioned,  
16 the option of having an online meeting instead of  
17 an in-person one. Is that true or did I  
18 misunderstand that?  
19 MS. VAIDYA: I don't see why that could not  
20 be possible. I'll be frank. We haven't received  
21 any requests for that, but I think that would be  
22 perfectly fine, yes. The key is to be able to

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1 reach the population and get the perspectives that  
2 you need.  
3 MS. PARZIALE: I wanted to gauge your  
4 thoughts on the appropriate role of industry in  
5 such a meeting in terms of inviting drug developers  
6 to come. Are they able to assist in the costs?  
7 What would be considered appropriate for something  
8 like that?  
9 MS. VAIDYA: So the role that we see overall  
10 in the meetings itself is that usually they're in  
11 listening mode at our meetings here, mainly to hear  
12 what the perspectives are so that they can identify  
13 areas where they may need to go and modify their  
14 approach, or think a little bit more about  
15 different endpoints.  
16 Now, thinking about the planning  
17 perspective, I would say I believe there have been  
18 cases in the past where it's perfectly fine to have  
19 industry if they are able to sponsor a meeting.  
20 And we would suggest that you at least put a  
21 disclosure out so that is known.  
22 But at the end of the day, these meetings

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1 are disease specific, they're not product specific,  
2 so it really shouldn't be a big deal.  
3 MS. PARZIALE: Great. Thank you so much.  
4 MS. BLAKEY: Thank you. Yes, ma'am?  
5 JENNIFER: Hi. I'm Jennifer. I just had a  
6 question regarding the new patient engagement  
7 initiative. You said the nominations would be  
8 through the Federal Register. What is the best  
9 way, I guess, to be alerted by FDA when the  
10 nominations are open? I don't regularly follow the  
11 Federal Register. It would be painful to read.  
12 MS. FURIA-HELMS: That's a perfect question.  
13 JENNIFER: What to subscribe to in FDA so  
14 you can make your --  
15 MS. FURIA-HELMS: So that's a great question  
16 because I'm going to leave some postcards at the  
17 registration table. We have a patient network  
18 newsletter, and that is your one-stop shop. That  
19 comes biweekly to your e-mail with all FDA  
20 activities regarding new approvals, recalls, any  
21 new activities and patient engagement  
22 opportunities, Federal Register notices, dockets

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1 that are open for commenting.  
2 Everything is there in that newsletter  
3 biweekly. So I'd encourage everyone to subscribe  
4 to that. We currently have, I think, 58,000  
5 subscribers, maybe 60,000 at this point. But that  
6 is your one-stop shop to get that kind of  
7 information and be informed of what's going on,  
8 very current information.  
9 JENNIFER: Thank you.  
10 MS. FURIA-HELMS: You're welcome.  
11 MS. BLAKEY: Do you mind? Hand the  
12 microphone to her. Thank you.  
13 MS. WEST: I have a couple questions. I'm  
14 Melissa West with the Kidney Health Initiative.  
15 First question, the externally-led PFDD meetings,  
16 are they published once you do accept a letter of  
17 request? Is that community notified?  
18 DR. YAO: So when you mean published, you  
19 mean --  
20 MS. WEST: Are you keeping a list of what  
21 you have accepted once you've reviewed?  
22 DR. YAO: We actually do not have that

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1 available on our website anywhere. But we can take  
2 that back and see how that's possible.  
3 MS. WEST: That would be great.  
4 DR. YAO: The only way that we've done it is  
5 that if you do reach out to us, we could let you  
6 know which group has had a meeting or if there are  
7 some coming up. They're doing a pretty job of  
8 outreach and advertising those meetings as well.  
9 So yes. I will definitely take that back and see  
10 what we can do.  
11 MS. WEST: That would be great. I'm seeing  
12 an opportunity for best practices, especially in  
13 the deliverables that are created.  
14 DR. YAO: Exactly, definitely.  
15 MS. WEST: For the Patient Representative  
16 Program, is that list publicly offered, or do we  
17 have the ability to contact you to determine if  
18 there's any of our membership who would be serving  
19 in that role? How would we get access to the list  
20 of patients, the 300 patients on the patient  
21 representatives?  
22 MS. FURIA-HELMS: The list of the patient

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1 representatives are not public, but you can contact  
2 me, and we can have a conversation, and see if  
3 there is representation. And if not, we can  
4 discuss that.  
5 MS. WEST: Perfect. And then my last  
6 question is I think there's an open docket right  
7 now around a new office of patient engagement. I'm  
8 curious in terms of any insight into that or what  
9 impact that will have in terms of the various  
10 constituency here.  
11 Then I also had a question specific to the  
12 Patient Engagement Collaborative that you're  
13 working on with city [ph], and what, if any,  
14 potential impact. Will that still be on its own  
15 track?  
16 MS. BLAKEY: Quickly, she can address the  
17 Patient Engagement Collaborative. We really don't  
18 have any other information other than the FRN for  
19 the first question that you asked, so  
20 unfortunately, we don't have anything more to  
21 address there, but yes.  
22 MS. FURIA-HELMS: So the Patient Engagement

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1 Collaborative has been in development since summer  
2 of last year. We developed with City's patient  
3 advocate steering committee members. Some of them  
4 have been part of the planning workgroup, and we've  
5 developed a framework. And we're in the process of  
6 getting that Federal Register notice out for a call  
7 for nominations. And it'll have outlined what the  
8 eligibility criteria is and things like that.  
9 So that should be up and coming. As I  
10 mentioned, it's been a little bit tough to get  
11 Federal Register notices with the transition. And  
12 we have a new commissioner starting today, so we're  
13 really hopeful that that will go soon.  
14 MS. BLAKEY: Just checking the time quickly,  
15 I think we just have time for these last two  
16 questions if they're brief. So yes, please. I'm  
17 actually directing it to you, yes, and the lady  
18 behind you.  
19 MEGAN: Hi. My name is Megan. I'm with the  
20 Parkinson's Foundation. Thank you for your  
21 information that you've provided today. My  
22 question was about the PFDD meetings. We were

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1 fortunate enough to have five of our research  
2 advocates actually contribute to the 2015 PFDD  
3 report. And I was just wondering if there are any  
4 specific outcomes that you guys are measuring that  
5 are coming out of the white pages that are being  
6 published, or if you've seen any uptake or anything  
7 like that with those reports.  
8 MS. VAIDYA: The voice of the patient  
9 reports are really supposed to serve as a resource  
10 for our FDA reviewers, so our OND reviewers and the  
11 other reviewers overall.  
12 From what I know right now, I'm not aware of  
13 anything. There may be stuff going on that I'm not  
14 aware of. But I would say the report itself right  
15 now, we would say is serving as a resource to them,  
16 to think about the therapeutic context overall.  
17 But unfortunately, I'm unable to give any more  
18 details on that. Sorry.  
19 FEMALE AUDIENCE MEMBER: Hi. My question is  
20 about -- actually, you've mentioned a lot of  
21 engagement with rare disease, or not just rare  
22 disease, but advocacy groups in the PFDD,



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1 et cetera. And I'm wondering, do you have any  
2 experience working with patient communities for  
3 which there is no formal advocacy group, no formal  
4 nonprofit representing them? If so, what is it?  
5 And if not, do you have any advice for those  
6 patient communities that do not yet have that  
7 organizational structure to approach the FDA and  
8 have their voices heard?  
9 MS. VAIDYA: Let me think back.  
10 MS. BLAKEY: Can I help you with that a  
11 little bit?  
12 MS. VAIDYA: Sure.  
13 MS. BLAKEY: That might be an area where you  
14 could reach out specifically to Professional  
15 Affairs and Stakeholder Engagement. We do deal  
16 with advocacy groups as well, but we do have a lot  
17 of people who are really naïve to the process. And  
18 so if you send an e-mail to either myself or Chris,  
19 whose name was actually in the FRN promoting this,  
20 we'll be glad to assist you.  
21 Oftentimes, we're able to get you exactly to  
22 where you need to be and create the meeting. We'll

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1 navigate as best we can on your behalf. So we like  
2 those more naïve people to come to us so that we  
3 can assist.  
4 I think we're probably beyond our time  
5 limit, and I thank you all for your time and  
6 attention. Thanks for playing the pop quiz. Thank  
7 you.  
8 (Applause.)  
9 DR. WHYTE: Thank you, Lynne Yao, for that  
10 metaphor of the castle and the moat. We'll use  
11 that.  
12 So it is a little after 12:30. We will now  
13 take roughly an hour lunch. Let's try to get back  
14 here at 1:30. Remember, this is Noah Goetzl, our  
15 young ORISE fellow, and Noah's going to help  
16 coordinate the teams for Jeopardy when we come  
17 back. So go have lunch, get caffeinated up, and  
18 not too much sugar, because I don't want you to  
19 fall asleep.  
20 We'll come back. We'll have a half-hour of  
21 Jeopardy questions. Then we'll hear from our  
22 colleagues about social media. And if anyone is

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1 tweeting things out, let me know. But see you all  
2 at 1:30.  
3 (Whereupon, at 12:35 p.m., a lunch recess  
4 was taken.)  
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1 AFTERNOON SESSION  
2 (1:32 p.m.)  
3 FDA Jeopardy – John Whyte  
4 MR. GOETZEL: Good afternoon. If we could  
5 please get the Jeopardy members to come up front,  
6 and you will be sitting at this front podium.  
7 Team 1 will be Gina Parziale; Rebecca Scott; Angie  
8 Onofre; Christa Kerkorian; and Shimere Sherwood.  
9 Please come up to the front and huddle around this  
10 first seat.  
11 Team 1, one more time: Gina Parziale;  
12 Rebecca Scott; Angie Onofre; Christa Kerkorian; and  
13 Shimere Sherwood, please come up to the stage.  
14 Team 2 will consist of Calvin Ho; Alyssa  
15 Reimer; David White; and Brittany Blocker. Come on  
16 up to the stage.  
17 On to Team 3, three of four, we've got  
18 Jessica Langton; Kamilah Rashid; Stephen Shaul; and  
19 Gay Grossman. Please come up front to the stage.  
20 Last but not least, Team number 4, Caila  
21 Brander; Chris Celeste; Melissa West; and Monica  
22 Weldon, please come up front. Thank you.

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1 DR. WHYTE: All right. Thank you, Noah.  
2 Let's get our teams and get ready. I know  
3 it's crowded up here, but it's going to be okay.  
4 So Team 1 is over there, Team 2, Team 3, and  
5 Team 4. So you have to pick one person to be your  
6 clicker, and you can huddle together. But we do  
7 need someone to sit here who can give the answer  
8 and to press the clicker.  
9 This is kind of like drug review, lot of  
10 people, lot of activity.  
11 Team 1, we need someone to take the lead.  
12 So I want to introduce you to Chad, who is our  
13 brains behind all of this and will control  
14 everything. To be fair, you're not going to be  
15 able to click in until the question is read. Like  
16 on real Jeopardy, I think you can click in at any  
17 time, but you have to click that on the top pretty  
18 hard. We always have people that say their clicker  
19 is not working. I'm not going to go for that. You  
20 go, hit it hard.  
21 Can we test it or no? Try to test it then.  
22 Yes. I think that's a government answer. I

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1 already checked them. They're all approved.  
2 They're kind of like a device.  
3 So may we start, Chad? Now, the computer  
4 will randomly decide who goes first. Is that how  
5 it works? So the categories are Acronym Soup,  
6 Drugs and Biologics, Play It Safe, Trials and  
7 Tribulations, and Advocacy Cheat Sheet.  
8 So where is Team number 2? Tell me your  
9 name. Calvin, go ahead and pick.  
10 TEAM 2: [Indiscernible – off mic].  
11 DR. WHYTE: IND, remember, in the form of a  
12 question. Team 2. Calvin, what's your answer?  
13 TEAM 2: Investigational new drug.  
14 DR. WHYTE: I'm going to need it in the form  
15 of a question, Calvin.  
16 (Laughter.)  
17 TEAM 2: What is an investigational new  
18 drug?  
19 DR. WHYTE: That is correct. Okay. Choose  
20 again, Calvin, your team.  
21 TEAM 2: Play it safe for 100, please.  
22 DR. WHYTE: Low numbers, okay. This center

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1 of the FDA evaluates new drugs before they can be  
2 sold, ensuring generic and brand-name drugs work  
3 correctly -- you guys aren't listening; you have to  
4 wait until I've finished reading -- and that their  
5 benefits outweigh their risks.  
6 Go. Is that Team 2? Yes. Team 2?  
7 TEAM 2: What is CDER?  
8 DR. WHYTE: What is CDER? That is correct.  
9 What does it stand for? I'll give it to you,  
10 Center for Drug Evaluation and Research. You've  
11 got to click right at the right time. You have to  
12 wait until I stop talking.  
13 Choose again, Team 2.  
14 TEAM 2: Drugs and Biologics for 300,  
15 please.  
16 DR. WHYTE: These type of drugs fill most of  
17 the prescriptions in the U.S., although they  
18 typically cost less than their brand-name  
19 counterparts -- you're not listening -- they're  
20 equivalent in terms of quality -- team 1, you're  
21 not listening -- performance, strength, and safety.  
22 Team 3?

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1 TEAM 3: Would that be generics?  
2 DR. WHYTE: Are you asking me or are you  
3 telling me? What is your question?  
4 TEAM 3: What is a generic?  
5 DR. WHYTE: Okay. What is a generic? Very  
6 good. Team 3, choose again.  
7 Okay. We're waiting.  
8 TEAM 3: Let's do Play It Safe for 500.  
9 DR. WHYTE: Play It Safe for 500. The FDA  
10 can require manufacturers to provide this safety  
11 strategy to manage serious, known, or potential  
12 risks associated with medicines and manage their  
13 use so that patients can continue using them. And  
14 there are multiple options for this.  
15 Team 1?  
16 TEAM 1: What is REMS?  
17 DR. WHYTE: What does REMS stand for?  
18 TEAM 1: Risk Evaluation Management  
19 Strategy.  
20 DR. WHYTE: I'm going to give it to you.  
21 What is REMS? That's one of the answers. Correct.  
22 (Laughter.)

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1 TEAM 1: Risk Evaluation and Mitigation  
2 Strategy.  
3 DR. WHYTE: Well, it's right in front of us.  
4 Okay.  
5 Team 1, choose again. Now we've got a game  
6 going on, people, except for Team 4.  
7 Team 1?  
8 TEAM 1: Advocacy Cheat Sheet for 500.  
9 DR. WHYTE: Advocacy Cheat Sheet for 500.  
10 Whoa! How much are you going to -- how much?  
11 TEAM 1: We're going to go all in.  
12 DR. WHYTE: 500, there you go. 500, she  
13 said. This organization engages its stakeholders,  
14 including patients, advocates, and healthcare  
15 professionals to improve their understanding of how  
16 the FDA approves and regulates drugs.  
17 Team 1, did you click? Is that right?  
18 TEAM 1: Yes, the PFDD. What is the PFDD?  
19 DR. WHYTE: No. What is Professional  
20 Affairs and Stakeholder Engagement? Remember,  
21 other people can click in when the -- you could  
22 have, yes. Remember, if the first person gets it

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1 wrong, other people can click in.  
2 But we're going to go back to Team 1 because  
3 no one else got it.  
4 TEAM 1: We'll do Acronym Soup for 500.  
5 DR. WHYTE: OND, Team 1? I know. Do it  
6 like that. Team 1, you had extra time.  
7 TEAM 1: Office of New Drugs.  
8 DR. WHYTE: In the form of a question.  
9 TEAM 1: What is the Office of New Drugs?  
10 DR. WHYTE: Very good. Team 1?  
11 TEAM 1: Drugs and Biologics for 500.  
12 DR. WHYTE: These products include vaccines,  
13 human blood, and blood components, human cells,  
14 gene therapy and tissues, gene-based and cellular  
15 products within this category at the forefront of  
16 biomedical research and may be used for conditions  
17 that lack other available treatments.  
18 You tried a new strategy. I didn't think it  
19 was going to work.  
20 TEAM 4: What are biologics?  
21 DR. WHYTE: What are biologics. That is  
22 correct. And look at you. It works after you said

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1 it doesn't. And look, you're tied for the lead  
2 after complaining.  
3 Team 4, choose again.  
4 TEAM 4: Let's try for Trials and  
5 Tribulations for 500.  
6 DR. WHYTE: Also known as compassionate use,  
7 this practice refers to the use of an unapproved  
8 investigational medical product outside of a  
9 clinical trial. Team 1?  
10 TEAM 1: What is the expanded access  
11 program?  
12 DR. WHYTE: That's correct. What is  
13 expanded access? Very good. Team 1, choose again.  
14 TEAM 1: Advocacy Cheat Sheet for 400.  
15 DR. WHYTE: This program helps consumers and  
16 healthcare professionals better understand who  
17 takes part in clinical trials by providing them  
18 with demographic data on the trial participants for  
19 FDA-approved new molecular entities.  
20 Team 3? You do get penalized if you get it  
21 wrong.  
22 Anyone else? Chime in. Team 1? It did.

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1 TEAM 1: What is a clinical drug snapshot?  
2 DR. WHYTE: No. That's not the exact  
3 phrase.  
4 Team 4?  
5 TEAM 4: What is clinical trials drugs  
6 snapshot, clinical trial snapshot?  
7 DR. WHYTE: It's just, what are drug trial  
8 snapshots? You didn't buzz in, he says.  
9 TEAM 4: Oh, perfect.  
10 DR. WHYTE: Let's just give her it. She's  
11 been complaining the whole time.  
12 (Laughter.)  
13 DR. WHYTE: We'll let her have it. Okay.  
14 All right.  
15 I know, I know, but -- okay. I'll let  
16 Team 1 choose. How's that?  
17 Okay. Fine. Chad wants to enforce the  
18 rules.  
19 Team 4?  
20 TEAM 4: Play It Safe for 400.  
21 DR. WHYTE: You're Team 1, but she agrees.  
22 Team 4. I don't know. Team 4. Yeah, it's all

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1 about collaboration.  
2 Play It Safe for 400. This is one of the  
3 many systems the FDA uses to collect reports on  
4 adverse drug events. There are a couple of  
5 answers. Team 3?  
6 TEAM 3: Would that be FDA MedWatch? What  
7 is the MedWatch?  
8 DR. WHYTE: What is the MedWatch program?  
9 That is one of them. Other answers are FAERS,  
10 Sentinel. That's correct. Yes.  
11 Team 3?  
12 TEAM 3: Let's do Advocacy Cheat Sheet for  
13 100.  
14 DR. WHYTE: For how much?  
15 TEAM 3: Sorry, for 300.  
16 DR. WHYTE: Three hundred. You're ordering  
17 off the menu. This FY, fiscal year, 2013-2017  
18 initiative seeks to gather patient perspectives on  
19 their conditions and available treatment therapies  
20 in a more systematic way to better inform the drug  
21 development and evaluation process.  
22 Team 1?

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1 TEAM 1: What is the PFDD?  
2 DR. WHYTE: What is the PFDD? Yes. That's  
3 correct, Patient-Focused Drug Development program.  
4 Choose again.  
5 TEAM 1: Play It Safe for 300.  
6 DR. WHYTE: Play It Safe for 300. This  
7 phase of the regulatory process occurs after the  
8 FDA has approved a drug or biologic product for  
9 marketing in the U.S. The FDA monitors these  
10 products to detect serious unexpected adverse  
11 events and takes action when necessary.  
12 TEAM 1: Phase 4 postmarketing, what is?  
13 DR. WHYTE: Go ahead. You're throwing a  
14 couple answers in that.  
15 TEAM 1: What is postmarketing?  
16 DR. WHYTE: You said phase 4. I'll give you  
17 that.  
18 TEAM 1: Phase 4.  
19 DR. WHYTE: Go ahead. We'll count that,  
20 postmarketing surveillance, but it's often referred  
21 to as a phase 4.  
22 Choose again. Everyone can still get in

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1 this, even Team 2.  
2 TEAM 1: Trials and Tribulations for 400.  
3 DR. WHYTE: This landmark legislation,  
4 enacted in 2016, builds on the FDA's critical path  
5 initiative efforts to foster innovation in the  
6 scientific processes for developing manufacturing  
7 and evaluating medical products.  
8 Team 2?  
9 TEAM 2: What is FDASIA?  
10 DR. WHYTE: No. That's wrong.  
11 Team 1?  
12 TEAM 1: What is 21st Century Cure?  
13 DR. WHYTE: What is 21st Century Cure?  
14 That's correct.  
15 You have gotten it, though, at times, so you  
16 can't use that excuse.  
17 Team 1 again. See, I think you're going too  
18 much like this. I don't know. Ask Team 1 what  
19 they're doing. Team 1 seems to be good at it.  
20 Team 1?  
21 TEAM 1: We'll take Play It Safe for 200.  
22 DR. WHYTE: We're going to clear that up.

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1 These entities are required to report adverse drug  
2 events to the FDA. They're required.  
3 Team 1?  
4 TEAM 1: What are pharmaceutical companies?  
5 DR. WHYTE: Yes, or manufacturers, yes.  
6 We'll accept that. What is manufacturers, packers,  
7 or distributors of products in question?  
8 Yes. Go ahead. Team 1.  
9 TEAM 1: We'll take Acronym Soup for 200.  
10 DR. WHYTE: NME? Team 3?  
11 TEAM 3: What is new molecular entity?  
12 DR. WHYTE: That is correct, Team 3. Very  
13 good. We're having a change of players.  
14 Go on. Team 3, choose again.  
15 TEAM 3: Let's do Acronym Soup for 300.  
16 DR. WHYTE: We had a practice, and there  
17 were plenty of people that said that, too.  
18 PDFUA. Team 2? Remember, give me all the  
19 letters.  
20 TEAM 2: What is the Prescription Drug User  
21 Fee Act?  
22 DR. WHYTE: Very good. You don't need the

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1 rest of that.  
2 Team 2, choose again.  
3 TEAM 2: Can we please have Acronym Soup for  
4 400?  
5 DR. WHYTE: Of course you can. Thank you  
6 for being so polite. GDUFA.  
7 Team 4? I guess it works, team 4.  
8 TEAM 4: Generic Drug User Fee Act.  
9 DR. WHYTE: Correct. Yes, thank you. Very  
10 good. Choose again. Wouldn't that be crazy if  
11 you're almost in the lead?  
12 Drugs and Biologics for 400. It clearly  
13 works. We hear this on devices all the time. Also  
14 known as the prescribing information or package  
15 insert, this informative communication provides  
16 healthcare professionals the necessary information  
17 to appropriately prescribe drugs for safe and  
18 effective use. Team 1?  
19 TEAM 1: What is a drug label?  
20 DR. WHYTE: What is the drug label? That's  
21 correct. And you are clicking it from the  
22 beginning. You maneuvered it well. Very good.

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1 Team 1, go again.  
2 TEAM 1: We'll do Trials and Tribulations  
3 for 300.  
4 DR. WHYTE: This entity seeking to market a  
5 drug is responsible for its development and proving  
6 it is safe and effective.  
7 Team 3?  
8 TEAM 3: What is the sponsor?  
9 DR. WHYTE: What is the sponsor? We'll  
10 accept that. It could be drug manufacturer, or  
11 distributor, et cetera.  
12 Team 3, choose again. I like your  
13 strategies. You click, and then you figure out the  
14 answer. That's good.  
15 (Laughter.)  
16 TEAM 3: I looked at the team. Let's do  
17 Advocacy Cheat Sheet for 200.  
18 DR. WHYTE: These free public seminars  
19 welcome patients, caregivers, and other members of  
20 the public to present data, information, or  
21 viewpoints on issues pending before the FDA  
22 committee.

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1 Team 1?  
2 TEAM 1: What is the drug advisory  
3 committee?  
4 DR. WHYTE: What's the answer to that, drug  
5 advisory committee? Sure. Let's accept it.  
6 What's the answer? Yes, let's see it. Yes.  
7 Accept it. I was going to be a stickler. They're  
8 sponsored public meetings, but they are similar, so  
9 we won't be too harsh. We'll demonstrate agency  
10 flexibility.  
11 (Crosstalk.)  
12 TEAM 1: Do Advocacy for 100.  
13 DR. WHYTE: This is one of the many ways  
14 patients and advocates can be more involved in the  
15 FDA's drug evaluation and approval process.  
16 Team 1?  
17 TEAM 1: The Patient Representative Program.  
18 DR. WHYTE: Okay. That works. Sure.  
19 There's multiple ways you heard about them today.  
20 You're right. We did give them a warning,  
21 and he insisted I use enforcement discretion. So  
22 we're going to give them a negative on that because

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1 they said you didn't answer it in the form of a  
2 question, and they said you were given warnings.  
3 This is your crowd, but we'll let you choose again.  
4 The rules are the rules. I mean, why do we have  
5 rules?  
6 TEAM 1: We'll do Trials and Tribulations  
7 for 200.  
8 DR. WHYTE: Trials and Tribulations for 200.  
9 This phase of clinical trials is typically the  
10 final phase before approval and involves human  
11 subjects to establish the safety and effectiveness  
12 of a drug.  
13 Team 3?  
14 TEAM 3: Wouldn't that be phase 3? What is  
15 phase 3?  
16 DR. WHYTE: That is correct. What is phase  
17 3? Very good. See, you learn.  
18 TEAM 3: I'm phrasing the question a little  
19 weird.  
20 DR. WHYTE: That's good. Finally, our last  
21 couple questions.  
22 Team 3, choose again.

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1 TEAM 3: Yes. Let's do Drugs and Biologics  
2 for 200, please.  
3 DR. WHYTE: These drug products are safe and  
4 effective for consumers to use without a doctor's  
5 prescription. Go ahead.  
6 TEAM 1: What are over-the-counter drugs?  
7 DR. WHYTE: That's correct. What are over-  
8 the-counter drugs?  
9 Team 1?  
10 TEAM 1: Drugs and Biologics for 100.  
11 DR. WHYTE: A substance intended for use in  
12 diagnosing, curing, mitigating, treating, and  
13 preventing a disease.  
14 Team 2?  
15 TEAM 2: What is a medication?  
16 DR. WHYTE: I'm going to say no. Who else?  
17 Because medications can be multiple things.  
18 TEAM 3: What is a drug?  
19 DR. WHYTE: What is a drug? That is the  
20 correct answer.  
21 Team 3, the last question. Are we having a  
22 Jeopardy question, though? Do we have a final

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1 Jeopardy? Okay.  
2 So Trials and Tribulations for 100, this  
3 drug evaluation study is designed to answer  
4 specific questions and discover if promising new  
5 treatments are safe and effective for patients.  
6 Team 1?  
7 TEAM 1: What is a clinical trial?  
8 DR. WHYTE: What is a clinical trial? That  
9 is correct. Excellent.  
10 So let's move to our final Jeopardy  
11 question. Now, can people bid whatever they want?  
12 Is that how it works? Don't people have to put  
13 their bids in now or something?  
14 Now you can wager. Team 1, how much are you  
15 going to -- are you going to wager at all? Are you  
16 all in?  
17 TEAM 1: We're going to go for 100.  
18 DR. WHYTE: Oh my. Okay. Fine. Yes.  
19 Team 2?  
20 TEAM 2: We're betting everything we have.  
21 DR. WHYTE: Good. You wouldn't even be  
22 eligible to be in it, but okay, we'll let you play.

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1 Team 3?  
2 TEAM 3: We are all in.  
3 DR. WHYTE: Okay. And Team 4?  
4 TEAM 4: All in.  
5 DR. WHYTE: Team 1, you sure you don't want  
6 to bid like \$210 or something?  
7 TEAM 1: We'll go 199.  
8 (Laughter.)  
9 DR. WHYTE: Let's see that final question.  
10 Remember, I give you the answer -- no. It's  
11 supposed to be the other way around. This is a  
12 hard one, then.  
13 The number of new molecular entities CDER  
14 approved in 2016. This wasn't the question that I  
15 was expecting.  
16 (Crosstalk.)  
17 DR. WHYTE: Yes. Yes. It does have to be  
18 exact. One second. Can they choose now? Buzz in.  
19 (Crosstalk.)  
20 DR. WHYTE: Let's have team 2 answer first.  
21 We'll have everyone answer, and then I'll tell you  
22 the right answer.

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1 TEAM 2: Since we have nothing riding on  
2 this, what is 13?  
3 DR. WHYTE: Okay. What about Team 1?  
4 TEAM 1: What is 16?  
5 DR. WHYTE: Okay. They're both wrong.  
6 What about Team 3? Team 3?  
7 TEAM 3: Thirteen. What is 13?  
8 DR. WHYTE: Didn't someone else say 13? And  
9 I said he was wrong, and you're wrong, too.  
10 (Laughter.)  
11 DR. WHYTE: Team 4, what's the answer?  
12 TEAM 4: Twenty-two.  
13 DR. WHYTE: Twenty-two is correct.  
14 TEAM 4: We got there at the end.  
15 DR. WHYTE: Well, no, because Team 1 only  
16 bid 199, so they're still going to be higher  
17 TEAM 1: You only lost by a dollar.  
18 DR. WHYTE: Yes. You only lost by a dollar  
19 with a broken clicker and unhappiness. But you all  
20 did very good. Clearly, you've learned a lot.  
21 So congratulations to Team 1, who pulled it  
22 out. You only lost by a dollar.

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1 (Applause.)  
2 DR. WHYTE: You did well. You won. Sadly,  
3 you can only have one winner in Jeopardy, but  
4 you're all winners in our book.  
5 Now we're going to talk a little bit about  
6 social media. I'll be honest. We're not always  
7 the best at social media, tweeting, and Facebook,  
8 et cetera, but we've made tremendous progress,  
9 especially in the Office of Communications.  
10 I'm very happy to introduce my colleagues  
11 from OCOM, our social media lead, Kim Chiu, as well  
12 as Raj Patel, who are going to talk about knowing  
13 the moment it happens, CDER's social media program.  
14 Now for Raj, he is from a family of eight  
15 pharmacists, so I'm sure there's lots of  
16 interesting discussions around the dinner table.  
17 And Kim is five months pregnant and expecting her  
18 first child. So what can be more fun than that?  
19 Until it comes to staying up late and changing  
20 diapers.  
21 So they're going to tell us about tweeting,  
22 and social media, and all those good things. So

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1 it's a duo, a powerful duo that's going to speak.  
2 Presentation – Kimberly Chiu  
3 DR. CHIU: Thank you, Dr. Whyte.  
4 As he mentioned, my name is Kimberly Chiu,  
5 and I am CDER's social media lead. And with me is  
6 my colleague, Dr. Raj Patel. We are here to  
7 present on CDER's social media program, which is  
8 designed to help the public, including patients,  
9 stay informed with the latest drug information.  
10 Now, a quick disclaimer before we begin.  
11 Neither one of us have backgrounds in social media.  
12 We're actually both pharmacists, healthcare  
13 providers who care deeply about patient safety and  
14 understand the importance of health communications  
15 and education.  
16 Also, being from the communications office,  
17 we understand and recognize that the public does  
18 not come to FDA's website for their information.  
19 So that's why part of our goal for this program is  
20 to make sure that we are pushing this information  
21 to where our audiences are. And in today's era,  
22 that also includes social media.

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1 It should be noted that patients are by no  
2 means the only target population for this program.  
3 For example, we also target healthcare providers  
4 among our audience, so physicians, nurses, and  
5 other pharmacists.  
6 Now, I'm going to turn it over to Dr. Patel,  
7 who is going to go into further detail about each  
8 of CDER's social media channels.  
9 Presentation- Raj Patel  
10 DR. PATEL: Can everyone hear me okay?  
11 Thank you. So as Dr. Chiu mentioned earlier, we're  
12 from the Office of Communications, but more  
13 specifically, we're from the Division of Drug  
14 Information.  
15 The offices consist of the Division of  
16 Online Communications, the Division of Health  
17 Communications, and the Division of Drug  
18 Information or DDI for short.  
19 DDI is the focal point for public inquiries  
20 regarding human drug products as well as center  
21 initiatives. Our mission is to optimize CDER's  
22 education and communication efforts to our global

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1 community, and we accomplish this by engaging in  
2 effective internal and external interactions to  
3 provide timely, accurate, and useful information  
4 through both our traditional channels as well as  
5 our social media channels.  
6 DDI is staffed with a team of pharmacists  
7 and other healthcare professionals who answer  
8 public inquiries that are received by both  
9 telephone, e-mail, social media, as well as  
10 traditional mail. So on average, our office  
11 responds to over 3700 phone calls, over 1400 e-  
12 mails, and about 64 letters each month.  
13 How do we disseminate CDER communications?  
14 We utilize several different platforms in order to  
15 disseminate information to our stakeholders. We  
16 initially began in 2010 with our @fdadruginfo  
17 Twitter handle, as well as drug safety  
18 communication podcasts.  
19 From there, we've grown to using Facebook as  
20 well as LinkedIn and other platforms, which we'll  
21 discuss further on in the presentation. Each  
22 platform provides us a unique audience to reach and

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1 to provide timely information to.  
2 We'll first begin with our Twitter page.  
3 And just by a show of hands, how many of you follow  
4 us on Twitter?  
5 (Show of hands.)  
6 DR. PATEL: Good. I see some hands out  
7 there, so I'm happy to hear that. As I previously  
8 mentioned, we created our Twitter account in 2010,  
9 and we had just a few followers at the time. And  
10 from there, we've grown to having more than 224,000  
11 followers.  
12 What's great about Twitter is that it has a  
13 140-character limitation, so this allows you to get  
14 short bits of information that you can overview at  
15 a glance and then determine if that information is  
16 pertinent to you as you scroll through your Twitter  
17 feed.  
18 We're also on Facebook, and currently we  
19 have 511,000 fans of our Facebook page. One  
20 important thing to note about the FDA's Facebook  
21 page is that CDER is not the only center within the  
22 agency that provides communications on the Facebook

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1 page, so you'll see communications from each of the  
2 centers within the agency.  
3 We're also on Pinterest. The agency's on  
4 Pinterest. And what we have is a drug-topic-  
5 specific board that provides drug approvals, drug  
6 safety communications, as well as drug trial  
7 snapshots that we discussed earlier today, and so  
8 has more information.  
9 So this provides a visual way to see our  
10 communications, and it's managed by our sister  
11 division, the Division of Online Communications.  
12 So what you can do is you can pin drug topics that  
13 are interesting to you, add them to your own  
14 personalized board, and this way it's very much  
15 individualized to what your needs are.  
16 The agency is also on LinkedIn. We have a  
17 LinkedIn page to target professionals, so feel free  
18 to follow us on LinkedIn to receive notifications  
19 about drug approvals as well as other drug safety  
20 information.  
21 In addition to our main FDA LinkedIn page,  
22 we have a LinkedIn group specifically for

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1 pharmacists called the Global Alliance of Drug  
2 Information Specialists or GADIS for short. The  
3 purpose of this group is really to target  
4 pharmacists.  
5 We recognize that pharmacists are an  
6 integral component of patient care, so we wanted to  
7 provide timely information to this important group  
8 of healthcare providers, so we have this special  
9 group for them.  
10 We also have another great platform that we  
11 use to disseminate information to our stakeholders,  
12 our drug information listserv. What's great about  
13 the listserv is that you're in control, so you can  
14 determine how often you receive communications from  
15 us. So you can control whether you receive  
16 information on a daily basis, a weekly basis, or a  
17 monthly basis.  
18 In addition, we also produce drug safety  
19 podcasts. The drug safety podcasts are for  
20 healthcare providers so that we can provide them  
21 with emerging safety information in conjunction  
22 with the release of a drug safety communication.

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1 And I personally love the podcasts. What I really  
2 enjoy about the podcasts is that it gives our  
3 stakeholders an ability to be on the go.  
4 So you can listen to these podcasts from a  
5 mobile device, your laptop, or an mp3 player. So  
6 this allows you to have the flexibility of  
7 listening to important communications from the FDA  
8 while you're driving to work or at the gym. And  
9 our podcasts are available on iTunes, they're  
10 available on ReachMD, as well as our FDA webpage.  
11 What is the type of information that we  
12 disseminate using these different platforms? We  
13 disseminate drug approvals as well as drug safety  
14 communications, important drug safety alerts like  
15 product recalls, meeting announcements such as this  
16 PASE meeting, as well as tainted dietary supplement  
17 products, as well as health campaigns and a lot  
18 more.  
19 At this time, I want to hand it over back to  
20 Dr. Chiu, who will discuss how we engage our  
21 stakeholders on social media.  
22 DR. CHIU: Thank you, Raj. So after the



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1 communication is disseminated through CDER's  
2 various social media channels, the Division of Drug  
3 Information or DDI will then begin monitoring and  
4 responding to comments that we receive through  
5 these channels. So during this next half of the  
6 presentation, we're going to focus on the social  
7 part of social media or engaging with our  
8 audiences.

9 We thought this may be best done through a  
10 real-life example to help take you through this  
11 timeline of events. And some of you may be  
12 familiar with this recent recall with EpiPen and  
13 EpiPen Jr.

14 A little bit of background about this  
15 recall, the firm recalled certain lots of EpiPen  
16 and EpiPen Jr. after the firm had received reports  
17 of two devices failing to activate. Now, this  
18 occurred outside of the United States, but out of  
19 an abundance of caution, the firm decided to also  
20 include lots or batches that were also distributed  
21 within the United States.

22 This communication posted on March 31st, so

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1 a little over a month ago. And once it posted and  
2 was made available online, CDER pushed it through  
3 our social media channels. And through these  
4 efforts, we were able to reach over 165,000  
5 subscribers of our e-mail listserv. Our tweet made  
6 over 12,000 impressions. The Facebook post reached  
7 over 365,000 individuals. Then also, on the GADIS  
8 LinkedIn group, we were able to reach over 140  
9 members at the time.

10 So after disseminating this recall notice,  
11 we then begin monitoring for the comments and  
12 questions from the public. It should be noted,  
13 though, that at this time, unfortunately, we only  
14 have the resources to engage with our audiences on  
15 the Facebook platform, but we are expanding and  
16 looking to engage with folks in the near future  
17 hopefully on Twitter soon.

18 So on the Facebook post, we received about  
19 250 comments. Now, the large majority of these  
20 comments were actually not directed to the agency.  
21 They were folks tagging their friends or family  
22 members, making sure that they saw the recall

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1 notice and making sure that it showed up in their  
2 Facebook feed.

3 Of the comments that the agency did receive,  
4 you can see on the slide highlights some of the  
5 common themes that we saw. So they were things  
6 such as will the firm issue refunds or  
7 replacements. Some expressed that they needed help  
8 with the recall process. And we also received  
9 comments about the general cost of these products  
10 in general as well.

11 So the agency will respond. We will answer  
12 questions, and we will address concerns to the best  
13 of our ability. One example on the right, we've  
14 received a question asking whether or not patients  
15 would be responsible for the payment of these  
16 replacement recalled products. And we were able to  
17 direct them to the firm's commitment to replacing  
18 these products free of charge.

19 We will also address misinformation and  
20 mistruths that we find on the Facebook page that we  
21 believe challenge our mission to protect the public  
22 health's health. So on the left-hand side, you'll

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1 see an example of an individual that promoted the  
2 use of an epinephrine product that's labeled for  
3 animal use and as an alternative to these recalled  
4 EpiPen and EpiPen Jr. products. So we warned  
5 patients not to use products that are not FDA  
6 approved for human use and also make sure that they  
7 refer to their healthcare provider before using any  
8 products.

9 It's important to remember that social media  
10 is only one small part, one cogwheel, of the  
11 overall communications landscape. At the Division  
12 of Drug Information, we still receive e-mails,  
13 phone calls, and even handwritten letters. And we  
14 want to make sure that we make ourselves available  
15 through the channels that patients and the public  
16 want to engage with us on.

17 We will also engage with the public through  
18 social media events. We will host and also  
19 participate in social media events, including live  
20 tweets and Twitter chats. For live tweets, for  
21 those of you who may not have had an opportunity to  
22 participate in one, these are when you send tweets

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1 while an event is occurring, for example an  
2 in-person presentation or a meeting. And what's  
3 great about live tweets is that it takes an event  
4 that may have only been accessible by attending in  
5 person and then bringing it to a larger audience  
6 that may only be able to participate online.  
7 So here's an example of a recent live tweet  
8 event that we did. It was an FDA meeting that  
9 discussed the possibility of over-the-counter  
10 monograph user fees for industry. This was an all-  
11 day FDA meeting, and we tweeted highlights from  
12 various speakers' presentations. We also tweeted a  
13 picture from the room so that folks online could  
14 feel as if they were there or at least get a sense  
15 of what the room felt like. And we also monitored  
16 for tweets looking for any common concerns or any  
17 questions that we could address during the event.  
18 As I mentioned previously, we also host and  
19 participate in Twitter chats. Twitter chats are  
20 live Twitter events where folks can come together  
21 online, and learn and talk about a specific topic,  
22 and they do this through an identified hashtag.

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1 This is a recent Twitter chat that we  
2 participated in that was hosted by our colleagues  
3 from the Office of Women's Health, and the topic  
4 was Safe Medication Use and Other Tips During  
5 Pregnancy. So CDER, we were able to support on  
6 that safe medication use piece.  
7 That's our presentation. Thank you very  
8 much for the opportunity to present on our social  
9 media program. We'll take any questions that you  
10 may have. And if you would ever like to reach out  
11 to us individually, please feel free to do so  
12 through our listed e-mail addresses. Thank you.  
13 (Applause.)  
14 Questions and Answers  
15 DR. CHIU: And I see we have one question.  
16 MALE AUDIENCE MEMBER: So I just have a real  
17 quick question. Can you give an idea of when you  
18 have an event that happens like maybe with the  
19 EpiPen example that you gave or something like  
20 that, how something like that and then reaction to  
21 that can inform you for the next time that  
22 something like that happens?

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1 DR. CHIU: So for the EpiPen, for something  
2 like this, sometimes we have advance notice that  
3 communication will be coming, so we want to make  
4 sure that we get that information out as soon as  
5 possible. So our team will actually stay on call,  
6 stay through late at night, until the information  
7 posts so we can get it out as soon as possible.  
8 Then we begin the monitoring process, and we  
9 collect the information, and we report it up to  
10 Dr. Woodcock, to the other office directors and say  
11 these are some of the questions that we're getting.  
12 These are some of the common concerns that we seem  
13 to be getting about this specific recall. Is there  
14 that we can do?  
15 Sometimes we'll issue follow-up  
16 communications, or sometimes we'll reach out to the  
17 firm or see if there's something else that needs to  
18 be tweaked. But we definitely take those comments  
19 that we receive, not just from social media, but  
20 through the phones and the other channels that we  
21 get, and we definitely use those.  
22 Any other questions?

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1 DR. WHYTE: That's our Twitter handle.  
2 Right? Do you have any other CDER Twitter pages?  
3 DR. CHIU: No. We just have that one  
4 Twitter handle.  
5 DR. WHYTE: Good. So follow us on Twitter.  
6 DR. CHIU: Yes, please.  
7 DR. WHYTE: We have to get ahead of Dr. Oz  
8 in the Twitterverse.  
9 (Laughter.)  
10 DR. WHYTE: So now, I'm going to introduce  
11 you to Shawn Brooks. His fun fact is, when he was  
12 a professional football player -- remember Regis  
13 and Kathy? He was on Regis and Kathy, he says,  
14 defending Shaq O'Neal in a basketball game, but I  
15 read what I'm told.  
16 Shawn?  
17 Audience Response Questions  
18 MR. BROOKS: It's the truth, by the way, and  
19 good afternoon. So we're on to the next portion  
20 for our audience response questions. You have your  
21 clickers readily available, and we'll have about 20  
22 seconds to answer each of the questions, statements

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1 that are presented to you.  
2 Ready? First statement, please rate your  
3 level of agreement or disagreement with the  
4 following statement. Following the how to get your  
5 voice heard presentation, I feel that I have the  
6 necessary information and resources to request a  
7 meeting with the FDA.  
8 A is strongly agree; B is somewhat agree; C,  
9 neutral; D, somewhat disagree; and E, strongly  
10 disagree.  
11 (Audience answers.)  
12 MR. BROOKS: It looks like everyone is  
13 there. Somewhat agree, very nice and strongly  
14 agree, so good showings there. And for the  
15 6 percent that doesn't have it, we're certainly  
16 available to discuss and see where you might be  
17 feeling like you're not as confident about  
18 interacting or engaging with the FDA.  
19 Next question, please. You can engage with  
20 the FDA using the following communication channels.  
21 A, Facebook; B, Twitter; C, e-mail; D, phone call;  
22 E, postal delivery letter; or F, all of the above.

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1 (Audience answers.)  
2 MR. BROOKS: Looks like we have 98 percent  
3 correct, so it's all of the above. For the  
4 Facebook folks, you were partially correct,  
5 considering the presentation we just had, but it's  
6 all of the above.  
7 (Laughter.)  
8 MR. BROOKS: Next. The status of any drug  
9 currently under review is public information, true  
10 or false?  
11 (Audience answers.)  
12 MR. BROOKS: Looks like everyone's in.  
13 There we go, 67 percent said false, 33 percent said  
14 true. The answer is false.  
15 DR. WHYTE: That's an important point, which  
16 we talked about earlier. Because it's not public  
17 information, we often can't discuss it. That  
18 doesn't mean that we're not interested in the issue  
19 or we're trying to be obstructive. That actually  
20 is the rule of the law.  
21 MR. BROOKS: Drug manufacturers are required  
22 to report adverse events from a drug to the FDA. A

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1 is true; B is false.  
2 (Audience answers.)  
3 MR. BROOKS: And the answer is true,  
4 96 percent. Very nice. So yes, drug companies are  
5 required.  
6 Thank you.  
7 (Applause.)  
8 DR. WHYTE: So now, you listened to the FDA  
9 since about 9:00 a.m. this morning, we wanted the  
10 opportunity to hear from folks that have had a lot  
11 of interaction with the FDA and can tell you what  
12 their tips are, what their best practices have been  
13 in terms of engaging and interacting with the  
14 agency.  
15 So it's completely uncensored and  
16 unfiltered. They can say what they want. I'm  
17 delighted to welcome up to the stage Cynthia Bens,  
18 who's the vice-president of public policy for the  
19 Alliance for Aging Research.  
20 Now, her fun fact is, she spent six years as  
21 a fashion model through high school and college  
22 before graduating and starting her career in public

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1 policy. But what I love about Cynthia, she  
2 included an "alternative" fact.  
3 (Laughter.)  
4 DR. WHYTE: But I think it actually is a  
5 fact in this setting. And her alternative  
6 fact -- and it actually says that -- is that she  
7 and her husband have made it a goal to visit all of  
8 the countries where their ancestors came from to  
9 better understand their heritage. So far, they've  
10 visited six countries.  
11 I will tell you, I was in Hamburg, Germany  
12 for a DIA Europe meeting, and there's Cynthia Bens  
13 in the audience. So I don't know if that was on  
14 your circuit at the time, but welcome.  
15 Now, are the two of you going to sit  
16 together, or talk independently, or how are you  
17 going to do it?  
18 I also want to welcome Jane Larkindale,  
19 who's the vice-president of research and  
20 development for the Friedreich's Ataxia Research  
21 Alliance, and she's been deeply involved in the  
22 externally-led PFDDs. You might want to talk about

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1 that on June 2nd.  
2 Her fun fact is, she's lived in big cities  
3 in seven countries, and then finally settled on the  
4 edge of Tucson, Arizona with a garden full of  
5 cacti, a resident bobcat, a javelina, which Noah  
6 and I looked up, and multiple desert creatures. So  
7 that's kind of like some big cities, too, in a way.  
8 So the time is yours. Say what you feel  
9 comfortable with, but the goal really is for all of  
10 you to hear from folks who have engaged fairly  
11 regularly and extensively with the agency. And I  
12 hope it's been in a good way, but I'll let you  
13 speak. Thank you.  
14 Presentation – Cynthia Bens  
15 MS. BENS: Thank you, everyone, for the  
16 opportunity to be here. I really think that this  
17 is an incredibly important meeting. I know I had  
18 the opportunity attend last year as well, and it's  
19 very humbling when the FDA recognizes you and your  
20 organization as a pro for engaging with CDER.  
21 I can honestly say everything that we've  
22 been able to accomplish in working with CDER and

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1 the disease areas we care about has only been  
2 because communication really is a two-way street,  
3 and we found that -- I know you had a presentation  
4 earlier today called "Have Your Voice Heard," and  
5 FDA has made it incredibly easy for us to have our  
6 voice heard. But it also takes a lot of work, so  
7 I'll walk through some steps with you.  
8 But before I start with the two examples I'm  
9 going to give today. I'll give you a bit of  
10 background on the Alliance for Aging Research. It  
11 was started 30 years ago because there was no  
12 organization that existed that was focused on the  
13 importance of prioritization of research into the  
14 aging process and to apply it in ways that help  
15 keep people healthier and more independent longer.  
16 When we initially started out, like a lot of  
17 groups that are here, I know we were focused on  
18 things like NIH funding for research, and we still  
19 very much to this day care about that. But it was  
20 about 11 years ago, when we started to look at the  
21 pace of application of research in specific disease  
22 areas and the problems that were happening with

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1 actually translating that into interventions for  
2 some really challenging diseases of aging.  
3 So the first example I'm going to talk about  
4 is work that we've done in the areas of Alzheimer's  
5 disease. We looked at Alzheimer's because of the  
6 increasing prevalence that was going to be coming,  
7 but also because there were a number of companies  
8 that were looking to develop treatments for  
9 Alzheimer's, and we're having a very tough time  
10 actually getting better treatments to market for  
11 Alzheimer's.  
12 We were all incredibly frustrated at the  
13 time we started the organization, Accelerate Cures  
14 and Treatments for Alzheimer's Disease. There were  
15 15 of us. We were all nonprofits, and we wanted to  
16 have our voice heard. And we were surprised that  
17 there was no single voice that was communicating  
18 directly with the Food and Drug Administration on  
19 ways to get past the hurdles with clinical trials  
20 for Alzheimer's.  
21 So we quickly grew the coalition to 53  
22 nonprofit members is what we have today. We have

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1 aligned ourselves with a number of experts in  
2 Alzheimer's disease, and we are very open about the  
3 way that we interact with the drug industry, and  
4 I'll talk a bit about that more.  
5 But when we first started, there was no  
6 Patient-Focused Drug Development initiative. There  
7 was really the Office of Constituent Affairs and  
8 Stakeholder Engagement. At the time, it was called  
9 OCSE, where we had to start beating on the door  
10 with saying that you have had a very proactive  
11 response in some disease areas like cancer, and  
12 HIV, and AIDS. And we know that Alzheimer's is  
13 going to be that big a deal, and we want to make  
14 sure that we're doing everything we can as  
15 advocates to get to the point of effective  
16 treatment.  
17 We were fortunate that one of the first  
18 things that the Office of Health and Constituent  
19 Affairs did for us was get us a meeting with the  
20 commissioner. We went in at the time with our  
21 leadership, and it was 10 other groups that now  
22 formed the advisory board in the nonprofit, the

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1 nonprofit side of our advisory board. And we asked  
2 for a number of different things because we did our  
3 homework and we saw why HIV-AIDS and the cancer  
4 community were so successful at getting to the  
5 point they were at.  
6 It was a couple things. The first is, there  
7 was representation from the patient community on  
8 every opportunity, every advisory committee that  
9 there could be, and there wasn't a program for  
10 there to be a patient and caregiver representative  
11 for Alzheimer's.  
12 So we asked for that in our meeting. That  
13 was our first ask, would you please set up a  
14 patient representative program for Alzheimer's  
15 disease? And FDA said, sure. You need to help us  
16 get the patients and caregivers. And we were like  
17 we can deliver that. So that was success number  
18 one.  
19 The second thing we asked for was the  
20 ability for the different centers and offices that  
21 have a hand in looking at new drugs for  
22 Alzheimer's, that they had the ability to, in some

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1 way, have an informal group where they talked to  
2 each other.  
3 We thought it should be more formal. We  
4 asked for an office of Alzheimer's, and they said  
5 we're not doing that, but they established  
6 something called the Neurology Across FDA Working  
7 Group. And the great thing about that group is it  
8 was actually co-chaired from the start by Bob  
9 Temple. So they took it very seriously, and it's  
10 active to this day. They talk about ways that they  
11 can share expertise on neurology issues, so it's  
12 broader than just Alzheimer's.  
13 The last thing that we asked for, for  
14 Alzheimer's, was the ability to work with the  
15 review divisions on an annual meeting because we  
16 know that it's really difficult for people from the  
17 review divisions to go to every scientific meeting  
18 that's out there for a particular disease.  
19 So they said, sure, we'll work with you on  
20 an annual meeting. We're going to be having our  
21 10th one in November. And what we did was we  
22 wanted to identify areas where there wasn't just a

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1 specific problem with one company's drug and one  
2 type of trial. We wanted to look at those areas  
3 that were really cross-cutting, where all of the  
4 companies seemed to have sticking points with  
5 looking at the populations of patients with  
6 Alzheimer's disease, selecting endpoints, measuring  
7 what actually matters to patients, so what would a  
8 clinically meaningful benefit actually be to  
9 patients. We talk about this in a three-quarter-  
10 day meeting, and it's a really robust discussion,  
11 and FDA does participate quite a bit.  
12 We even got to the point to where, about  
13 halfway through our sessions with FDA, they suggest  
14 back topics to us where they see that there's  
15 particular sticking points where there's a need for  
16 more research, a need for more input from a  
17 specific community, and even looking at things like  
18 combination therapy.  
19 We don't even have one disease-modifying  
20 drug for Alzheimer's yet, and FDA said we think  
21 we're going to get to a point with you where  
22 there's going to be a need for combinations, and we

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1 want to start talking about that and how we can  
2 actually make that a reality.  
3 So unfortunately, we don't have an approved  
4 therapy that's better than the ones that are  
5 currently on the market, but we feel like we really  
6 have had some success with Alzheimer's in that area  
7 and with FDA.  
8 We took our success and working in cognitive  
9 impairment in older adults and started looking at  
10 physical frailty in the elderly. This is a  
11 coalition called Aging in Motion that we started.  
12 We're the chair of it. There's 35 nonprofit  
13 organizations. As you can see in a similar model,  
14 we align ourselves with the scientific experts in a  
15 specific disease area.  
16 Then we also work with industry. And what's  
17 unique about sarcopenia and functional decline in  
18 older adults is it's not just pharmaceuticals.  
19 It's actually nutrition interventions, and there's  
20 going to be an imaging component as well to  
21 diagnosing sarcopenia. So we bring everybody under  
22 the tent, and we come up with what our agenda

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1 should be.

2       What's been really unique for this coalition

3 is, unlike Alzheimer's disease, where there is a

4 lot of entrenched attitudes about how you approach

5 drug development, it's really a blank slate. We

6 saw that there was 25 years of research into this

7 condition. We were compelled by the numbers of

8 people who would potentially be diagnosed with it

9 and the rates of institutionalization that would

10 come as a result of it. So we really felt that

11 this is something that was ripe for us to play a

12 role in convening folks.

13       So we've done a couple of different things.

14 The first, we were surprised that sarcopenia in the

15 aging space is a household name, but it wasn't a

16 diagnosed condition yet. So we first had to take

17 on working with the CDC to get a diagnosis code for

18 it, which is a totally new process that took us two

19 years, but we now have one. So it's formally

20 recognized as a condition.

21       The second thing we noticed is that in

22 clinical trials, there was a real paucity of

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1 endpoints. While there were a number of tools

2 validated for use in looking at sarcopenia, none of

3 them were at the point where they could be

4 recognized for use as outcome measures.

5       So naively, we took on the role as the

6 leading organization to start going through the

7 qualification process for functional measures for

8 this disease. I'm sure many of you are familiar

9 with this process. It's fairly long. But it has

10 had a really positive effect in getting the

11 community who recognized ways that you would

12 measure functional impairment from sarcopenia to

13 notice that there's a need to now bring the patient

14 and caregiver voice into the process to understand

15 the tools that are already out there that people

16 want to use as endpoints, are they really measuring

17 what matters most to patients?

18       So we're the ones that are working with

19 qualitative researchers to actually produce that

20 data, and then if we're successful in making it

21 through the qualification process, like every other

22 tool that's gone through that process, it'll be

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1 publicly available for everyone to use.

2       So it's not like any one company will have

3 the benefit of having ownership of the endpoint and

4 people who have just an idea about pursuing a

5 program will be able to use it as well. So we're

6 excited about that.

7       Then the last thing that we did, we just

8 thought that this was an area where FDA needed to

9 have a bit more understanding of the patient and

10 caregiver experience with the disease. So we just

11 submitted comments like anyone else through the

12 Federal Register notice to have a disease added to

13 the list of 20 that was funded under PDUFA V for a

14 PFDD meeting, and we were really surprised when we

15 made the list.

16       So we were one of the last meetings, but the

17 meeting was just held on April 6th amidst

18 9 tornadoes and horrible weather. But FDA did a

19 really bang-up job at reaching out to the patient

20 community and trying to get people to attend the

21 meeting in person. And the docket is actually

22 open, so they've been working to try to get

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1 additional patient feedback into that process. So

2 we're excited for the voice of the patient report

3 to come out.

4       I'll go quickly. So why am I telling you

5 all this? I'm just going to go through quickly

6 some of the key lessons that I wish someone had

7 been able to tell me when we first started.

8       I've been at the organization now for

9 11 years. The first thing is you really do need to

10 educate yourself in the clinical trials process,

11 and there is absolutely no shortcut around this.

12 People will like to tell you things that you need

13 to know about it, but you really just need to put

14 in the time and understand how it works,

15 particularly for your specific disease area.

16       The most important thing I think that I can

17 stress is learning what information is actually

18 useful for the regulatory process. I know, as

19 people who care deeply about patients and

20 caregivers, we want to make sure that FDA has the

21 full context of everything that patients and

22 caregivers go through, but there is specific

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1 information that may be lacking and gaps that you  
2 can identify by just understanding more about the  
3 clinical trial process.

4 I never thought that we were going to have  
5 to lead an effort to go through qualification of  
6 functional endpoints. I'm not a special person. I  
7 say this a lot. I'm not a scientist. I'm not a  
8 regulatory expert. I have my B.A. degree in  
9 political science. But there was a gap, nobody  
10 else was doing it, and it was something that was a  
11 real hurdle to drug development.

12 So if you identify that gap and you align  
13 yourselves with the right people, you can actually  
14 make some significant progress.

15 I think it's important to reconcile your  
16 goals with those of the research community and  
17 regulatory industry. The reason I say that is a  
18 lot of times, research can tend to just continue  
19 on, and on, and on with no end. And if there's any  
20 way that you as an advocate can play a role in  
21 trying to get where the research can better align  
22 with drug development, you can be a really

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1 important force there.

2 Then with industry, I put that on there  
3 because some of the most meaningful conversations  
4 that we've had -- and FDA cannot talk about failed  
5 trials. But if you're able to engage with industry  
6 in understanding what led to some of the trial  
7 failures in your disease area, it's been  
8 particularly instructive. Sometimes companies  
9 can't talk about it, but many of them can, and  
10 people are very willing to do it.

11 So we've learned a lot about struggles just  
12 broadly in the clinical trials process by having  
13 conversations with industry, but not doing their  
14 bidding for them, just better understanding.

15 The next thing I'd say is work with advocacy  
16 groups in your space, and I think that this is  
17 working better. One of the things that I think was  
18 challenging was when PFDD was going into the  
19 externally-led patient-focused drug development  
20 meetings. There were a lot of groups that weren't  
21 necessarily coming together to put in proposals for  
22 these meetings, but I understand that this is

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1 happening a lot more. And the more you can align  
2 together, the more impactful your meeting is going  
3 to be to FDA.

4 Then I'll say listen when FDA speaks about  
5 your disease, the only example I'll give you  
6 related to this and why I think it's important to  
7 sign up for Facebook, and Twitter, and every blog  
8 post, and newsletter you can find, even if it  
9 doesn't have patient in the name.

10 FDA put out a sleeper report about three  
11 years ago and targeted drug development, and  
12 nothing in the title related to Alzheimer's  
13 disease. But if you read the report, it actually  
14 pointed to Alzheimer's several times.

15 No one in the community -- it didn't really  
16 register with us until we started looking at it,  
17 and it was using Alzheimer's as an example of where  
18 there are discrete areas in understanding the  
19 biology of the disease, a lack of information about  
20 the prognostic value of biomarkers.

21 It was basically a roadmap for, here's where  
22 FDA thinks all your knowledge needs to be gained,

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1 and it gave us sort of enough material for two  
2 meetings to talk through where those challenges  
3 were. But nobody would have seen it if I and some  
4 of my colleagues weren't on every listserv that FDA  
5 has getting a lot of e-mails from you guys.

6 Then just realize that you have to temper  
7 your expectations that successful engagement  
8 doesn't always result in a drug approval. I'm here  
9 to say that I feel like we've sort of been on a  
10 journey with FDA, and they're really poised to sort  
11 of be responsive when we do have a drug that's  
12 ultimately going to be effective for Alzheimer's  
13 and sarcopenia. And I don't think that we would  
14 have been in this place if we didn't take this  
15 journey with them.

16 So just know that having a positive dialogue  
17 and ongoing interaction with the agency is a win in  
18 and of itself.

19 Then always acknowledge when the FDA has  
20 gone above and beyond. Really, I think it's a  
21 thankless job to work here. A lot of times, the  
22 only thing that you hear in the media is when FDA

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1 has done something wrong or they've come short,  
2 come up short in some area. But they do a lot of  
3 incredible things, and I think it's our job as  
4 advocates to call attention to that.

5 So I always put up my hall of fame for  
6 engagement because if anybody's boss on this list  
7 is watching, they all deserve gold stars for how  
8 they've really worked with our organizations,  
9 because I've gotten e-mails late in the night from  
10 some of the people on this list, and I just think  
11 they do an incredible job.

12 So we thank all of them. But I'll stop and  
13 answer any questions anyone has. There's my  
14 information. Thank you.

15 (Applause.)

16 Presentation – Jane Larkindale

17 DR. LARKINDALE: First of all, thank you  
18 very much to the organizers for inviting me. Like  
19 Cynthia, it's really an honor for the Friedreich's  
20 Ataxia Research Alliance to be considered an  
21 example of working well with the FDA. We certainly  
22 try to. We certainly hope to. But it's really

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1 nice to be recognized as an example of that.

2 Unlike Cynthia's organization, we present a  
3 very small number of patients. Friedreich's  
4 ataxia, if you haven't heard of it, is a very rare  
5 disease.

6 Back in 1997, when FARA was formed, our  
7 founder, Ron Bartek and Raychel Bartek had a son,  
8 Keith, who was 11 who was diagnosed with  
9 Friedrich's. And what they found was a whole lot  
10 of bad news. It's a disease that affects pretty  
11 much everything. It's called ataxia. It certainly  
12 isn't ataxia, but it also affects the heart, sight,  
13 hearing, causes scoliosis, and a host of other  
14 problems.

15 At the time, there was no treatment, no  
16 clinical trials, very little research, and no  
17 organization, and Rob and Raychel started there.  
18 At the time, they felt there was no help and no  
19 hope, but that's certainly changed now. And  
20 really, the way that Ron and Raychel set up our  
21 foundation, I think has really set the tone for the  
22 organization in the field since then.

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1 FARA was founded based on two principles,  
2 research and collaboration. And right from the  
3 start, Ron and Raychel said we've got to  
4 collaborate with everybody. We've got to pull  
5 everybody into our field. We have to work with  
6 everyone. We've got to be partners. We're a small  
7 disease. We can only work with others.

8 They pulled in everybody they could think  
9 in, all the scientists, the clinicians, they  
10 brought new people into the field, all the drug  
11 developers. Just like Cynthia's organization, we  
12 work with everybody. But right from the start,  
13 they also pulled in both NIH and FDA, even though  
14 at that point there was no treatment, no thoughts  
15 of treatment.

16 We were going to need to know what the  
17 regulations we were going to want later further  
18 down the path. There are always gaps in every  
19 area. I think of 1997, in Friedreich's, there were  
20 an awful lot of gaps, though they had just  
21 discovered the gene, which I suppose was one step  
22 in the right direction.

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1 I have a quote here at the bottom that  
2 really summarizes Rob's attitude at the time, and I  
3 think still our attitude now is, "If you're  
4 interested in Friedreich's research and we're not  
5 collaborating with you, it means we haven't found  
6 you. We will."

7 I would add that these days, even if you're  
8 not interested in Friedreich's research and we  
9 think you should be, we'll probably still find you,  
10 and we will make you interested in Friedreich's  
11 research.

12 It's a really good field and, as I say,  
13 right from the start, we really wanted to bring  
14 everybody in, work with everybody, and it's been a  
15 great journey.

16 We focus on partnership, and as Cynthia  
17 said, we're focusing on the gaps that we need to  
18 fill to move forward. Back about eight years ago,  
19 we knew we had no really good clinical endpoints,  
20 so FARA pulled together a meeting to discuss  
21 clinical endpoints. And at that meeting, we  
22 invited FDA, and we had engagement across several



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1 different groups.  
2       They came. They didn't just sit in the  
3 background. They led discussions. They engaged in  
4 discussions. They got involved with our community,  
5 and relationships were formed. And that really  
6 started a long-term relationship. And I would say,  
7 since then, I don't know how often we meet with FDA  
8 in one form or another. They might say it was too  
9 often. I never believed that. But it's been a  
10 really good relationship.  
11       It all comes down to respect partnership  
12 collaboration. We all want the same thing. We  
13 want patients to get better. We want medicines  
14 that really work for our patient population. And  
15 it's been a great relationship.  
16       So in terms of basic lessons, I think I'm  
17 going to repeat a lot of what Cynthia said, but we  
18 work under the assumption of partnership. We're  
19 not going to FDA and say you need to do this; you  
20 need to do this. It's really, what do you need  
21 from us and what can we offer to you?  
22       If you need information about our very rare

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1 disease, we'll find it for you. If there's a gap  
2 that you see that you need, we'll figure out how to  
3 answer that question because we know our patient  
4 community, we know our clinicians, we know the  
5 people who are working the space.  
6       We very much work in the pre-competitive  
7 space. You very rarely see FARA doing anything for  
8 one drug company. We're doing it for everybody  
9 because we're a small disease. We know we've got  
10 to work together, and fortunately the companies  
11 understand that, too.  
12       Secondly, we're very much an organization  
13 focused on research, so a lot of our interactions  
14 with FDA are going to be based around what data do  
15 you need, what data do we have, what can we provide  
16 you with to help you make your decision making  
17 easier?  
18       This comes back to some of the things  
19 Cynthia was talking about, about endpoints,  
20 biomarkers, understanding of natural history data.  
21 We know that we have holes in this area and we're  
22 working very hard to fill them. I'd like to say we

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1 have all the answers, but I would be lying if I  
2 said that.  
3       We also very much recognize the FDA is busy.  
4 We're all busy. Let's face it. We would all like  
5 to have 48 hours in the day. So we try to engage  
6 once we have solid questions that we need answered,  
7 solid information we need to give, and engage with  
8 people who can specifically answer specific  
9 questions we need or we can answer questions that  
10 they have for us. So we try and keep a very  
11 respectful relationship.  
12       I put this slide up just because in the last  
13 year or so, these are some of the meetings we've  
14 had with FDA, and it really draws attention to the  
15 fact that these are answering very specific  
16 questions.  
17       The first one was a very small meeting. We  
18 heard from a number of companies that they were  
19 getting asked to do something with our mouse models  
20 that wasn't very practical with our not-very-good  
21 mouse models. So we immediately set up a meeting  
22 with the Office of Orphan Product Development. It

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1 was a small meeting. Our mouse experts went  
2 through what our models can and can't do.  
3       I'd love to say we have a perfect model of  
4 the disease. We don't. We have nine models, and  
5 they're all far from perfect. So it was really a  
6 discussion of what we can and can't do with those  
7 models. It was a small meeting, very precise.  
8       In January of this year, we're on the verge  
9 of beginning our first gene therapies beginning to  
10 go into the clinic, and we have many, many  
11 interactions with CDER. Through the years, we've  
12 had drugs go through CDER. We've never engaged  
13 with CBER.  
14       So we had a small meeting with CBER just to  
15 talk about what natural history data we have  
16 available, what background data we have on  
17 endpoints and biomarkers and say, hey, this data is  
18 available to you. If you have questions, you can  
19 come back to us. If you need to know more about  
20 the disease, come back to us. So again, it was a  
21 small meeting. It was a focused meeting with a  
22 very precise goal in mind.

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1 The final meeting hasn't happened yet.  
2 June 2nd, we're having our externally-led patient-  
3 focused drug development meeting. And again in  
4 this case, we're doing it with Muscular Dystrophy  
5 Association and the National Ataxia Foundation, who  
6 are the other two disease groups in the U.S. that  
7 cover the ataxias.  
8 It's been a very collaborative process. I  
9 have to say that for the very first time, when we  
10 sent them the letter of intent and our first  
11 communication back from FDA, I have had so much  
12 help. Every time I sent an e-mail, I get an answer  
13 within 24 hours, however small and piddling a  
14 question it is.  
15 It's been a great interaction. We've worked  
16 through all the official channels. We've also  
17 reached out to our many contacts at FDA, and I  
18 think it's going to be very well attended looking  
19 at our registration list. I think Katy [ph] was  
20 just telling me we have almost 150 people  
21 registered now in total, so I think it's going to  
22 be a really good meeting.

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1 It's going to be in the same format as all  
2 the internally-led ones. The only difference is  
3 it's not going to be on FDA property. We will  
4 produce a voice of the patients report at the end  
5 of it. It will not be an FDA document; it will be  
6 a FARA document. But we hope it will be able to be  
7 used in the same way.  
8 I think our patients are really looking  
9 forward to being able to explain which of the  
10 outcome measures they find most important, which of  
11 the things they find in their everyday lives really  
12 affect their lives. And I think the drug  
13 developers have an interest in being there to hear  
14 that, too, and I think it's going to be a great  
15 meeting.  
16 So I really thank FDA for the opportunity to  
17 have that meeting and for all your help in setting  
18 it up because it's not an inconsiderable amount of  
19 work. So thank you.  
20 (Applause.)  
21 Questions and Answers  
22 DR. WHYTE: I want to make sure people had

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1 an opportunity to ask some questions.  
2 FEMALE AUDIENCE MEMBER: Hi. I hope this is  
3 quick. I just had a question, even though I had a  
4 chance to speak a little bit.  
5 From a logistical level, planning an  
6 external meeting, I know that earlier today, it was  
7 that they are here to help guide us with the  
8 questions and things like that. What exactly,  
9 time-wise, resource-wise, is an organization who is  
10 planning on doing something like that looking at?  
11 DR. LARKINDALE: So in terms of resources,  
12 we've obviously got a budget because you've got to  
13 pay for the meeting space, and we've got to support  
14 travel for a number of the patients and panelists  
15 to take part. So in terms of resources, it's quite  
16 a lot from that perspective. The rest of it, we've  
17 largely done with internal staff.  
18 It's mostly been a lot of time between  
19 talking to our panelists, making sure they know  
20 what the whole process is. We've had a number of  
21 webinars with our community to make sure they know  
22 what the whole purpose is, what sort of testimony

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1 we're going to expect from them, figuring out what  
2 questions we want to ask. They are very much based  
3 on the ones that have been asked previously, so  
4 that actually wasn't so hard.  
5 We've been collecting a lot of preliminary  
6 data from our community, sending out surveys,  
7 talking to our community members, and such like,  
8 and then developing polling questions, finding  
9 software, finding technology for webcasting, all of  
10 those details.  
11 We're a small staff, so it lands on two or  
12 three people to do all of that from designing the  
13 polling questions, to analyzing the data, to  
14 figuring out what kind of polling software do I  
15 want to use. There's only a small number of us, so  
16 it begins to be quite a long thing.  
17 FEMALE AUDIENCE MEMBER: For things like  
18 polling software, is there a way for those of us  
19 who are coming just a little bit after you to steal  
20 those ideas beyond reaching out to exactly, like is  
21 there a plan for best practices, sharing  
22 [indiscernible – off mic].

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1 DR. LARKINDALE: I'm not aware of anything  
2 formal, but certainly, because I've worked in other  
3 disease areas previously, I reached out to both my  
4 atomic dystrophy and spinal muscular atrophy who  
5 had meetings ahead of us, and they gave me all  
6 their materials, which we copied nicely.  
7 We're also working with a consultant, James  
8 Valentine, who used to be at FDA, and he's very  
9 good at passing on materials from previous meetings  
10 with information, of course.  
11 By all means, if you're going into this  
12 process, feel free to reach out to me. Those other  
13 organizations were so great for helping me that I'm  
14 perfectly happy to pass that on and help others.  
15 MS. BENS: I'll just add, even though FDA  
16 did host the PFDD meeting for sarcopenia, they did  
17 work with us on things. They needed us to get a  
18 wheelchair-enabled bus for some of the patients  
19 because it wasn't in the budget, and they connected  
20 us with one of the other groups who had had an  
21 FDA-led patient-focused drug development meeting  
22 and had a really nice conversation with that group.

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1 But I would say that another thing that you  
2 want to think about in terms of planning for it and  
3 the resource intensity is related to making sure  
4 that you have a range of patient experience. I  
5 think even though it wasn't an Aging in Motion  
6 coalition-led effort, we wanted to make sure, to  
7 the extent we could, that there was a range of  
8 patient experience represented at the meeting.  
9 So we would keep in close contact with FDA  
10 about patients that they were hearing from, whether  
11 they self-identified, if they needed more patients  
12 who were immobile. And unfortunately, we came up  
13 short. I mean, it was really difficult to get  
14 people who had significant mobility issues to the  
15 meeting in person. That's where the webcast  
16 function was I think the most useful, and the  
17 docket was useful. But we did spend an incredible  
18 amount of time working with FDA on making sure that  
19 there was a range of patient experience. So that  
20 takes time.  
21 DR. LARKINDALE: If I could add to that, we  
22 have the same issue, that we have a very diverse

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1 disease, and we have young children and people who  
2 are extremely physically disabled, including people  
3 who have severe dysarthria and can't speak very  
4 clearly. And we would include a video to be able  
5 to represent some of those patients.  
6 We have one speaker of a patient who was  
7 recently deceased. You need the voice of  
8 everybody. We decided we couldn't really ask young  
9 children to speak in that venue, so their parents  
10 will speak for them, but you definitely have to  
11 think about it.  
12 MS. TAYLOR: Hello. Thank you both so much  
13 for sharing your expertise. I really hope that our  
14 organization can be up there with you maybe next  
15 time. So my name is Emily Taylor. I'm with the  
16 Solve ME/CFS Initiative. We were actually the very  
17 first disease to have a PFDD, and that was back in  
18 2013.  
19 So my question to you is what's the next  
20 step? We got our voice of our patients. How can  
21 we convert that into actionable steps for finding  
22 solutions?

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1 DR. LARKINDALE: So I think there are lots  
2 and lots of things we could do. You could go in  
3 many, many different directions. One of the areas  
4 that I'm very interested in is developing outcomes,  
5 and biomarkers, and such like. And certainly, if  
6 you look at that testimony and say, well, what's  
7 most important to my position is X and our outcome  
8 measures don't measure that, maybe that's something  
9 you might want to look at.  
10 An expected outcome from ours is we know  
11 that fatigue is a big issue in our community, and  
12 we don't have a good way of measuring it. So if  
13 there are things like that, that might come out,  
14 it's good guidance as to where to look for future  
15 outcome measures.  
16 MS. BENS: Also, it was timely for us to  
17 have the patient-focused drug development meeting  
18 on sarcopenia when we did because we're just  
19 entering into this phase of helping to support the  
20 qualitative research for the tool that we're trying  
21 to do. And it gave us some insights into ways that  
22 people who have the condition, how it's limited

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1 their life in ways that we're not thinking about.  
2 I mean, when we think of the measures that  
3 currently exist, it's things like inability to use  
4 the bathroom by yourself, get in and out of a  
5 chair. But there were some insights that we got  
6 where one of the woman's mobility limitations  
7 impacted her ability to volunteer. So she still  
8 tried to find ways to volunteer through a phone  
9 bank, but she physically couldn't do the active  
10 volunteer work that she used to do anymore.  
11 So depending on how we were phrasing  
12 questions and the type of research we did, that was  
13 actually a really useful insight for us to have,  
14 and I think for FDA to know, as they're thinking  
15 about a potential conceptualization of a treatment.  
16 How does that map back to some of the things that  
17 they heard that were anecdotal that patients did  
18 experience?  
19 Then I'd also echo the research gaps. I  
20 think that's really important. We as advocates can  
21 try to convince NIH they need to be spending more  
22 money in certain areas. And to the extent that

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1 there may be research gaps that NIH is lucky enough  
2 to be able to fill or groups that we can work with  
3 who can fill the research, that's how we're using  
4 it.  
5 DR. WHYTE: I think you also want to think,  
6 when you engage with the agency, there should be an  
7 ask, and it should be explicit. What do you want  
8 the agency to do?  
9 So in some ways, when you talk about  
10 patient-focused drug development, what is your  
11 goal? Is your goal you want to educate reviewers  
12 about a disease process? Is it that you want to  
13 talk about the need for different endpoints, a  
14 specific patient-reported outcome? Is it about  
15 drug approval? Is it about drug safety?  
16 This building and this agency can be  
17 imposing, both literally and figuratively, and  
18 confusing. But in many ways, thinking through what  
19 are you going to ask the agency to do and to be  
20 explicit about that is very important for effective  
21 engagement.  
22 Both of you are very good at that, and I

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1 want to thank you for taking the time. I know  
2 you're both available by e-mail and by phone to  
3 talk to all of you because one of the goals is to  
4 learn best practices, and there's no one-size-fits-  
5 all, and the process is iterative. This is still a  
6 very new process for the agency.  
7 Stand up and stretch. I want to introduce  
8 my colleague, Dr. Scott Winiiecki, to just have some  
9 final polling questions. Scott practiced  
10 pediatrics for 12 years before he came to the  
11 agency, and his fun fact is he likes to photograph  
12 birds. So Scott's going to bring us into the home  
13 stretch.  
14 Final Poll Questions - Scott Winiiecki  
15 DR. WINIECKI: I'm also at the back table,  
16 and I'm happy to talk with anybody. I've already  
17 answered some questions, or at least attempted to.  
18 And I'm happy to stay once the meeting finishes if  
19 you don't have a flight and you're not afraid of  
20 D.C. traffic on a Friday afternoon.  
21 So three final polling questions. The first  
22 one is, how confident are you in understanding the

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1 functions of CDER, so A not at all;, B, somewhat;  
2 and C, very confident?  
3 (Audience answers.)  
4 DR. WINIECKI: It looks like the majority of  
5 people said somewhat or very confident. That's  
6 good. That's sort of the whole purpose of today's  
7 meeting. And if you're in that 2 percent, by all  
8 means, stop by the table, and I'll see what I can  
9 do to help. I don't have all the answers, but I  
10 certainly have some of them.  
11 Our next question, how confident are you in  
12 your ability to navigate through and engage with  
13 CDER? A, not at all; B, somewhat; C, very.  
14 (Audience answers.)  
15 DR. WINIECKI: I appreciate your honesty in  
16 saying somewhat in the majority. I've been at the  
17 agency almost eight years. I've been in CDER for  
18 almost a year. And figuring out who to call, and  
19 who to turn to, and to navigate is not at all an  
20 easy task. Even figuring out the acronyms is still  
21 a challenge for me some days. And again, I've  
22 worked here for almost eight years.

1 But even though I moved two buildings from  
2 the Center for Biologics to the Center for Drugs,  
3 all the acronyms change. So navigating is not  
4 easy. Hopefully, what you've heard today has made  
5 it somewhat easier and given you some increased  
6 confidence.

7 Our final polling question, would you  
8 recommend this workshop to others? A, yes; B, no.

9 We're also very interested in your feedback  
10 because, obviously, the only way we can improve  
11 this for the group of people who are doing this  
12 next year, whether it's some of the same people in  
13 the room or new people, new advocacy organizations,  
14 is to learn what to add, what to change.

15 So by all means, provide us with lots of  
16 feedback because we really do use that. I think  
17 today you've seen most of the people in  
18 Professional Affairs and Stakeholder Engagement,  
19 and we're not a huge group. And obviously, we meet  
20 together frequently and work on how to develop  
21 these things and how to improve them, so we are  
22 very interested in your feedback.

1 Last year, I opened with Dr. Woodcock's  
2 comments that patients are experts in their own  
3 disease. And you think, "Well, that's obvious.  
4 Shouldn't folks know that all the time?" And it's  
5 really a recognition that we need to talk to the  
6 experts in their disease, and we need to engage  
7 them. And that's patients. It's caregivers.

8 So today is not meant to be a single point  
9 in time, but really to start a dialogue. So all of  
10 our information is available in the handouts. You  
11 should feel free to reach out to me or any member  
12 of our team. We'll be around for a few more  
13 intersection, so if you have questions and you  
14 didn't want to ask at a mic, you can feel free to  
15 come up and ask us individually, and we look  
16 forward to hearing from you.

17 So safe travels on the Beltway if that's the  
18 way you're going.

19 (Applause.)

20 (Whereupon, at 2:55 p.m., the meeting was  
21 adjourned.)

22

1 (Audience answers.)

2 DR. WINIECKI: So we appreciate your very  
3 kind response. Thank you so much for listening  
4 today, and we're going to wrap up with a few words  
5 of wisdom from Dr. John Whyte.

6 (Applause.)

7 Words of Wisdom – John Whyte

8 DR. WHYTE: Thank you. I don't know if  
9 they'll be a few words of wisdom because I know  
10 people want to get going. But I do want to thank  
11 Chad for helping out with Jeopardy and making it  
12 happen, as well as the audience response questions.

13 I want to give special recognition to the  
14 many folks of our team. As you know, this is a big  
15 effort, this is an important effort, but we wanted  
16 to do it. And I want to recognize Rea and Noah  
17 particularly, who have done an enormous amount of  
18 planning for this, as well as Milena, and Francis,  
19 and my assistant Diane, and Scott, and Mary, and  
20 Chris, and Dave, and Shawn. We wanted to be here  
21 today to introduce ourselves because we want this  
22 climate and culture of engagement.

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