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U.S. FOOD AND DRUG ADMINISTRATION  
PUBLIC MEETING  
ON  
PATIENT-FOCUSED DRUG DEVELOPMENT  
FOR SARCOPENIA  
Thursday, April 6, 2017  
1:06 p.m.

Tommy Douglas Conference Center  
10000 New Hampshire Avenue  
Silver Spring, Maryland 20903  
(301) 796-0684

Reported by: Michael Farkas

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

2 MS. CHALASANI: Good afternoon, everyone.  
3 Hello. Hi. I'm so glad you guys all were courageous  
4 enough to brave the beautiful weather outside and make  
5 your way to talk to all of us today.

6 My name is Meghana Chalasani. And I work in  
7 the Office of Strategic Programs within the Center for  
8 Drug Evaluation and Research at FDA. I will be co-  
9 facilitating the discussion today with my colleague  
10 Sara Eggers. Many of you guys may have met her. I  
11 think she's helping someone outside right now. But  
12 I'll make sure she waves a little bit later.

13 It's an intimate group this afternoon, so  
14 please, please feel free to work your way forward.  
15 There's plenty of empty seats up here, too, as well.

16 Today's meeting, conducted as part of FDA's  
17 Patient-Focused Drug Development Initiative, is focused  
18 on hearing from many of you living with muscle loss and  
19 weakness, also known as sarcopenia. Dr. Jean-Marc  
20 Guettier will provide some opening remarks in a few  
21 minutes, but first let me start by asking my colleagues  
22 sitting here in the front to state their names and

1 their role within the Agency.

2 DR. GUETTIER: Good afternoon. My name is  
3 Jean-Marc Guettier. I'm the Division Director in the  
4 Division of Metabolism and Endocrine Products. Our  
5 division reviews drugs to treat sarcopenia.

6 DR. SHARRETT: Hi. My name is John  
7 Sharretts. I'm a medical officer in the Division of  
8 Metabolism and Endocrinology Products.

9 DR. SULLIVAN: My name is Shannon Sullivan.  
10 I'm also a medical officer in the Division of  
11 Metabolism and Endocrinology Products.

12 DR. BORGES: I'm Silvana Borges, the Assistant  
13 Director for Regulatory Science, and I also work with  
14 the Division.

15 DR. CHEN: Good afternoon. My name is Wen-  
16 Hung Chen. I am the reviewer at in the Clinical  
17 Outcome Assessment Staff at the Office of New Drugs.  
18 Thank you.

19 MS. CHALASANI: We also have our colleagues  
20 over there: Graham Thompson, who is going to be  
21 moderating our webcast; and Pujita Vaidya, as well as  
22 very amazing, helpful A/D staff as well. And then we

1 also have Shannon Woodward and Alyse (phonetic), who  
2 helped us welcome all of you this morning.

3 Now, to give you all a brief overview of the  
4 agenda today, after Jean-Marc's opening remarks, we  
5 will spend a bit more time providing background on  
6 sarcopenia.

7 Then we will move into our discussion with  
8 seniors and their family members. Our two main topics  
9 are How Sarcopenia Affects Your Daily Life, and  
10 Treatments for Sarcopenia. Sara will provide some more  
11 details about the exact format of the discussion in a  
12 little bit.

13 We do have some time set aside for open public  
14 comment later this afternoon. While the primary  
15 discussion today is focused dialog with seniors and  
16 their family members, the open public comment session  
17 will give anyone in the audience the opportunity to  
18 make a comment.

19 To participate in that, you will need to sign  
20 at the registration table. Participation is first-  
21 come, first-served. And we'll close that signup around  
22 2:45 at the end of our break. The time allowed for

1 each speaker will depend on the number of participants  
2 who express interest -- most likely, one to two minutes  
3 each.

4 Now, just for a few logistical and  
5 housekeeping points, there is a cafeteria downstairs  
6 where snacks and beverages will be available for  
7 purchase for the rest of the afternoon. Restrooms are  
8 located right outside of this meeting room. The  
9 Ladies' is to the right, and the Men's is to the left.

10 At any point, please feel free to move around  
11 and get up and use the restroom or grab a snack. It's  
12 a very informal setting today. As I mentioned, we will  
13 be taking a 15-minute break around 2:30.

14 I will ask that everyone please take a moment  
15 to silence your cell phones right now. Thank you.

16 Also, this meeting is being transcribed, and a  
17 live webcast is being recorded, both of which will be  
18 archived on our public website.

19 With that, I'd like to welcome Jean-Marc for  
20 opening remarks.

21 OPENING REMARKS

22 DR. GUETTIER: So, good afternoon. Again my

1 name is Jean-Marc Guettier, and I'm the Division  
2 Director in the Division of Metabolism and  
3 Endocrinology Products.

4 Our division is housed within the Office of  
5 New Drugs at FDA. And we are essentially responsible  
6 for reviewing medications to treat metabolic and  
7 endocrine conditions, as well as medications that treat  
8 disorders caused by the loss of muscle mass, strength,  
9 and function related to aging.

10 Loss of muscle mass, strength, and function  
11 related to aging has also been coined "sarcopenia," and  
12 today you will hear these two terminologies used  
13 interchangeably.

14 We are happy to see so many patients,  
15 caregivers, advocates in the audience. And I  
16 understand we also have many more of you joining us  
17 remotely. Thank you all for agreeing to be part of  
18 this meeting and for being willing to share your  
19 personal experiences with us. We are excited for this  
20 opportunity to engage directly with you and to learn  
21 how sarcopenia has affected your lives.

22 We understand that sarcopenia may have

1 emotional, physical, and social impacts. And we're  
2 hoping to hear about the broad range of experiences  
3 that affect people with sarcopenia.

4 In the course of the discussion this  
5 afternoon, we will ask you to describe in details the  
6 various aspects of your lives that have changed and  
7 that you have attributed to sarcopenia. We are also  
8 very interested in learning more about how you have  
9 coped with, managed, or adapted to sarcopenia over  
10 time.

11 An understanding of how sarcopenia has  
12 impacted various aspects of your lives is very  
13 important to us. This knowledge can, for example, help  
14 us focus on developing tools to measure aspects of the  
15 conditions that matter most to patients. These tools  
16 can then be used in studies to evaluate the clinical  
17 benefits of drugs that aim to treat sarcopenia.

18 The knowledge we gain from your personal  
19 experience also provides context for our interpretation  
20 of benefits and risks identified in the evaluation of  
21 therapies to treat sarcopenia.

22 I know we also have representation from

1 industry, academia, and other government partners in  
2 the room and on the web. While FDA plays a critical  
3 role in drug development, we are just one piece of the  
4 puzzle. And I'm glad to see a high level of interest  
5 and engagement from other stakeholders who also play  
6 important roles in drug development.

7 FDA's role is to protect and promote public  
8 health by ensuring that drugs marketed in the United  
9 States are safe and effective for their use. But the  
10 FDA does not develop drugs or conduct the clinical  
11 studies that test whether these drugs work or are safe.

12 Drug companies, sometimes working with  
13 researchers and patient communities, are the ones who  
14 develop new drugs and conduct the clinical studies that  
15 generate the evidence necessary to establish that the  
16 benefits of a new drug for a given condition outweigh  
17 its risks.

18 A good understanding of the types of benefits  
19 people living with sarcopenia expect from therapies  
20 aiming to treat sarcopenia and an understanding of the  
21 level of risks patients are willing to tolerate for  
22 this benefit will help the FDA and all stakeholders

1 involved in developing drugs to treat this condition.

2 To conclude, we are all here today to hear the  
3 voice of the patient. We are grateful to each of you  
4 for being here and for being willing to share your  
5 personal stories, experiences, and perspectives. We  
6 look forward to incorporating what we learn today into  
7 the Agency's thinking, and I would like to thank you  
8 again for your participation.

9 The next speaker is Dr. John Sharretts, who  
10 works in our division and will provide a brief overview  
11 of sarcopenia and current treatment options.

12 OVERVIEW OF SARCOOPENIA AND CURRENT TREATMENT OPTIONS

13 DR. SHARRETTS: Good afternoon. Thank you,  
14 Jean-Marcus. He said my name is John Sharretts, and  
15 I'm a medical officer in the Division of Metabolism and  
16 Endocrinology Products.

17 So, my talk today is going to be an overview  
18 of what sarcopenia is and how it is detected, and also  
19 what currently we're doing to treat sarcopenia and how  
20 this meeting might help in the development of future  
21 treatments.

22 Sarcopenia is a word that's derived from

1 Greek. Literally, it means a lack of muscle or flesh.  
2 But as a medical term, it's used to describe the loss  
3 of muscle mass, strength, and function that are  
4 associated with aging. At the current time, there's  
5 not one widely agreed-upon definition of what  
6 sarcopenia is or an agreed-upon way on how to diagnose  
7 it.

8           What we do know about the condition right now  
9 is that it affects up to a third of people over the age  
10 of 60, and these are the best estimates by public  
11 health researchers currently. The actual rate of this  
12 condition in the population depends on a lot of other  
13 factors, including what definition of sarcopenia is  
14 used, the methods to diagnose it, the geographical  
15 location, and other factors.

16           So, how is sarcopenia measured? The three  
17 main, big categories on measuring sarcopenia are,  
18 number one, methods to detect the amount of muscle  
19 mass, or more specifically, lean body mass. The most  
20 common ways this is done are body scans, or imaging, to  
21 look at the muscles. But it may be other methods,  
22 including blood tests or other methods.

1           The second category is measurements to test  
2 muscle strength. And the most commonly used techniques  
3 are methods to measure grip strength, which I have  
4 demonstrated in the picture. But also, there might be  
5 methods to measure lower body strength -- for example,  
6 things like knee extension.

7           The third category of testing for sarcopenia  
8 is methods to test muscle function. And this category  
9 is varied. It can be things like walking speed. It  
10 may involve things like timed rising-out-of-a-chair or  
11 measurement of climbing stairs.

12           The reason that there isn't a widely agreed-  
13 upon diagnosis has to do with these factors,  
14 determining how much muscle loss is important, how much  
15 loss of strength or how much loss of function. And  
16 also, what techniques are the best ways to measure  
17 these?

18           So, what are the causes of sarcopenia? Well,  
19 right now the simple answer is that the causes of  
20 sarcopenia are not known. We know that there are a lot  
21 of risk factors that are associated with muscle loss.  
22 These can start with lack of exercise for various

1 factors, decrease in muscle growth, changes in the  
2 nerve supply that supply the muscles.

3 Other illnesses may be associated with muscle  
4 loss, in particular I think of things like cancer and  
5 heart disease. But there may be other unknown factors  
6 that are either still being researched or are not yet  
7 identified.

8 So, why is sarcopenia important to us to  
9 study? Well, the overall importance is that muscle  
10 loss may lead to worse health outcomes for people who  
11 have it, have this condition.

12 Muscle weakness is known to be a risk factor  
13 for falls, and falls can cause fractures and other  
14 serious injuries in older adults. Loss of muscle  
15 strength and loss of muscle function can lead to  
16 disability and loss of independence, specifically  
17 people's ability to care for themselves.

18 For an example of a decline in muscle  
19 function, which is slow walking speed is known to be  
20 associated with a higher risk of dying, especially in  
21 people who are older than age 75.

22 But with a lot of things that are identified

1 in the field, we know that walking speed may depend on  
2 factors other than muscle. And it's important to  
3 remember that just because conditions may be  
4 associated, that doesn't necessarily mean that one  
5 causes the other. So the same things that may be  
6 causing the decline in walking speed may be related to  
7 the conditions that cause increased death or risk for  
8 death.

9 So, what are the current treatment options for  
10 sarcopenia? Well, the best-studied treatments so far  
11 have been exercise. And as far as we know right now,  
12 these are the most effective treatments. Exercise  
13 consistently shows that it improves muscle strength and  
14 muscle function in different populations.

15 However, in studies, the effects of muscle  
16 mass are inconsistent. In some studies, exercise  
17 improves muscle mass; in others, it does not.

18 The second category that's been studied more  
19 considerably is nutritional supplementation, and the  
20 effects with nutrition have been much more varied. The  
21 effects on both muscle function, strength, and size  
22 have varied in different studies. Some have found

1 effects, and others have not.

2 But some of it may be dependent on the  
3 specific types of supplements that have been used in  
4 different research, and it may depend on specific  
5 deficiencies that the patients enrolled in those  
6 studies may have had.

7 Currently, there are no medications that are  
8 approved by the FDA for the treatment of sarcopenia.  
9 And that's part of the reason that we're here is to  
10 help guide our ability to find ways to approve new  
11 medications that may be helpful.

12 So, why is it important to us to hear from  
13 people who might have sarcopenia? Well, the  
14 information in these sessions will help us understand  
15 how the condition impacts the lives of patients who  
16 have it, understand what patients most want in the  
17 therapies that aim to improve the condition.

18 And furthermore, patient information helps us  
19 identify concepts that are important to patients who  
20 are living with the condition. They help to develop  
21 instruments to measure how patients with the condition  
22 feel or function.

1           And also, to develop instruments that can  
2           measure the treatment benefit of therapies aiming to  
3           improve the condition, because ultimately, to improve a  
4           drug, it requires demonstrating that the treatment  
5           improves patients' outcomes.

6           That is my overview of sarcopenia. And we'll  
7           move on to the next speaker.

8           OVERVIEW OF PATIENT-FOCUSED DRUG DEVELOPMENT MEETING

9           DR. EGGERS: Thank you, John.

10           I think we are -- can everyone hear now? Is  
11           it better? Great.

12           Okay. My name is Sara Eggers. And I'm in the  
13           Office of Strategic Programs at FDA. And it is my  
14           pleasure to serve as one of the facilitators for  
15           today's meeting.

16           If you have any trouble at any time hearing,  
17           just raise your hand and give a thumbs-down sign that  
18           you can't hear, and we'll work on that.

19           So, I'm going to give an overview of what the  
20           meeting is today. And then we're going to get into our  
21           facilitated discussion, because you didn't come here to  
22           hear us talk. You came to hear our valuable

1 participants talk today.

2 But a bit of background. This is a program  
3 called Patient-Focused Drug Development. And it came  
4 about as a program five years ago with the realization  
5 that FDA and others could use more systematic ways to  
6 really engage patients, people living with various  
7 conditions, to learn their perspectives on what it's  
8 like to live with their condition and their thinking on  
9 available treatment options and potential future  
10 treatment options, how they might think of those.

11 This perspective, as has been mentioned  
12 before, is critical to inform FDA's and others'  
13 understanding of the context for assessing the benefits  
14 and risks of medications. And it can inform FDA in our  
15 role to help drug developers and researchers during  
16 drug development to identify ways to evaluate  
17 treatments. It can also help our review of the  
18 potential therapies that come in for our marketing for  
19 review.

20 So, as part of this Patient-Focused Drug  
21 Development Initiative, FDA is holding 24 meetings. We  
22 started in April of 2013. This is our 22nd of 24

1 meetings. And we have a few more meetings for the  
2 remainder of 2017.

3 And for those of you who would be interested  
4 in this, this is part of a commitment that FDA made  
5 under the Prescription Drug User Fee Act, and that is  
6 an act that allowed FDA to gather fees from marketing,  
7 from drug developers who want us to review their  
8 products.

9 As part of that, FDA makes certain commitments  
10 to advance regulatory science or drug development, and  
11 this was one of the important commitments we made.  
12 These meetings are helping us to develop approaches,  
13 more systematic approaches, to gathering patient input  
14 more broadly.

15 Each meeting is focused on a specific disease  
16 area or disease areas. Meetings in the past that we've  
17 had have been on breast cancer, fibromyalgia,  
18 narcolepsy, HIV, so a wide range of conditions and a  
19 wide range of people who are attending our meetings.

20 Even as our 22nd meeting, we have learned from  
21 every meeting, and we continue learn even from our  
22 meeting today about how to successfully and effectively

1 engage with people who have lived with conditions.

2 After each meeting, we publish a Voice of the  
3 Patient Report. And it's available on our website.

4 And what it does is summarize the input and  
5 perspectives we hear today in the meeting with the  
6 input we get over the webcast and the input that the  
7 public can continually submit for the next two months  
8 through our website. I'll give some information on  
9 that in a minute.

10 And these reports are very informative.  
11 They're useful for our own staff at FDA, and we also  
12 hope that they're useful to researchers, drug  
13 developers, and others.

14 So, today's meeting is focusing on the two  
15 topics that Meghana outlined today. And for the, I  
16 want to say patient panelists, but I mean that in the  
17 term of seniors who may be experiencing or concerned  
18 about muscle weakness and muscle loss, what we're  
19 interested in understanding is how sarcopenia, how  
20 muscle loss and weakness, affects your daily life.

21 What aspects of muscle loss and weakness are  
22 most important to you? How does muscle weakness,

1 muscle loss and weakness affect your life, specific  
2 activities that are important to you that you can't do  
3 any longer or no longer as fulfilling as you'd like?

4 How has your condition changed over time? And  
5 what worries you most as your muscle loss and weakness  
6 progresses? Or if you're a senior who has not yet  
7 fully experienced muscle loss and muscle weakness, what  
8 concerns you the most as you think about getting older?

9 And then, regarding treatments, what are you  
10 doing to manage your muscle loss and weakness? How  
11 well are your treatments addressing what's important to  
12 you about muscle loss and weakness? And what would be  
13 a meaningful benefit or an improvement in your  
14 condition if there were medications available to treat  
15 it, or any other therapy? What are you looking for to  
16 improve regarding muscle strength and muscle function?

17 So, what our discussion is going to look like  
18 today is to start with a panel of seniors and a  
19 nutritionist who span a wide spectrum of experiences  
20 and perspectives on sarcopenia and its treatments. And  
21 your comments are going to set the context for a  
22 facilitated discussion.

1           Once we go through your comments, then we will  
2 open it up to talk to all the seniors in the room and  
3 to really build upon what you've talked about. We're  
4 going to delve more deeply into certain topics.

5           We will ask questions. And just raise your  
6 hand to respond. It's really open. Meghana and I will  
7 be roaming the room, and it's very much an open forum.

8           Please state your name before answering. And  
9 if anyone sponsored your travel, that's usually helpful  
10 to know.

11           So we will also have polling questions. And I  
12 realize that this is very small text. But we're going  
13 to go our best to try to answer some polling questions  
14 that really just give us a chance to hear from everyone  
15 in the room and on the web. It's not at all a  
16 scientific survey that we're conducting. It just gives  
17 us a sense of what perspectives are in the room. We'll  
18 practice this in a few minutes.

19           We're going to ask that seniors or a family  
20 member of a senior are the only ones who answer the  
21 clicker questions, please.

22           And on the web, feel free to answer the

1 questions as they're posed on your webcast. If you  
2 have any difficulties, just send us a little note  
3 saying that you're having some trouble, and we'll see  
4 what we can do, throughout. If you're on the web and  
5 you have trouble hearing or seeing something, just let  
6 us know. Okay?

7 So, web participants, you can also type in  
8 your comments to the webcast, and although we won't  
9 read them out in their entirety, we will summarize  
10 those and they will be included in our report. So feel  
11 free.

12 If you're hearing something that really, that  
13 you say, "Okay, I agree with that," chime in then. If  
14 you say, "No, I have a different perspective" and  
15 you're on the web, also type in your answers. We're  
16 interested in those.

17 If you would like to -- we do have phone  
18 today. Is that correct? So if you're on the web and  
19 you'd like to make a phone comment and contribute,  
20 please -- we'll let you know when it's time to do that.  
21 Okay?

22 So there are a few ground rules we've learned

1 over time that make these meetings be very effective.  
2 We're encouraging seniors to contribute to the dialog.  
3 Family members, health care providers, and patient  
4 advocates -- people who work with seniors and can put  
5 yourself as much as possible into the shoes of senior  
6 citizens or people who are struggling with sarcopenia  
7 -- we encourage you to comment as well.

8 This is a very intimate setting and an  
9 intimate group. So we really want to get all the input  
10 we can.

11 If you're from the drug developer community,  
12 we'll just ask you to stay in listening mode. And  
13 there is a chance for open public comment at the end of  
14 our discussion.

15 FDA is here to listen. So, except for this  
16 background we've shared now, we don't have a lot to  
17 share with you. But if there's a bit of time at the  
18 end, we'll be able to open it up to see if the seniors  
19 in the audience have any questions for FDA colleagues.

20 The views expressed here today and the  
21 experiences are personal experiences and personal  
22 opinions. And we will be getting into very sensitive

1 topics. So, with that, respect for one another and the  
2 different experiences, the different perspectives, and  
3 the different viewpoints we have is critical to having  
4 a successful meeting.

5 And finally, let us know how the meeting went  
6 today. As I said, we've conducted 22, but we continue  
7 to learn. There will be evaluation forms at the  
8 registration table.

9 Again, if you have to get up at any point for  
10 any reason, please feel free to do so.

11 And there's also one more chance to  
12 participate. If you hear something today and you don't  
13 get a chance to fully say your thought, you can submit  
14 to a website that's available here. And I think that  
15 link will go out to everyone who has participated in  
16 the meeting. You can also go to regulations.gov and  
17 search for sarcopenia, and you should be able to find  
18 it.

19 But this, we have a website available to  
20 submit further comments. So you can comment if you're  
21 here today and you think of something, or if you're on  
22 the web and you'd like to comment, or if you know of

1 other seniors who are experiencing these conditions who  
2 may have differing perspectives. Their perspectives  
3 are very important.

4 We are going to take what we learn today and  
5 also what we gather from the web to incorporate into  
6 our findings. So, please, encourage others to  
7 participate and comment. And anyone is welcome to  
8 comment.

9 Okay. So at that, we're going to get the  
10 clickers out. And let's see. So if you're up here in  
11 front, it's the little thing that looks like a tiny  
12 remote control. And you're going to be clicking a  
13 button that best matches your response to a question.

14 So, the first one we're going to ask is -- and  
15 this will be for seniors or family members of seniors  
16 or -- I would say you probably, Rose, the questions  
17 wouldn't make sense for you. So.

18 So, have you ever consulted a health care  
19 professional about age-related loss of muscle mass,  
20 strength, or function? You'll press the 1 or A if yes,  
21 and 2 or B, I believe, if no.

22 (Pause)

1 DR. EGGERS: So, yes would be a 1 or an A, and  
2 no would be 2 or a B. Or, you know what? The one  
3 reason we do the polling is because in case there are  
4 people who don't feel comfortable raising their hands.  
5 So if you have -- let's do another thought.

6 If you have any trouble with the clickers at  
7 any time, just give us a big thumbs-down and we will  
8 figure out some other way to get the input or someone  
9 to help. Okay. So.

10 So, several of you have talked to your health  
11 care provider about sarcopenia or muscle mass.

12 So the next polling question is What is your  
13 age? A if you're younger than 40. You'll click B if  
14 you're 40, in your 40s. You'll click C if you're in  
15 your 50s, D if you're in your 60s, E if you're in your  
16 70s, and F if you're better than 80.

17 (Pause)

18 DR. EGGERS: Okay. This is what we thought.  
19 We have half of you here who are better than 80. We  
20 thank all of you for coming. Usually, we ask a  
21 question of -- can I have a show of hands for who  
22 traveled outside of the metropolitan area?

1 (Show of hands)

2 DR. EGGERS: Okay. Okay. We thank you for  
3 making this trek today. It's bad enough on the Beltway  
4 if you live here all the time. But it may be quite a  
5 surprise if you're traveling.

6 The next polling question is Are you  
7 male/female? So A if you're male, and B if you're  
8 female.

9 MR. THOMPSON: I just want to add for those on  
10 the webcast, you can click the little pie-chart link at  
11 the bottom right and you'll see the polling questions.

12 DR. EGGERS: Okay.

13 And, Graham, while they're doing that, what  
14 was our age characterization on the web?

15 MR. THOMPSON: Similar to that in the room.

16 DR. EGGERS: Okay.

17 (Pause)

18 DR. EGGERS: Okay. So we have a nice split.

19 I think that is our last polling question.

20 So now we are going to go through, and we're  
21 going to hear from Greta first. And Greta is going to  
22 give her comments, and then we'll go on down. And I

1 may stop you with a question or something to clarify as  
2 we go through. But otherwise, we'll let you speak.

3 SETTING THE CONTEXT ON PATIENTS' EXPERIENCES

4 AND PERSPECTIVES

5 MS. DERSHIMER: In 1999, I volunteered to be a  
6 participant at the University of Virginia in Dr.  
7 Michael Thorner's NIH-funded study related to  
8 sarcopenia. The study of the drug MK-677 was  
9 investigating the effects of the growth hormone  
10 secretagogue on healthy older adults, with particular  
11 attention to the effects on muscle mass.

12 I received the study drug during both years of  
13 the study. And my growth hormone levels were restored  
14 to those seen in 30-year-old, or on young, subjects. I  
15 experienced particularly high levels of energy  
16 throughout the study. I gained muscle mass, and I  
17 improved on all the function tasks that were tested.

18 Sixteen years later, at 85, I still qualify as  
19 an older healthy adult. I haven't been diagnosed with  
20 sarcopenia. The physical problems I have are mainly  
21 related to arthritis in my lower back. But those  
22 problems include difficulty with balance and falling,

1 which are typical of sarcopenia. So, I've learned what  
2 muscle pain and falling feel like.

3 Looking back, I can recall two particularly  
4 distressing periods which illustrate how muscle and  
5 balance problems have affected me and taught me  
6 valuable lessons.

7 The first lesson involved a dinner party. I  
8 have a friend who loves to cook for her crowd, but  
9 doesn't have space to serve a crowd in her home. So  
10 three years ago, I agreed to have a dinner for 14  
11 people at my house. We agreed that she would plan the  
12 menu and do the cooking, and I would provide the space.

13 On the day of the event, I worked really hard.  
14 I was cleaning the house and moving furniture around to  
15 accommodate extra guests, and so forth. I overdid it.  
16 I strained the muscles in my right leg, and I ended up  
17 with severe pain. The guests pitched in to help. They  
18 greeted people at the door. They helped to serve the  
19 food. They served the wine. And they even washed the  
20 dishes.

21 But I just sat on the couch, trying to conceal  
22 my pain and feeling really embarrassed to be such a

1 poor hostess at my own party.

2           When everyone left, I crawled up the stairs to  
3 bed, feeling miserable both physically and emotionally.  
4 And that was just one of my many bitter lessons about  
5 the need to acknowledge my physical limitations.

6           I no longer have the strength or stamina to  
7 handle the tasks I used to manage. Like many elderly  
8 adults, I want to remain independent, but if I push  
9 myself too hard, I injure myself and undermine that  
10 goal. It's a really hard lesson to learn.

11           My second lesson came from a bad fall. While  
12 I was at a conference in D.C., I was backing away from  
13 a window in my hotel room. And I tripped over a  
14 hassock that was behind me. I fell hard on my right  
15 side and badly hurt my hip.

16           I was able to sit or stand, but it was very  
17 painful to walk. I didn't want to miss the conference  
18 presentations, which I had paid for. So I borrowed a  
19 crutch from the hotel, just one, and managed to get  
20 around the conference for the day.

21           Back home, my doctor x-rayed my hip and said  
22 that nothing was broken, but I had a deep bruise. I

1 stayed at home for days, using a cane to move around.  
2 My hip was very sore. I couldn't sleep. So I got  
3 little real rest.

4 But a more serious problem was the  
5 psychological reaction to the fall. For weeks after  
6 the bruise had healed and I was able to walk normally,  
7 I kept using the cane whenever I left the house. I was  
8 afraid someone would bump into me, knock me over, and  
9 injure me badly. I felt really quite fearful and  
10 fragile.

11 I avoided activities where a crowd might be  
12 expected. It took ages to get back to a normal routine  
13 of activities. And from that experience, I learned  
14 that I need to be extra careful in unfamiliar  
15 territory. And that the psychological effects of  
16 falling can be worse and longer lasting than the  
17 physical effects.

18 I've recovered from episodes like these  
19 because I found a helpful treatment. Arthritis in my  
20 lower back led to two back surgeries for me in 1998 and  
21 2010. I lost the feeling in my big toes after the  
22 first surgery, and in all my other toes after the

1 second. These resulted in difficult balance problems,  
2 several minor falls, and some restricted activity --  
3 for example, no more dancing, no more cross-country  
4 skiing.

5 After the second surgery, I began doing water  
6 exercises that were suggested by a personal trainer at  
7 my gym. These focused on balance, strength, and  
8 flexibility, and included cardio exercises. Over time,  
9 I lost weight, got a big improvement in my balance, and  
10 gained a fair amount of feeling back in my toes.

11 Recently, arthritis in my neck sent me to a  
12 physical therapist and a new doctor. Both of them  
13 seemed to be surprised about how strong I am for my  
14 age. I even surprised myself when the doctor asked me  
15 to walk across the room on my toes, and I found out I  
16 could do it.

17 I credit the water exercises for these  
18 results. With pool exercise, there's far less stress  
19 on joints, and every movement involves some resistant  
20 from the water. In addition, the water provides  
21 support so that exercises that are difficult, balance  
22 exercises that are difficult, are easier. And that

1 better enables muscle development.

2 So, I've become a big advocate for a  
3 particular kind of water exercise, which I think could  
4 be helpful for people with sarcopenia. I advocate  
5 first individual exercise, using routines that are  
6 designed specifically to deal with the particular  
7 problems faced by the individual.

8 I stress exercise in warm water pools, because  
9 warm water is relaxing and soothes painful muscles. I  
10 recommend exercise routines that involve many varied  
11 exercises to maintain the interest and attention of the  
12 person exercising. Rather than jogging in the water  
13 for 30 minutes, for example, I do five different cardio  
14 exercises for 5 minutes each and am never bored.

15 In my warm-water pool, we socialize as we  
16 exercise. We encourage each other's efforts. These  
17 four features of water exercise provide positive  
18 reinforcement to continue working and improving. They  
19 are the features that keep me getting out of bed at  
20 5:00 and into the pool at 6:20 three mornings a week.  
21 And I do continue to improve.

22 So, while we wait for new drugs to be

1 developed and tested to alleviate sarcopenia, I think  
2 we should encourage and enable forms of exercise that  
3 assist people with sarcopenia to maintain as much  
4 muscle mass as possible. I believe that the kind of  
5 water exercise I described here and that I've been  
6 practicing for the last seven years is worthy of such  
7 encouragement.

8           So, for now, I'm going to keep exercising  
9 regularly. And when a drug that provides the benefits  
10 I experienced in the UVA study of MK-677, when it gets  
11 approved, I hope I'll still be around to use it.

12           DR. EGGERS: Thank you so much, Greta.

13           (Applause)

14           DR. EGGERS: Yes. A round of applause,  
15 please.

16           (Applause)

17           DR. EGGERS: I'm going to introduce Fred  
18 Bartlit, who will be going next.

19           MR. BARTLIT: Okay. Good. So, when I got  
20 here I figured I'd be the oldest person here. But I'm  
21 tied with Greta. We're both 85. So I have a very -- I  
22 guess I'd be called a patient. I have a long, deep,

1 personal interest in sarcopenia, the downward spiral of  
2 frailty with aging.

3           When you get near 50, you get a little weaker,  
4 so you do a little less. When you do a little less,  
5 you get a little weaker. You do a little less, you get  
6 weaker. And when you're 70 you get weak. And a lot of  
7 people are bedbound, and people get disabled.

8           I've studied this for 20 years, man and boy.  
9 I'm a trial lawyer and an engineer. I was President  
10 Obama's lawyer in the Deepwater Horizon. I still do  
11 that for a living. But this is my life's work now.

12           I've learned in the last 20 years that almost  
13 all the work being done with regard to sarcopenia by  
14 the medical community is how to deal with people when  
15 they're at the bottom of the downward spiral, when  
16 they're bedbound, when they can't walk and they're  
17 disabled. And the geniuses in the medical profession  
18 want to bring people up a notch.

19           Almost nothing is written or done or taught  
20 about how to stop the downward spiral when you're 45,  
21 how not to get sarcopenia, how to be able to do every  
22 single thing at 85 you could do at 22. It's just not

1 part of the literature.

2 Now, how do I find out how to really stop in  
3 its tracks the downward spiral? Like most things in  
4 life, a woman was involved.

5 (Laughter)

6 MR. BARTLIT: Thirty-five years ago, I'm 50.  
7 I meet a woman 35. She blew my barn doors off. I  
8 thought I was really fit and God's gift, as a lot of  
9 men do at that age.

10 (Laughter)

11 MR. BARTLIT: So I said, "Let's go to the gym  
12 and work out." So I went to the gym with her. We  
13 walked out. I can remember right now, she turned to me  
14 and she said, "That's the silliest thing I've ever seen  
15 in my entire life."

16 I thought I was fit. I said, "What do you  
17 mean, Janna?" I'm now married to her for 36 years. I  
18 said, "What do you mean?"

19 She says, "You're weak, and you're going to  
20 get weaker, and you'll never be the man you are now in  
21 15 years." I said, "What do I do?" She said, "I'll  
22 find a strip mall in a crappy shopping center, and

1 we'll find you a real trainer. And you'll learn how to  
2 do real exercise."

3 I started right then. And I was feeling  
4 better all along. And I got to be 60. I love to ski,  
5 I love to play basketball, I love to play golf. And I  
6 noticed, at 60, all of my lifelong skiing buddies were  
7 falling by the wayside. "Oh, my knees hurt. I'm  
8 tired. I can't do that." I got curious. Why would it  
9 be that I love skiing more than ever, love being up at  
10 Vail on a powder day, and all my buddies have quit?

11 So I start reading. That's what lawyers do.  
12 Medline, all the big databanks out there. And I find  
13 in 1994 a piece, a collected piece of research by Dr.  
14 Roger Fielding. I'm sure you've heard of Dr. Fielding.  
15 And I see the word "sarcopenia." And I've got two  
16 sons-in-law who are surgeons, and I start saying,  
17 "What's this sarcopenia stuff?"

18 None of them had heard of it. And I start  
19 reading more and more. And I see that there's, now  
20 recognized since last October by the AMA, sarcopenia is  
21 now a disease. It used to be a condition or a  
22 syndrome, now recognized by the AMA as a disease. And

1 I've read everything you can read in the field.

2 And I've learned that both my darling wife,  
3 who told me I was wasting my time in the gym, and what  
4 I've learned from Dr. Fielding and his team is that  
5 there is a remedy. It is intense physical activity.  
6 There's no easy way around it.

7 I don't want to discuss it now because it  
8 would take too long. But I think it's tied in to what  
9 the real cause is. I think there's more known about  
10 the cause than many people think is known. It's an  
11 interesting debate. I agree with that.

12 Now, how's that changed my life? Okay, I'm  
13 85. I'm working seven -- I'm not bragging. I was not  
14 a good athlete in high school or college. I got cut  
15 from every team I ever played on. But when my wife,  
16 who I wanted to marry, said, "If you don't watch out,  
17 you're going to be an old man," I thought, "I'm not  
18 going to be an old man." Okay?

19 So, I'm a better skier than when I was 40. I  
20 shot my age in golf last year two or three times. I've  
21 planned my son's basketball team. And I get to do  
22 that. And I get to enjoy every day of my life doing

1 exactly what I did before because of what I read from  
2 Dr. Fielding and all the research that I've read since  
3 then, and because of what my darling wife got me  
4 started 35 years ago. Thank you.

5 DR. EGGERS: Thank you, Fred.

6 (Applause)

7 DR. EGGERS: And now we have Rose.

8 MS. CLIFFORD: Well, good afternoon. Wow, I'm  
9 following Fred. That was really dynamic. I'm going to  
10 have to do a good job here.

11 My name is Rose Clifford, and I'm the  
12 Nutrition Program Manager at Iona Senior Services in  
13 Tenleytown in Ward 3 in D.C. I've been a registered  
14 dietitian/nutritionist for 35 years, and I've worked at  
15 Iona for the past 8 years.

16 I primarily work as a senior hunger advocate.  
17 I consider myself a warrior in the tireless fight  
18 against senior food insecurity and senior malnutrition.  
19 Nationwide, nearly one in six adults 60 and over faces  
20 the threat of hunger, and up to one in two older adults  
21 are at risk of malnutrition.

22 My team and I work directly with older adults

1 both individually and in groups, and that work is a  
2 spectrum from healthy active aging and a Mediterranean  
3 style of eating to what we are here today discussing  
4 and sharing thoughts on, which is sarcopenia, or what I  
5 refer to with my clients as "physical frailty."

6           Sarcopenia is a form of senior malnutrition in  
7 my world. Older adults become physically frail very  
8 quickly, given the combination of poor or inadequate  
9 nutrition; acute medical situations that render them  
10 temporarily bedridden or less mobile, such as surgery  
11 or rehab.

12           Limited mobility from chronic conditions such  
13 as arthritis, which even I at age 57 am starting to  
14 get; a general lack of exercise and a sedentary  
15 lifestyle; and also, isolation is a critical factor for  
16 a lot of the clients that I work with.

17           This perfect storm of conditions sets the  
18 stage for physical frailty that can lead to, as you've  
19 heard from some of the other panelists, falls,  
20 fractures, increased disability, a poor life quality,  
21 and even increased mortality.

22           Unintentional weight loss and physical frailty

1 are the most common nutrition concerns that I work  
2 with. Almost all of my clients have this condition,  
3 even though it may not be recognized as such  
4 officially. Many of my clients would think it's just  
5 inevitable to get weak and wobbly as they get older.

6 They would describe themselves as "not being  
7 able to get around as well anymore." The weather today  
8 is terrible sarcopenia weather, right, this dreadful  
9 rain. Somebody that's very stable, feeling a little  
10 weak, would hesitate to go out today.

11 It's tiring and harder to summon the energy  
12 and strength needed to carry groceries, to cook or  
13 prepare food, to clean your home, to bathe yourself or  
14 drive or take transportation -- very important  
15 activities of independent daily living. I would say  
16 that most of my clients have limited life space due to  
17 their challenges as their world gets smaller and more  
18 difficult to navigate.

19 Some of my clients are very thin and  
20 physically frail. But many of them are overweight and  
21 physically frail. And this is known as sarcopenic  
22 obesity. Many people don't realize that you can be

1 overweight and malnourished. And, no, you cannot just  
2 live off your fat stores.

3 As a dietician/nutritionist, I use science-  
4 based practical personalized information to advise my  
5 clients about what to eat to improve their overall  
6 muscle health and strength. Exercise, both resistant  
7 and aerobic, in combination with adequate protein and  
8 calories, are key to prevent or manage sarcopenia. You  
9 also need to correct low levels of vitamin D.

10 A lot of seniors are on what I would call a  
11 frailty-promoting diet of tea and toast, or cereal, for  
12 breakfast, and canned soup and crackers for lunch, and  
13 maybe a microwave frozen meal or a sandwich for dinner.

14 Seniors need to eat enough protein at every  
15 meal. Thirty grams at each meal, or ninety grams per  
16 day, is the recommendation for sarcopenia, which is  
17 hard to do because many older adults do not eat three  
18 meals per day and they do not necessarily eat adequate  
19 protein at each meal or snack.

20 Good sources of animal protein include  
21 poultry, fish, lean meat, eggs, and dairy products such  
22 as my favorite, Greek yogurt, dairy or soy milk, and

1 natural cheeses.

2 Good sources of plant-based protein include  
3 beans and legumes, such as black beans, or chick peas  
4 and lentils; nuts and nut butters; seeds such as  
5 quinoa, pumpkin, or sunflower; tofu or soy-based  
6 products; whole grains such as oatmeal, brown or wild  
7 rice, whole-grain pastas; and all vegetables.

8 Protein supplements are also a useful way to  
9 increase dietary protein intake when food sources are  
10 not adequate for whatever reason.

11 In addition, it's very important that older  
12 adults spread their protein intake out throughout the  
13 day. There is a limit to the rebuilding process of  
14 your muscles and how much your muscles can uptake the  
15 amino acids from a dietary protein that you're eating.  
16 You can't just eat all your protein at dinner and hope  
17 your muscle strength and health will improve.

18 Thank you very much.

19 DR. EGGERS: Thank you very much, Rose.

20 (Applause)

21 DR. EGGERS: And finally, we have Ray.

22 MR. LIPICKY: It's hard to know where to

1 begin. A word about why I'm here. I'm a retired  
2 physician, and I worked for FDA for 30 years, from 1979  
3 till 2002. And I've participated in sarcopenia  
4 meetings, international meetings on two occasions.  
5 Both times I told these people they didn't know what  
6 they were talking about. They said, "Go away," and  
7 they never invited me back.

8 (Laughter)

9 MR. LIPICKY: I've been talking to two  
10 different drug companies who are trying to develop a  
11 new drug as part of -- I do consulting now, since I  
12 left FDA in 2002. And I told them they're nuts. They  
13 said, "Here's your check. Go away."

14 And so, I was at a meeting in Milan on the  
15 development of a new drug for congestive heart failure.  
16 Somebody was at that meeting, and they said, "Why are  
17 you using a walker?" I said, "I have sarcopenia."  
18 They said, "Oh, we all know a lady who's interested in  
19 sarcopenia. We'll put you in touch with her." And I  
20 ended up here, saying, "Well, I struck out in science.  
21 I struck out in industry. Maybe I can be an advocate."

22 (Laughter)

1 MR. LIPICKY: We'll see.

2 It's obvious that sarcopenia differs depending  
3 on who it is, right? If you're an NFL quarterback and  
4 you develop sarcopenia, you're worried about different  
5 things than if you're a 90-year-old male who has that  
6 Alzheimer's disease. And that's different.

7 For me it was primarily a problem of having  
8 core muscle problems and of getting weary, feeling bad,  
9 feeling that I couldn't move anymore. I had to sit  
10 down. I couldn't walk for long distances. Not because  
11 of weakness, but because I had the feeling if I kept  
12 going, I'd fall down because my core muscles wouldn't  
13 support me.

14 So that was my problem. Idiosyncratic?  
15 Probably not true for anybody else? Who knows? I  
16 don't know.

17 Quadriceps weakness -- I can't get up out of a  
18 chair. I imagine at the end of the day today, people  
19 are going to help me stand up. That's embarrassing,  
20 frankly. I don't want to go places because I don't  
21 want to have people hauling up out of a chair and  
22 making a big fuss, and having people say, "Ooh, ah,"

1 and running and looking and seeing what's going to  
2 happen. But I frankly can't get out of a chair.

3 Then there's little things like lower-leg  
4 weakness, where I was at Christmas Carol, and I was  
5 going to go to a Christmas party. And my lower leg  
6 muscle weakness led to an inversion of my foot and an  
7 ankle sprain that had me end up in the emergency room.  
8 And I was bedridden for two weeks. It sort of messed  
9 up Christmas Eve pretty badly.

10 So that kind of stuff is the stuff that I've  
11 been dealing with that is hard to know how to deal with  
12 and hard to know how to evaluate. And I've been  
13 through 15 million physical therapy people, when there  
14 were physical therapists and there were physical  
15 therapists, I'll tell you. And most of them don't know  
16 what they're doing.

17 Most doctors you see don't even have the  
18 knowledge of what sarcopenia means. They don't even  
19 have -- they haven't even heard the meaning, the word,  
20 let alone have any idea of what to do. Deep-water  
21 exercising kept me going from 2002 till about -- well,  
22 currently, I moved from Maryland to Tampa, and there

1 isn't any deep-water exercising in Tampa.

2 But it kept me going, kept me able to go to  
3 Morocco on a trip with my two granddaughters -- I'm  
4 sorry, with my two daughters and grandchildren. And  
5 most people don't even know what deep-water exercising  
6 is. I tell my doctor I'm going deep-water exercising,  
7 he says, "Oh, yeah, sure."

8 So, the point I'm making, I guess, is that it  
9 really is very different. I don't think there's a  
10 generalization that can be made that sarcopenia means  
11 this or sarcopenia means that, or this functionality is  
12 gone or this functionality is missing.

13 And I can guarantee you from my vantage point  
14 that the science that's involved is nuts and that the  
15 people who are trying to currently develop any drugs  
16 for the treatment of sarcopenia have no idea of what  
17 they're doing. So, now you can be a patient advocate.  
18 I don't know what you're going to advocate.

19 DR. EGGERS: Thanks a lot, Ray.

20 (Applause)

21 MR. LIPICKY: That ought to be written on  
22 everybody's bedroom wall, top to bottom. They ought to

1 read it every morning when they get up. I'm not  
2 kidding. Not kidding. Thank you.

3 DR. EGGERS: Well, I think we have then a  
4 sense of resonating from the panel up here. Just again  
5 another round of applause for the panel.

6 (Applause)

7 DR. EGGERS: For coming, for advocating, and  
8 for telling us your experiences.

9 LARGE-GROUP FACILITATED DISCUSSION

10 DR. EGGERS: We'll have some time for more  
11 follow-up questions as we get along. But first, so the  
12 seniors and the family members and the other health  
13 care providers who work with seniors, did you hear your  
14 experiences, those of your loved ones, those of your  
15 friends or your clients in the comments up here? Then  
16 we did as best as we could to span the range of  
17 perspectives that we thought might be shared today.

18 But if you have a different perspective, this  
19 is going to be your chance. So, we really hope to hear  
20 from you in this discussion now. So Meghana and I will  
21 be asking some questions. I think I have a piece of  
22 paper somewhere that I lost. Right here. All right.

1 I'm going to start with a polling question.  
2 Now, you guys can give me a big thumbs-down if you  
3 can't read this. But if you can read this, we're going  
4 to try to go through it. And we would like to set the  
5 stage for what other types of conditions that you may  
6 have. So, you can check all that apply. So you can  
7 check more than one letter.

8 FEMALE VOICE: You have osteoporosis, but what  
9 about osteopenia?

10 DR. EGGERS: Then put that with "other."

11 So A is arthritis or osteoporosis; B, cancer;  
12 C, cardiovascular diseases; D, kidney disease; E, lung  
13 disease, so if you have COPD; F would be neurological  
14 conditions, such as stroke or cognitive impairments; G,  
15 psychiatric conditions, such as anxiety or depression;  
16 H would be other conditions. So that's where  
17 osteopenia would go. And I, if you don't know of any  
18 other conditions that you have.

19 And we'll give you some time to do it. Does  
20 anyone need a clicker?

21 (No audible response)

22 (Pause)

1 DR. EGGERS: And by the way, this is not a  
2 test. So if you don't get to it or if you click the  
3 wrong thing, don't worry.

4 (Inaudible comment)

5 DR. EGGERS: Did it buzz for you? Okay, click  
6 an I for me for a second.

7 MS. CHALASANI: I don't think it will work  
8 now, Sara. We have to wait for the next one.

9 DR. EGGERS: Oh. We'll have to wait again  
10 because we stopped. That's okay.

11 (Inaudible comment)

12 DR. EGGERS: Chronic, yeah.

13 (Pause)

14 DR. EGGERS: Okay. So, as Greta described, a  
15 lot of arthritis. Basically, many of the conditions up  
16 here are represented. So you're dealing with muscle  
17 loss and weakness in addition to the other conditions  
18 that you have. And one thing we're going to want to  
19 tease out a little bit later in our discussion is how  
20 you distinguish between those.

21 We heard from some, from the panelists, about  
22 how you might distinguish those. But we'll want to get

1 into that, how weakness means different to you. But  
2 before we do that, I think there is another polling  
3 question that I'd like to go to. Okay.

4 So when you think about sarcopenia primarily  
5 and in its relationship to the other conditions you  
6 have, we would like to know what health effects are  
7 most bothersome to you. Again, you can choose up to  
8 three. And you'll know it's working, we learned, if  
9 you hear, if you feel the little buzz when you click on  
10 it.

11 So, A, pain; B, fatigue or lack of energy; C,  
12 poor balance; D, difficulty walking; E, reduced muscle  
13 strength or increased muscle weakness; F, depression;  
14 G, other symptoms not mentioned.

15 (Pause)

16 DR. EGGERS: Okay. So, except with  
17 depression, in the room no one chose that. But the  
18 rest, everything else is represented here, with fatigue  
19 or lack of energy being the number one, the most  
20 frequent in the room, followed by difficulty walking.  
21 And then, pain and reduced muscle strength or increased  
22 muscle weakness.

1           Graham, are we getting any responses on the  
2 web?

3           MR. THOMPSON: Just as before, the responses  
4 on the web are very similar to this room.

5           DR. EGGERS: Okay. All right.

6           Now, this may have been a hard question to  
7 answer. We had to pick some terms to use, and we want  
8 to know what terms you would use to describe what  
9 you're feeling. So we guessed at some. And now we  
10 would like to hear from you about -- when we said this  
11 meeting was about loss of muscle mass, muscle strength,  
12 weakness, what does weakness mean to you?

13           Can we have someone? Okay. Let's --

14           (Inaudible comment)

15           DR. EGGERS: These are -- we have eight here,  
16 eight responses in the room. Yes. Let me remind  
17 everyone this is just a sense of what's in the room so  
18 we know where to ask our questions. It should not at  
19 all be interpreted as any kind of survey or study.

20           Okay. So, can anyone describe what weakness,  
21 when we say "weakness," what you think of? And maybe  
22 someone from the roundtables first, back over there

1 with Fernando?

2 MR. CRUZ-VILLALBA: Unable to open a can of  
3 soda.

4 DR. EGGERS: Okay. That's "weakness" to you?

5 MR. CRUZ-VILLALBA: Sure. You can't drink  
6 anything then.

7 DR. EGGERS: Okay. Anyone else? What's  
8 "weakness" to you?

9 (Pause)

10 MR. THOMPSON: Can I make one quick statement  
11 for those on the webcast?

12 DR. EGGERS: Um-hm.

13 MR. THOMPSON: At the bottom right there's a  
14 little speech-bubble icon, says, "Ask a question."  
15 Feel free to ask questions there if you have them.

16 DR. EGGERS: Yeah. We're interested in, how  
17 do you think about weakness? This is your chance to  
18 tell drug developers and FDA, what is weakness to you?

19 PRU: Inability to get out of the car,  
20 particularly after a long journey.

21 DR. EGGERS: Okay. Can you describe why?

22 PRU: Because my lower leg muscles aren't

1 strong enough.

2 DR. EGGERS: Okay.

3 PRU: Pru.

4 DR. EGGERS: Thanks, Pru.

5 All right. So more ideas about what

6 "weakness" means?

7 Okay. If you're on the panel, just use your  
8 -- let's bring all the microphones up real close. You  
9 can just keep them on, I think. Can we keep the mics  
10 on? Okay. All right.

11 Ray, were you going to say something?

12 MR. LIPICKY: Yeah. I was wondering why you  
13 were interested in knowing the answer to these things.  
14 They don't mean anything.

15 DR. EGGERS: Okay.

16 MR. LIPICKY: Why are you asking the  
17 questions, and why are we spending time on this?

18 DR. EGGERS: What question was --

19 MR. LIPICKY: What are you going to do with  
20 the answers? How are you going to translate that to  
21 some functional thing that you're going to recommend be  
22 used as a basis for doing anything?

1 DR. EGGERS: Okay. Then what question would  
2 you like us to ask?

3 MR. LIPICKY: Not these.

4 DR. EGGERS: Okay.

5 MR. LIPICKY: Okay? I mean, I just don't see  
6 any sense in them.

7 DR. EGGERS: Okay.

8 (Cross-talk)

9 MR. BARTLIT: Questions people ask --

10 MR. LIPICKY: You know, you might ask -- you  
11 might ask what kind of functional thing one cares  
12 about?

13 MS. GEPHARDT: Okay. Um-hm.

14 MR. LIPICKY: But that, obviously, is going to  
15 depend on whether you are male or female. And someone  
16 might want to be able to cook for their family. Well,  
17 I guess that's nowadays male as well as female; I don't  
18 know. And that kind of thing. So I don't see that you  
19 can generalize any of this thing to any functional  
20 meaning.

21 DR. EGGERS: So, let's go to Fred and see, and  
22 then we'll ask another type of question.

1 MR. BARTLIT: So we're thinking of prevention  
2 all the time. Everybody knows what a functional  
3 movement assessment is, okay? These real simple seven-  
4 minute tests that universities give beginning athletes  
5 that are starting out, young women, et cetera.

6 You can have a functional movement assessment  
7 done of yourself when you're 45. And it will tell you,  
8 it will be a little embarrassing because it will tell  
9 you what's weakening in your body. And then an  
10 exercise physiologist tells you, "Work on that." And  
11 that won't be the link that fails. You'll always know  
12 what the weakest link is and what to work on. Those  
13 are just simple things that you do.

14 What's amazing to me is, I have the same deal  
15 that he does about doctors, medical. I have two son-  
16 in-laws who are surgeons. And I gave a talk recently  
17 before the 300 top cancer surgeons in the world. I  
18 said, "How many here have heard of sarcopenia?" No  
19 hands went up. Not one.

20 I then said, "How many people here think that  
21 frailty with aging is inevitable?" Every hand went up.  
22 The medical profession is in this silo, and the

1 exercise physiologists are over here, and their paths  
2 never cross.

3 DR. EGGERS: Okay. All right.

4 So what we're hearing is very useful to say  
5 that it's difficult to ask questions about muscle --  
6 about the functioning. What I'm going to ask, for this  
7 meeting, is that we focus on what matters to you. And  
8 we won't focus as much on -- we do want to get in,  
9 after the break, we'll get back into follow-up on what  
10 Greta, Fred, Ray, and Rose talked about about what  
11 you're doing and what can be done.

12 But for right now, we'll just focus on what  
13 the condition is and how it manifests for you and what  
14 really bothers you about it. We'll move to functional  
15 things here in a minute. But does that sound okay?

16 Then we'll go over here to Steve.

17 STEVE: One thing I've found in -- when I was  
18 very weak and sick, the things that come up are, "Gee,  
19 I wish I could lift the kids."

20 DR. EGGERS: Okay.

21 STEVE: You know? "Gee, if I fell down, I'd  
22 like to be able to get up off the floor." The kinds of

1 help that we need, and you know, it can be easily  
2 estimated. Well, how big is the kid? Well, it's 25  
3 pounds. Okay? All right. You need to lift 25 pounds.  
4 You know, here's how you can safely do that.

5 That would be very helpful.

6 DR. EGGERS: Great. And, Steve, would that be  
7 -- I have a nine-month-old and a four-year-old. So I  
8 wish I could do that better, too.

9 STEVE: They're harder to lift when they get  
10 bigger.

11 (Laughter)

12 DR. EGGERS: Is it the bending down and the  
13 coordination of picking up a child? Or is it the  
14 stamina to carry that child for the length of time that  
15 they want you to carry them?

16 STEVE: In my experience, upper-body strength  
17 went first.

18 DR. EGGERS: Okay.

19 STEVE: You know, so that legs lasted a little  
20 longer as I lost weight. But then you get to those  
21 problems, too, where getting out of bed became  
22 difficult. And also, you know, just bending over to

1 lift, my back could go out just bending over, let alone  
2 lifting up the weight. And then I'd be stuck like  
3 that, hauled back into bed.

4 So, the small things that are from there. And  
5 it does go all the way to where, dang it, can't get the  
6 orange juice carton open. Those kinds of things are  
7 each increments in, you know, the -- that. But from  
8 every point, if you start progressively at that point,  
9 you can work back up out of it.

10 So the modalities of therapy have to be gauged  
11 to the individual. And the things that motivate me,  
12 you know, would be things like wanting to lift the  
13 kids, you know, when they came over to visit.

14 DR. EGGERS: Yep.

15 STEVE: This was real important. And there's  
16 the lights that are in everybody's life that are along  
17 that way, or, you know, or grandma was, you know,  
18 wanting to make cookies for them, you know, when they  
19 came. So those are the kinds of things that's hard,  
20 but they can each easily translate into a physical  
21 therapy that can get back to that point with work on it  
22 and, as Rose says, very importantly, good diet.

1 DR. EGGERS: Okay.

2 STEVE: Because in working, I had a hard time  
3 building muscle back until I actually started to get  
4 proper protein intake.

5 DR. EGGERS: Um-hm. All right.

6 Does anyone want to follow up? Does what  
7 Steve say make you think of anything about experiencing  
8 the limited functions of what you -- the limits to what  
9 you can do? And provide concrete examples.

10 Because one way -- FDA, please, my colleagues,  
11 correct me if I'm wrong. But one way is if we can come  
12 up with specific functions that could be translated  
13 into some sort of endpoint at the end of the day for  
14 what a drug might be showing an improvement in. You  
15 can pick up an eight-year-old and not just a six-year-  
16 old. I don't think that would actually be an endpoint,  
17 but --

18 (Laughter)

19 DR. EGGERS: If we could have those concrete  
20 examples, they can spur thinking about what endpoints  
21 maybe could look like at the end of the day.

22 So, any other thoughts?

1 MS. CHALASANI: I think Greta wanted to speak.

2 DR. EGGERS: Okay. Greta, yes, please.

3 MS. DERSHIMER: Well, I have a friend who had  
4 a stroke three-and-a-half years ago. And she had lived  
5 in Hawaii for a long time, and her regular exercise was  
6 swimming. She was paralyzed on her left side. She was  
7 able to come back by working very hard to the point  
8 where she could walk with a cane. But she wanted to  
9 swim.

10 DR. EGGERS: Okay.

11 MS. DERSHIMER: And a year ago, I started  
12 working with her one day a week for an hour on water  
13 exercises. And she now swims back and forth across the  
14 pool with a noodle under her arms. And she is able to  
15 flutter kick and frog kick. She doesn't do so well  
16 with her left arm, but she can get around. And it's  
17 the most important part of her week, actually.

18 DR. EGGERS: Um-hm. Is getting out of the  
19 house --

20 MS. DERSHIMER: Getting out and getting in the  
21 water and being able to swim.

22 DR. EGGERS: Um-hm.

1 MS. DERSHIMER: Now, I think that, and I guess  
2 maybe I agree a little bit. I think what is most  
3 important is very idiosyncratic. And so, I don't know  
4 how that can guide drug development in any way. But I  
5 think the idea that it is individual and therefore the  
6 idea that physical therapists need to have training  
7 that's pretty varied so that they can deal with  
8 individual issues --

9 DR. EGGERS: All right.

10 Yes, Jean-Marc.

11 DR. GUETTIER: Yeah. So, I think for this  
12 question it's -- and we've heard a few people saying  
13 that -- this is a question about, how does the  
14 condition kind of make you feel? And we're going to  
15 get into it a little bit later, but then there's  
16 another question about, well, what are the objective  
17 functions that you've lost because of the condition?

18 And the two are somewhat related. And I think  
19 we've heard from several panelists that, you know, they  
20 don't do things because they know that from past  
21 experience they can't do them anymore. And so, they  
22 decide not to do them. And so, that's more of a

1 feeling aspect.

2 And so, if we are going to sort of go down the  
3 road of developing therapies that treat the  
4 functionality aspect of it, A, we'd want to know, do  
5 you relate -- does your experience relate to any of  
6 these things that you see here? If you don't, what is  
7 the one thing that you most closely relate to? Is it  
8 something like, "Gee, I wish I could still do  
9 something, but I don't want to try it because" -- is it  
10 something like that?

11 Or is it something that you could pinpoint  
12 that's sort of common symptoms that are associated with  
13 the disease that we put together on the slide there,  
14 but they might not relate to you?

15 But, you know, "What is it you feel about the  
16 condition?" is sort of what this question is saying.  
17 And it could be something that's not there, and we  
18 would be interested in hearing what it is that you have  
19 to say about that.

20 MS. CLIFFORD: Can I make a comment?

21 DR. EGGERS: Sure. Yes, Rose.

22 MS. CLIFFORD: So, as a health professional

1 and somebody who works with older adults and tries to  
2 get them to change a behavior or do something different  
3 that would benefit them, I look at things such as  
4 people that are fatigued or lack energy, or people who  
5 are depressed.

6           And I know zero people said depression wasn't  
7 an issue with them. But I have to tell you, so many of  
8 the older adults I work with have mental health and  
9 emotional issues. And there's a lot of stigma in  
10 certain circumstances about that sort of situation.  
11 They have to really feel trust in order to open up  
12 about those kinds of things.

13           But I think sometimes, if you can deal with  
14 the fatigue or lack of energy and depression and other  
15 issues, then you have the motivation and the ability to  
16 do what you need to do to address the difficulty  
17 walking, the poor balance, the pain, and the muscle  
18 strength and weakness, by various interventions that,  
19 you know, centers around physical activity as well as  
20 proper nutrition and other things.

21           And I just want to comment about the -- I,  
22 too, love a heated pool for arthritis. I go to the

1 Sibley therapeutic pool, which is 93 degrees, two or  
2 three times a week. And it is really effective at  
3 working with some of these conditions here. So.

4 DR. EGGERS: Okay. Thank you, Rose.

5 MS. CLIFFORD: We've figured out one of the  
6 things that really helps.

7 DR. EGGERS: Thank you, Rose.

8 So I think we've gotten some good points about  
9 what concerns people living with sarcopenia, whether  
10 related to functionality and some of the health  
11 effects.

12 So we have a lot of other people in the room.  
13 So I'm going to ask. Loved ones, family members,  
14 everyone in this room must know someone who has some  
15 kind of muscle loss or muscle wasting. So, what  
16 concerns you about this condition, whether it's the  
17 balance, the fatigue and lack of energy, difficulty  
18 walking. Anyone? It's a lot of you. I'm going to  
19 start putting the microphone.

20 (Pause)

21 STEVE: One thing I wanted to comment on is  
22 the way that I became -- lost muscle and became weak

1 and frail, was first I got cancer, a large melanoma on  
2 my right thigh and half of the -- or rather, calf. And  
3 half of the calf got cut off. So it started with a  
4 surgery.

5 After three months, they put me on Interferon  
6 for 12 months. And that made me very sick, in bed a  
7 lot, lowered my blood counts. Seven months into the  
8 Interferon, I got valley fever and pneumonia. And that  
9 put me in the hospital with fungal pneumonia  
10 misdiagnosed as bacterial pneumonia, almost to the  
11 point of death.

12 They finally send the blood to the CDC, get  
13 correct diagnosis. Diflucan had just been approved six  
14 months before. Took Diflucan, I began to come out of  
15 it.

16 During that time, it's like I wasn't able to  
17 sleep for two weeks, respirator on continually, barely  
18 able to choke a little breath, and no food. No  
19 nutrition at all, just on an IV. So -- oh, and 104-105  
20 temperatures. So I'm sweating like crazy, losing  
21 muscle mass, and just wasting away. Went from 200  
22 pounds to 145 pounds.

1 I come out of it. There's no discussion about  
2 what's happened to my muscles. There's no discussion  
3 about what nutrition I need now. There's no discussion  
4 of physical therapy. Just, "Go home to get well now.  
5 You have your pill." So, continued to lose more  
6 because I'm still bedridden.

7 After about a year-and-a-half, very poor  
8 health, more surgeries, more complications, and so on.  
9 Five years very bad health.

10 Then cardiac condition. Open-chest surgery,  
11 bypass surgery, okay? Now weak as a kitten and very,  
12 very small and thin. Fred is the one who told me, "You  
13 have to start building your muscles back up." And I  
14 started working on that. And that's been about four-  
15 and-a-half, five years now. I'm now stronger than I've  
16 ever been in my life.

17 So you can come from that point and come back.  
18 And the most dangerous thing was telling myself, "Oh,  
19 this is it. This is my life. I have to accept it."  
20 It's like that was the slippery slope that was most  
21 dangerous. So that's where the counseling has to be  
22 there, along with just the handy things like Rose is

1 saying, as well as progressive steps, turns things  
2 around. So that's my story.

3 DR. EGGERS: Can I follow up on what Steve's  
4 saying? Because I think, Greta, someone else talked  
5 about an acute health scare that you had, or condition,  
6 that then you think made your -- if you didn't have  
7 sarcopenia before, you had muscle loss and weakness  
8 now. How many of you felt your muscle weakness, you  
9 can pinpoint it, the majority of it, to some event like  
10 Steve just described?

11 (Pause)

12 DR. EGGERS: Okay.

13 MR. BARTLIT: Can I make a one-sentence  
14 comment?

15 DR. EGGERS: Yeah, yeah, yeah.

16 MR. BARTLIT: When somebody over 60 spends one  
17 week on bedrest, they lose half of their strength. And  
18 you don't get it back just by getting out of bed.

19 MALE VOICE: That's right.

20 MR. BARTLIT: You've got to start all over.  
21 Think about that.

22 DR. EGGERS: Okay. Okay.

1 MS. DERSHIMER: Well, I talked about it a lot.

2 (Laughter)

3 DR. EGGERS: Anyone else?

4 (No audible response)

5 DR. EGGERS: You know, it's almost time for  
6 our break.

7 MS. CHALASANI: I do think we have one more  
8 polling question left, though.

9 DR. EGGERS: Let's stop with the polling  
10 question. We'll do the polling question, and then  
11 we'll come back after break and we'll discuss what we  
12 got.

13 MS. CHALASANI: Um-hm.

14 DR. EGGERS: Oh, but before we do that, let's  
15 hear from Jack.

16 MR. GWALTNEY: Is there any -- what is the  
17 scientific evidence if it is available that fatigue is  
18 related to muscle weakness, sarcopenia? Are they the  
19 same thing? Or are they possibly two different things?  
20 They are the two major things.

21 DR. GUETTIER: Well, they could certainly be  
22 two separate things. I think what we're trying to see

1 and hear from patients is whether or not you relate  
2 your muscle weakness to fatigue. Or do you relate it  
3 to something else? Or is it an important component of  
4 your disorder, for you as an individual person  
5 experiencing this?

6 We've heard from Ray that he doesn't think  
7 that that is the case for him, that he doesn't relate  
8 to a lot of these things. But it may be that for  
9 others it is an important component. And then if that  
10 is an important component, we'd like to know, how do  
11 you define "fatigue" and how does fatigue manifest  
12 itself? And how do you know it's related to your  
13 weakness?

14 So we sort of want to hear from you why you  
15 said fatigue was important. And you believe that it's  
16 really --

17 MR. GWALTNEY: I understand that. My  
18 question, though, is not the subjective part of this  
19 about what people think, but whether there are any  
20 objective ways to look at this and separate it based on  
21 some kind of scientific testing, which I'm not sure  
22 what that would be.

1           But it seems to me these two things, they're  
2 related, and people say, "Yeah, we got both of them."  
3 But is there any -- I'm not sure what types of testing  
4 would be done that would show there was relationship or  
5 that they were separate entities.

6           DR. GUETTIER: So, I mean, there are ways to  
7 sort of investigate each question scientifically. You  
8 could compare a group with muscle weakness sarcopenia  
9 and one without and then, you know, determine whether  
10 or not fatigue levels are different or people report  
11 fatigue more in one group than the other. And then,  
12 you know, there are ways that we can get at that.

13           Again, this is more of, how do you experience  
14 your disease? And it's all about subjectivity. And  
15 ultimately, you know, if we can actually get, arrive at  
16 an understanding of what patients really feel that  
17 sarcopenia means for them, is important for them, a  
18 drug that treats it should reverse some of those  
19 feelings that are associated with the condition, if it  
20 actually is treating it.

21           So the other way that you can tell whether or  
22 not it's related is by treating the condition. And if

1 the symptoms associated with the condition improve,  
2 then you know that it's related. So those are things  
3 that we'll be looking at.

4 MS. CHALASANI: Okay. So I think we're  
5 cutting a little bit into our break. But I do want to  
6 really quickly go on to the next polling question, I  
7 think, if that's okay.

8 MR. LIPICKY: Well, I'd like to ask you a  
9 question. You've obviously been listening. So next  
10 time someone comes into FDA and talks to you, how are  
11 you going to put what you heard in the last half-an-  
12 hour into action? How is it going to alter your  
13 thinking process? How is it going to alter how you  
14 advise somebody with respect to how a drug should be  
15 developed or how it should be tested?

16 Is there anything operational that has come  
17 out of this last half-hour?

18 DR. GUETTIER: So, we have our friends from  
19 the DOA staff, who -- no, I think that, again --

20 MR. LIPICKY: So you're not going to answer  
21 the question. You're going to drop it.

22 (Cross-talk)

1 DR. GUETTIER: Yeah, I'm going to answer the  
2 question.

3 DR. EGGERS: Wow.

4 MR. LIPICKY: Good. That answers my question.

5 DR. GUETTIER: No. So, no. I think that if  
6 we can actually get -- so, you know, there are ways to  
7 measure function scientifically. There are ways to  
8 measure how people feel, scientifically.

9 MR. LIPICKY: What ways are there? Name one.

10 DR. GUETTIER: We have our experts here.

11 MR. LIPICKY: You're ducking.

12 (Cross-talk)

13 DR. GUETTIER: We have our experts on the  
14 panel.

15 (Cross-talk)

16 MR. LIPICKY: They're going to come to you for  
17 advice.

18 DR. EGGERS: So, I think --

19 MS. CHALASANI: Who wants to go ahead and --

20 DR. EGGERS: You know what? I think let's go  
21 to a break now. We do have some closing comments that  
22 we will have at the end of this. I think Ray is asking

1 a very complicated question for right before break. So  
2 let's take a break.

3 So our Office Director, Theresa, is here, and  
4 I think she wanted to say a few words right before the  
5 break, actually.

6 MS. MULLIN: I just want to add -- I don't  
7 want Ray Lipicky to think we're not answering. But the  
8 fact is, Ray, this meeting is not -- many meetings, and  
9 maybe many of the meetings you remember being at FDA,  
10 FDA did all the talking or most of the talking.

11 And what makes these meetings different is  
12 that we're really here not to talk and take up the air  
13 time, but to really hear from the patients about their  
14 experiences. And the more we understand in their words  
15 what they're going through, the more likely we are to  
16 come up with instruments and data-collection tools that  
17 actually use their words, that are written in ways that  
18 they're going to understand and it's clear to them.

19 So what we need is to hear people here  
20 talking. We don't want to take up the air time. It  
21 was hard enough to get these -- we're taking up  
22 precious time from these people today. We want to hear

1 from them. We don't want to do all the talking.  
2 That's why we keep going back to, what do the people  
3 here who came, who are giving us their afternoon, what  
4 do they think? Not what do we think, right now.

5 Thank you.

6 DR. EGGERS: Thank you

7 Yes. Silvana.

8 DR. BORGES: So, I think that to add to that  
9 is that -- and following up to your question about  
10 fatigue as well, is that these symptoms that we are  
11 discussing today, most of them are symptoms that the  
12 patients report. We don't have any instrument in the  
13 sense of a device that we can measure your fatigue like  
14 that or other symptoms that we're talking about.

15 Difficulty walking? Yes, we can measure the  
16 distance that you can walk. But the strength that you  
17 have and how you feel, maybe, maybe we can have a  
18 treatment that makes you walk, I don't know, five more  
19 steps in that measurement. Is that significant to you?  
20 Is that something that you would consider it's an  
21 improvement? We can maybe measure that.

22 But there's another aspect that is more

1 subjective. But that subjectivity, it's important as  
2 well. So, how do we measure that? And while we're  
3 talking about developing the instruments to measure  
4 that, we're not talking about a device, because we  
5 cannot measure how you feel with a device.

6 But there are, let's say, questionnaires or  
7 other ways of assessing, getting that information in a  
8 systematic way that can give us, let's say, a score  
9 that would be significant. But then, if we have a  
10 score, let's say then we want to now -- well, in this  
11 10-point scale, what is significant to you? If you  
12 improve two points, five points? If you go down to  
13 zero, what is important to you?

14 And all of these we are asking because it's at  
15 the heart of what we need, we at the FDA need to work  
16 with other people to develop these instruments. But we  
17 need to know what's important to you because maybe we  
18 are developing something to measure fatigue, but your  
19 main issue is walking. Maybe it's all of the above.  
20 So, then we need an instrument to measure all of the  
21 above.

22 So we need to know, what is it that sarcopenia

1 really affects patients, how they affect them, so we  
2 can know where we have to put our focus on.

3 DR. EGGERS: Great.

4 FEMALE VOICE: Why do you only ask for three  
5 health effects when I could have said the first six  
6 would be relevant to me?

7 DR. EGGERS: So -- oh, go ahead.

8 DR. BORGES: Maybe that goes to -- in light of  
9 what I was saying, we are asking what are the most  
10 bothersome to you? Because we know that there's an  
11 array of symptoms that you feel. And even though we  
12 would like for, you know, a pill or a treatment that  
13 would address all of them, most of the time our  
14 experience is that we treat some aspects of the  
15 disease. We cannot treat all of them, many times.

16 So, if that is the case, we want to know what  
17 is most important to you. Is it the fatigue issue? Is  
18 it being able to walk longer? Is it being able to be  
19 strong enough to lift your kids or, you know, to get  
20 out of bed? What is it?

21 And of course, it's very -- I mean, it varies  
22 a lot from patient to patient. But we want to hear it

1 all so we can get an idea of what this disease means to  
2 the patients that are suffering from it.

3 DR. EGGERS: And with that, I'm going to put  
4 the timekeeper hat on. And I'm going to call for a  
5 break. And it is twenty till three now. If you could  
6 be back at five till three. We will resume this  
7 discussion and carry it forth. And it's just going to  
8 keep on rolling. Thank you.

9 Remember, the women's restrooms are over this  
10 way, and the men's restrooms are over this way. And  
11 the cafeteria --

12 MS. CHALASANI: It's closed.

13 DR. EGGERS: Closed?

14 (Laughter)

15 DR. EGGERS: We'll check. We'll check. It  
16 might have just been closed for a couple of minutes.

17 MS. CHALASANI: It closed between 1:00 to  
18 1:30, I think. But then they reopened it at 1:30 with  
19 just some coffee and snacks, is what I was told.

20 DR. EGGERS: So it might be reopened.

21 (Whereupon, at 3:41 p.m., a recess was taken,  
22 to reconvene at 4:00 p.m.)

1           LARGE-GROUP FACILITATED DISCUSSION (Cont'd)

2           MS. CHALASANI:    Thank you, everyone.  I hope  
3           you were able to get some refreshments in.  I think  
4           we're going to go ahead and get started with the second  
5           half of our discussion.

6           And to jump right in, we're going to have  
7           another polling question.  And this one is aimed at  
8           kind of getting a little bit more of the effects  
9           translated into more of the more daily impacts that you  
10          might experience day to day.

11          So, the question is How does sarcopenia affect  
12          your life the most?  And we are going to ask you to  
13          choose up to three impacts so that we can really  
14          understand the most aspects of it.  So, A is ability to  
15          perform work or hobbies.

16          DR. EGGERS:  And this means that sarcopenia  
17          affects your ability to do work or your --

18          MS. CHALASANI:  Your hobbies, um-hm.

19          B is sarcopenia or muscle loss or weakness  
20          affects your ability to care for yourself  
21          independently.  C is the ability to leave the home.  D,  
22          risks to safety of self or others.  E, impact on

1 relationships with family and friends. F, emotional  
2 impacts. Or G, other impacts not mentioned.

3 And so, once again, you can choose up to three  
4 impacts.

5 (Pause)

6 DR. EGGERS: And we'll give you a bit of time  
7 for this one.

8 (Pause)

9 DR. EGGERS: Can you give them a bit more  
10 time?

11 (Pause)

12 DR. EGGERS: Okay. So this is just a handful  
13 of people in the room. But it gives us a place to  
14 start our conversation.

15 MS. CHALASANI: Okay. So --

16 DR. EGGERS: Work and hobbies.

17 MS. CHALASANI: Yes, yes. A hundred percent.  
18 So everyone answered this question about sarcopenia  
19 affected their ability to perform work or hobbies. And  
20 then we have ability to care for myself independently,  
21 as well as impact on relationships with family and  
22 friends, about half of the participants. And then a

1 third of the participants said risks to safety of self  
2 or others and emotional impacts.

3 DR. EGGERS: So, the small number, we can  
4 interpret this as that the impact on work or hobbies,  
5 those of you that answered, was universally. And then  
6 the rest of these are a smattering. There's not much  
7 difference. But they were identified.

8 MS. CHALASANI: Um-hm. So I think we touched  
9 a little bit upon ability to perform work or hobbies.  
10 But does anyone want to expand a little bit more on any  
11 other anecdotal stories or experiences that they may  
12 not have shared yet today?

13 FEMALE VOICE: Hi. I just want to add to the  
14 work and problems is that I find the volunteer work  
15 that I used to do was very meaningful to me. And I've  
16 had to cut way, way back.

17 MS. CHALASANI: Why? Why have you then?

18 FEMALE VOICE: Well, I'm just too tired to  
19 take it all on.

20 MS. CHALASANI: If you wouldn't mind, what  
21 kind of volunteer work was it? Was it physical or --

22 FEMALE VOICE: Well, one was more physical,

1 and the other one was too much distance and mentally  
2 fatiguing. But what I do now is I just sit and I write  
3 thank-you notes.

4 (Laughter)

5 FEMALE VOICE: Thank you for being here and  
6 doing all this, really, everybody.

7 DR. EGGERS: Okay. Anyone else? Anyone?

8 (No audible response)

9 DR. EGGERS: Let's look a little bit more into  
10 ability to care for yourself independently. Anyone  
11 want to talk a little bit about that maybe?

12 MS. CHALASANI: And think about, as you think  
13 of yourself as progressing down in muscle weakness,  
14 what concerns you the most about that?

15 DR. EGGERS: I think Fernando.

16 MR. CRUZ-VILLALBA: Thank you. Thank you.

17 There is much that goes along with this  
18 heading. Going up the stairs is certainly a problem.  
19 And it faces a problem for the rest of the family,  
20 really, that if we have to move to a one-level house,  
21 that would be a financial hit. What would we do?

22 In matters of dignity loss, it's another one

1 that is really a thing that affects me. I used to be  
2 very active in the community, a member of Leadership  
3 Montgomery. I don't know if any of you would be there.  
4 But it's a rather significant group in Montgomery  
5 County. And I have had to pull away from doing that,  
6 and as a consequence, pulling away from all of the  
7 friends that I had that influenced government at one  
8 point. So that is a great loss.

9 I don't know how much more I can say to you  
10 that would be of concern. But I did raise a point  
11 about how I got the weakness in the first place. It  
12 was an underlying Lupus condition, or a flare, that of  
13 course systemically affected all of my body, including  
14 the heart.

15 But during the course of treatment, four years  
16 into it, I had to have a surgery for which a antibiotic  
17 was required, and that was Cipro, which is one of the  
18 family of fluocinolones that affect tendons and  
19 muscles.

20 And what this does is it really paralyzed me  
21 for about a week after I had it. I didn't know what it  
22 was and finally decided, yes, you have a black-label

1 warning on that product. And the doctors generally  
2 don't look at it because it's out of the box. In other  
3 words, they gave you the pill, but not reading the  
4 instructions on it.

5 DR. EGGERS: And can I follow up? So you are  
6 saying, I think it's to the point that Steve made, that  
7 you had a period of illness and inactivity. And then  
8 your weakness got worse?

9 MR. CRUZ-VILLALBA: Got worse.

10 DR. EGGERS: Okay. Okay. Yes. That's a  
11 common theme that we're hearing today.

12 MR. CRUZ-VILLALBA: And so, about three, two  
13 years ago, I began this downward trend. And now I'm  
14 really very weak. And I'm basically kind of skin on  
15 bones from having lost all of that. You know, I look  
16 like one of those cartoon characters in the beach with  
17 a big belly and little skinny legs. That bothers me.

18 DR. EGGERS: When you think of where you'll be  
19 in three years from now, Fernando, what are you  
20 concerned about progressing in weakness? What concerns  
21 you?

22 MR. CRUZ-VILLALBA: That I don't want to lose

1 any more of it. Because I really can't afford.

2 Earlier, I mentioned something about popping  
3 open a can of soda. It also goes to the issue of  
4 nutrition, because now many of the canned foods that we  
5 contain have these pry-open things that you pull off.  
6 You don't have the can opener anymore. And that is  
7 hard when you don't have power in your fingers to lift  
8 it open.

9 DR. EGGERS: So the living independently and  
10 being able to --

11 MR. CRUZ-VILLALBA: Absolutely. That's always  
12 in the back of my head. I have a very good wife that  
13 takes care of me and makes sure I have my medications  
14 every day, of which there are many.

15 But in the absence of her, what would I do?  
16 And my wife -- daughter lives in North Planta, and I'm  
17 here? No. You know, who's going to take care of me?  
18 There's not that much of an extended family anymore.  
19 And other people may not have that problem, but I do.

20 DR. EGGERS: Thank you very much, Fernando.

21 Can I ask about the risk and risk to safety of  
22 self and others, so yourself and others? Can anyone

1 explain that further about what that fear or anxiety  
2 is, about your safety or your -- I guess mainly safety  
3 about falls or other injuries, as Greta explained? Can  
4 someone build upon what was said? We have Jack here.

5 MR. GWALTNEY: Well, I have a hobby of  
6 training Labrador retrievers for field trials. And I  
7 have three of them. They weigh about 70 pounds.  
8 They've got a lot of energy. And at night, before I go  
9 to bed, I go out the last thing and let them out so  
10 they can go out and do their business.

11 And when I go out at night, I always tell my  
12 wife, "I'm going out to let the dogs out." So if they  
13 knock me over or break my leg, which they sometimes do  
14 to people, she'll know I'm out there, because I won't  
15 be able to get back in the house. Because I can't get  
16 up -- well, I can get up if I can crawl over to  
17 something that I can grab ahold of and pull myself up.

18 But if I can't do that, then I'm out there all  
19 night, which is okay in the summer, but in the winter  
20 it wouldn't be too good. And that does, every time I  
21 go out at night, I think about that.

22 MS. CHALASANI: Okay. Maybe we can switch

1 gears a little bit now --

2 DR. EGGERS: Well, first, let's -- is there  
3 any other functional impacts that our colleagues would  
4 like to ask about?

5 (Pause)

6 DR. EGGERS: Any other impacts of function  
7 that we haven't discussed today that you'd like to talk  
8 about? We'll go to Steve, and then we'll move on.

9 STEVE: Just briefly, being very sick and  
10 bedridden, after the first year or so people quit  
11 stopping by. People quit calling on the phone.  
12 Profession is lost. Engagement in work is lost. All  
13 of those things stop. And the isolation becomes  
14 terrible.

15 DR. EGGERS: Um-hm, um-hm, right.

16 STEVE: And then it goes on for the whole  
17 time. So there is a loss of community connection and  
18 just all of the everyday interactions that actually  
19 help keep you bright and alive.

20 DR. EGGERS: So should isolation have been up  
21 as one of the choices?

22 STEVE: For me, after a period of time, that

1 became a big factor.

2 DR. EGGERS: Okay. So a choice. Okay.

3 Great.

4 So I think now we want to move into thinking  
5 about how medical treatments could one day help address  
6 these issues. And first of all, can I ask a question?  
7 We have talked a lot about the things that you're doing  
8 and the things that are important to do that are not  
9 medicine -- the physical therapy, the nutrition, the  
10 swimming and other exercises.

11 If you feel comfortable raising your hands,  
12 how many of you think that that's all, for you  
13 personally, that's all you need at this point right now  
14 is what you're doing in all of your other therapies?

15 (Pause)

16 DR. EGGERS: Okay. So, how many think that  
17 what you're doing today with exercise or diet is enough  
18 for you?

19 (Pause)

20 DR. EGGERS: Okay. Okay. How many of you say  
21 if there could be some medicine that you felt  
22 comfortable with, that you wish that there would be

1 some treatments available to help combat the muscle  
2 weakness and strength -- okay. Okay.

3 So we have varying perspectives here. And I'm  
4 going to ask you to keep those, the fact that we have  
5 varying perspectives, in mind in your own personal  
6 experiences. But what we would like to do is to find  
7 out, what would be the benefit of a treatment that you  
8 would look for, that would be important to you?

9 And it could be a number of things. It could  
10 be, we think it's going to be improving function  
11 somehow, or it's going to be improving how you feel  
12 somehow. And we have a number of those things up on  
13 this polling question here.

14 And, you know, I know we're putting you into a  
15 thought, to think in a different way. But if you could  
16 help answer this polling question or answer this  
17 question for us, what we'd like to know is, if you were  
18 considering a new treatment for sarcopenia to address  
19 what we've been talking about today, which one thing --  
20 and then you can tell us later that it's very difficult  
21 to pick one thing -- but for now, which one of the  
22 following things would you consider to be the biggest

1 benefit for you, the most meaningful benefit?

2 So would you rather have a reduction in pain?

3 Click A. If you'd rather have a reduction in fatigue

4 and lack of energy so you'd have more energy, pick B.

5 If you'd like to work on balance, have improved

6 balance, you'd pick C. More endurance during your

7 physical activity, D.

8 Increased mobility, walking across the room,

9 getting out of a chair, going up and down the steps,

10 that would be E. And then just generally improved

11 muscle strength or muscle weakness as a feeling of

12 those, that would be F.

13 And if we missed something and there's

14 something else that you think a medicine, you wish a

15 medicine, would treat for you, then you would pick G.

16 (Pause)

17 DR. EGGERS: So we'll give you a few minutes

18 to think about this because it's a different way of

19 thinking.

20 (Pause)

21 MR. BARTLIT: You know, there is peer-reviewed

22 research saying that the thing that is most correlated

1 with success -- doctors use the term "success." I  
2 guess it kind of means you're getting by all right.  
3 The one thing that's most correlated with success in  
4 the last 20 years of your life is strength. Period.

5 All those things hang on strength. If you're  
6 strong, all those things will be cured. The thing --  
7 this is peer-reviewed stuff. Strength is the thing  
8 that's most important.

9 DR. EGGERS: Okay. But what we're interested  
10 in knowing is, maybe that's the most important. But  
11 what do you want in your day-to-life to be treated the  
12 most, to be improved in your day-to-day life? And I  
13 think we have -- I imagine -- has everyone had a chance  
14 to respond? So we'll let Steve go, and then we'll take  
15 --

16 STEVE: I have some specific examples where I  
17 think drug companies could really help. And that is to  
18 look at all of the treatments from the vantage point of  
19 what creates longer bed rest and what harms muscles.  
20 So, for example, after heart surgery, I'm put on  
21 statins. And it was Lipitor, which is common -- caused  
22 terrible muscle cramping and caused inability to

1 exercise and caused me to be in bed more.

2 This is a severe consequence of a particular  
3 drug. So better drugs that don't have that particular  
4 effect, over time I found my way to Livalo, which  
5 worked okay. But to me, the new drugs, if they're  
6 focused from the over-arching understanding that muscle  
7 health is fundamental to whole body health, and that if  
8 they are being lost in significant measure and that's  
9 not being addressed, that becomes a life-threatening  
10 crisis of its own.

11 And so, in terms of drugs, there may not be  
12 something to go directly at, "Oh, just how do we build  
13 muscle?" It's like, what can we replace the drugs that  
14 are robbing people of muscle and having them lose their  
15 abilities? And how can we find better modalities?  
16 That would be very interesting, and I think there's big  
17 opportunity there.

18 DR. EGGERS: Thanks, Steve. So we won't be  
19 able to get into this discussion, but the point you're  
20 raising is, get other medicines and other conditions to  
21 recognize that either medicines can contribute to  
22 muscle weakness or the fact that I'm ill contributes to

1 muscle weakness, and address it then.

2 Okay. So that point is noted. Thank you for  
3 making that point.

4 Let's go to the results of what we heard about  
5 from the handful of you in the room. Okay. So it  
6 sounds like improved muscle strength or reducing muscle  
7 weakness, just on its own, is what you are looking for.

8 So we heard from Fred. Can someone else give  
9 -- can we hear from someone else about why F was  
10 important to you? Why did you choose F? Is what Fred  
11 said? Anyone want to -- okay. Yes.

12 (Inaudible comments)

13 MS. CHALASANI: Sure. I can read the  
14 percentages. So, for reduced pain we had 13 percent.  
15 We also had 13 percent for increased mobilities such as  
16 walking across the room and getting out of a chair.  
17 And then 13 percent again for G, or "Other."

18 FEMALE VOICE: I would please ask that you  
19 don't report the percents. They don't mean much  
20 because it's a very small number.

21 DR. EGGERS: I'm sorry. And what was your  
22 name?

1 FEMALE VOICE: Oh, I was just going to say  
2 that if you choose F, that is what you need for all  
3 those other options.

4 DR. EGGERS: Okay. And so, then -- boy, I  
5 wish we would have had to pick two things.

6 (Laughter)

7 MS. CHALASANI: I'm interested to know what  
8 the "other" may have been. I think at least one person  
9 said "other."

10 Oh, Fernando.

11 MR. CRUZ-VILLALBA: What is the meaning of a  
12 new treatment? Are you talking about moving around, or  
13 are you talking about a pill?

14 DR. EGGERS: Let's imagine a medicine that  
15 could be a pill or it could be some other way that  
16 medicine -- that you take medicine. And if you're  
17 thinking about a medicine and looking at -- what could  
18 that medicine address? What could it treat? That's  
19 what we were asking.

20 MR. CRUZ-VILLALBA: I can't believe that a  
21 medicine is going to do something for the muscles. And  
22 that's because I don't know a pharmacology of the

1 medicines. But, you know, that's why I went with pain.  
2 I know that I can take Tylenol.

3 MS. CHALASANI: Um-hm, um-hm. Okay. Well, I  
4 think another thing that it could potentially do is  
5 also slow the progression of that downward spiral that  
6 folks have been talking about as well. Maybe that  
7 would be a meaningful benefit, the process happening at  
8 a slower rate, or stopping it at a certain point.

9 DR. EGGERS: So we'll let Jack go.

10 MR. GWALTNEY: Well, I was actually in a study  
11 in which there was a medicine which was designed to do  
12 that. It was the study that was referred to earlier  
13 that Dr. Michael Thorner did at the University of  
14 Virginia.

15 He had a compound called MK-677, which is a  
16 secretagogue for growth hormone. It makes the body  
17 release normal growth hormone. And the design was, it  
18 was a two-year study. Some people were on active for  
19 one year, placebo the second year; some for active two  
20 years and some placebo two years. And it was a double-  
21 blind study.

22 Had a tremendously complicated protocol,

1 including the fact that Mike had them drawing blood  
2 from me every 10 minutes for 12 hours -- 24 hours,  
3 excuse me.

4 (Laughter)

5 MR. GWALTNEY: And you had to have a lot of  
6 good veins. And it showed that my growth hormone  
7 level, as you heard earlier, it went back to the normal  
8 levels it would be if I were in my 20s or 30s. So the  
9 drug really did what it was supposed to do.

10 There were a number of things I thought maybe  
11 happened. But these are very subjective, and it's hard  
12 to know. And it could have been the placebo effect. I  
13 thought I woke up less at night. I felt like I did  
14 have more stamina. I had urinary urgency, which  
15 decreased some. These things later returned.

16 One of the major things was the stiffness and  
17 the little aches and pains, that all old people have  
18 and that young people don't know what we're talking  
19 about, went away. And what's hurting right now, is it  
20 your knee or your shoulder or whatever, nothing major,  
21 but you're always there and you're stiff.

22 And when you start to move as a young person,

1 you just get up and go. Now, if I were to get up here  
2 -- I've already decided this table is sturdy enough so  
3 when I push on it to get up, it's not going to turn  
4 over and all the stuff's going to fall on the floor and  
5 I can get my hand back here.

6 And so it's a major thing. Every time I get  
7 up, and if I'm in a restaurant and it looks like the  
8 table is going to turn over when I push on it, then I'm  
9 in trouble. But that seemed to go away.

10 Now, one thing that happened which I thought  
11 was very interesting, which was objective, I had a  
12 *Trichophyton rubrum, rubrum*, a fungus infection in the  
13 palm of my hand, which I had for as long as 15 years.  
14 And it had been treated several times by a  
15 dermatologist at the University of the Virginia.

16 And this caused just little tiny blisters on  
17 the palm of my hand. And then they would coalesce, and  
18 the skin would slough off and look kind of red. It  
19 wasn't painful, and it wasn't very deep. But it was  
20 annoying, and my hand looked terrible.

21 It went away after I had been in the study for  
22 several months, and this never returned. I also had a

1 fungus infection of one of my toenails. It went away,  
2 but it did return several months after I discontinued  
3 the medicine.

4 But one of the things that comes up in this  
5 type of approach is, you've got this growth hormone,  
6 and what's it going to do if you've got malignancies?  
7 Will it stimulate the growth of malignant tumors? And  
8 I say that you could at least hypothesize, particularly  
9 in relation to this Trichophyton thing, that maybe it  
10 stimulates humoral cellular immunity and it may have a  
11 positive effect in terms of prevention of malignancy  
12 rather than a negative effect.

13 I think if other studies are done, it would be  
14 very interesting to do things in which you measure --  
15 you look at measurements of cellular immunity and of  
16 humoral immunity, and see what happens in vaccine  
17 responses, which we know, say, with the influenza  
18 vaccine, they're not good in older people. But put  
19 that also into the study to see if this is not  
20 strengthening the immune system and maybe having a  
21 positive effect.

22 I also got bilateral carpal tunnel syndrome.

1 The tendons in my wrists become entrapped by the tissue  
2 through which they go, which occurs with acromegaly,  
3 which is, of course, the condition where you have  
4 increased human growth hormone. And so, I think that  
5 may well have been a complication of the treatment that  
6 I was on.

7 I did have to have surgery. I would not mind  
8 paying that price if I had something that would reverse  
9 these other things we've talked about.

10 One other thing I thought that was  
11 interesting, and I don't quite understand, but this  
12 compound did not lead to increase in testosterone  
13 levels. And I never was very good in endocrinology and  
14 I've never asked Mike why that's so. But I had a  
15 radical prostatectomy for prostate cancer.

16 And two years afterwards, my PSA became  
17 positive again, and I then had radiation. And I'm  
18 still negative now after four years, and my urologist  
19 says I may be cured, but he says, "I don't think you  
20 should try testosterone for your weakness," which has  
21 been used and which is available and there are some  
22 side effects. But anyway, I've not elected to do that

1 because of that particular situation.

2 So, I think that this is certainly a viable  
3 approach. And I hope that further work will be done in  
4 this area. And I've told Mike, if they do, I want some  
5 more of those pills.

6 (Laughter)

7 MR. GWALTNEY: You can't get them now at the  
8 present time.

9 MS. CHALASANI: Thank you. Thank you.

10 DR. EGGERS: Well, Jack has a good -- we won't  
11 be talking about any particular treatments in the final  
12 few minutes that we have. We're going to go for  
13 another five or ten minutes. Does that sound  
14 appropriate? Okay. We can go 10 minutes. Because you  
15 have bridged us into another topic.

16 So we do want to, and if you're encouraging  
17 people to send in comments, if you encourage people to  
18 send comments to our docket on that website that we  
19 have, these are the types of things that FDA wants to  
20 know about -- is what would you look for in benefits?

21 And then the final thing to discuss is how you  
22 might think of tradeoffs between benefits and risks of

1 a medicine that could treat muscle loss and weakness?  
2 So I'm going to ask you a question, and we're going to  
3 put the words up on the screen. But it's maybe pretty  
4 small -- small font. So don't worry. You don't have  
5 to read the question. I'm going to tell you about  
6 this.

7 Hypothetical treatment. It does not exist.  
8 There is no FDA-approved treatment for this. But  
9 imagine that FDA has approved a new treatment that's a  
10 monthly injectable medication. And it will treat  
11 sarcopenia. And your doctor thinks that you may be a  
12 good candidate for this medicine. Okay.

13 So in the clinical studies like the one Jack  
14 was in, one-half of the older adults who took the  
15 medicine achieved a 20 percent increase in walking  
16 speed -- 20 percent increase in walking speed. And  
17 they did that within three months.

18 The common side effects are fatigue,  
19 headaches, weight gain. And the medication is also  
20 believed to cause rare, but serious, side effects such  
21 as liver problems or cancer. Okay.

22 So, what first questions would you have, do

1 you have, as I just read that scenario out, that  
2 hypothetical treatment? What comes to your mind? You  
3 have something in mind.

4 (Laughter)

5 DR. EGGERS: I hear some laughing and some  
6 thinking. So what's your first thought?

7 FEMALE VOICE: I'm not going to take it.

8 DR. EGGERS: You're not going to take it.  
9 Okay.

10 Others? First thought?

11 FEMALE VOICE: It's going to make life worse  
12 rather than better.

13 DR. EGGERS: Makes life -- potentially makes  
14 life worse rather than better.

15 Okay. Back there, Fernando.

16 MR. CRUZ-VILLALBA: The other one is, of  
17 course, who's going to pay for it?

18 DR. EGGERS: Okay. Who's going to pay for it?

19 Other questions? Steve.

20 STEVE: We've started with friends, Fred and  
21 I, and like we had a guy who had HIV for 30 years and  
22 was thin and frail. We've had women that are 400

1 pounds and are sarcopenic, obese. It's not uncommon at  
2 all. And in fact, we don't have a single case where  
3 after working for them for four to six months they  
4 weren't 200 to 300 percent stronger. And you can do  
5 that without any side effect.

6 So I'd say first thing, first thing, look at  
7 what's available and what can be done. And if the risk  
8 is high or even significant, and the increase is low,  
9 much lower than you can get just with decent physical  
10 therapy, just set it aside and go on to the next until  
11 something comes along that actually adds an additional  
12 benefit to modalities that are not toxic and are easily  
13 available.

14 DR. EGGERS: And an additional benefit, you  
15 could imagine, might be -- what's a kind of additional  
16 benefit?

17 STEVE: Oh, it's cheap.

18 DR. EGGERS: Okay.

19 STEVE: You're going to get involved with  
20 people. You'll go to places where things are  
21 happening. As your strength increases --

22 DR. EGGERS: Oh, those types of benefits.

1 Okay. Okay.

2 STEVE: Yeah. Every kind of -- you know, all  
3 the things of life, you know, come with being able to  
4 do all those things.

5 DR. EGGERS: Okay. Yes, Rose.

6 MS. CHALASANI: Yeah. I want to say that I'm  
7 really a minimal medicine person. So many older  
8 adults, people with sarcopenia, take so much medicine  
9 it's unbelievable. And I think medicine causes -- I  
10 mean, some medicine can have positive effects. But  
11 you're right, there's risks to everything.

12 And I think that everyone is always looking  
13 for a magic bullet, a quick fix. And there really  
14 isn't a quick fix for sarcopenia. You have to do the  
15 work. The work includes physical activity and  
16 improving your nutrition, as well as other things.

17 But, you know, a pill would be, especially --  
18 I think you can achieve some of your objectives with  
19 much safer alternatives. It's just that they're  
20 harder. And they require a different set of skills and  
21 a different set of motivation and a different set of  
22 beliefs. Is that right?

1 DR. EGGERS: Okay.

2 So, Greta, please.

3 MS. DERSHIMER: Well, I think the first thing  
4 is the benefit is a minimum benefit. I mean, what is  
5 the magic of walking 20 percent faster?

6 DR. EGGERS: Okay.

7 MS. DERSHIMER: I mean, it doesn't stop you  
8 from doing anything else with speed with which you can  
9 walk, really. So it's a low benefit. It's high risks.  
10 And it's an injectable medication, which I think a lot  
11 of people would have difficulty with. I can't conceive  
12 of very many people that would want -- would be happy  
13 about that as a new treatment available.

14 DR. EGGERS: Okay. And I'm seeing some head  
15 nods in the room. Does anyone make a different case,  
16 anyone brave enough to say, "Yeah, I would be willing  
17 to treat this if I was now, or if I was in a certain  
18 place in my life"?

19 (No audible response)

20 DR. EGGERS: I'm going to turn to my FDA  
21 colleagues. Are there any in the final minutes we have  
22 remaining, any specific questions that you had about

1 any of the stuff we've been talking about or about this  
2 treatment in general?

3 Yes, Wen-Hung.

4 DR. CHEN: I have a question. When Fred  
5 mentioned about like the downward spiral, you feel  
6 weaker and weaker, I want to know how you noticed that?  
7 What made you notice that you were getting weaker and  
8 weaker?

9 What came to you to say, "Wow, I'm weaker now  
10 than when I was like a month ago or a year ago"? What  
11 strike you as, say --

12 MR. BARTLIT: That's a very good question.  
13 It's insidious. It sneaks up on you. And it's not  
14 like you're 48 and you get out here. You pick up your  
15 golf clubs and play a hole, and then two months later  
16 you can't. That's why so many people get caught in  
17 this spiral, because the changes are insidious.

18 And, you know, I've been through them. And  
19 you notice that you're 74, and you never used to catch  
20 your toe when you climbed and went hiking in the woods.  
21 Suddenly, you start catching your toe. And you say,  
22 "Something is happening with my body. I have to change  
that." What do I do? Believe it or not, go to an NBA

1 basketball game. You know what they do before the  
2 game? They skip.

3 So try skipping down this as fast as you can.  
4 Skipping is great for lifting your feet higher. You  
5 learn to stand on one leg whenever you're waiting for  
6 an elevator. You learn to do all these things, and  
7 pretty soon, a week or so later, or six months or so  
8 later, you're not catching your toe anymore. You're  
9 not starting to fall down.

10 You have to be aware of your body. But the  
11 functional movement assessment is key. And everybody  
12 should have those done. I'll bet there isn't a single  
13 person in this room that's ever had a functional  
14 movement assessment. It's key. That teaches you what  
15 part of your body is failing the fastest.

16 And then you work on that part of your body.  
17 And you guys never even heard of it. Right? I mean,  
18 you've got to be honest. Never heard of it.

19 Can I make one more point about medical  
20 science?

21 DR. EGGERS: You can.

22 MR. BARTLIT: No, I'm serious. Again, I've

1 got two son-in-laws who are surgeons. They're great  
2 guys. They're academic surgeons. They give up their  
3 lives. They go to China and fix people's faces for  
4 free, and they do all the -- you know, Doctors Sans  
5 Borders kind of stuff. They're great guys.

6           Okay. Here's what the smartest doctor in  
7 America thinks about sarcopenia: Smartest doctor in  
8 America, brilliant man, Oxford, Harvard, Penn, great  
9 bio-ethicist, wrote a long piece recently discussing  
10 what he didn't call sarcopenia. It was just the  
11 frailty of aging. This wonderful man wrote a piece.  
12 It's in the Atlantic. You can look it up.

13           You all know the man. You know Ezekiel  
14 Emanuel, great guy, friend of mine, Rahm Emanuel's  
15 brother. He wrote a piece which said, "Nobody should  
16 live older than 75 because the frailties of aging are  
17 so awful that life's no fun anymore." Think about  
18 that!

19           This guy is one of the smartest physicians and  
20 medical researchers and scientists in the world, and  
21 he's advising -- get the Atlantic article and read it.  
22 It will make your blood boil. He says, "We've got too

1 many of these people who are 75 and trying to exercise  
2 and fight off old age."

3           When I read that, I was with my 14-year-old  
4 granddaughter in Vail, skiing the deep powder. And I  
5 realized it's Zeke, I wrote him an email. "I'm  
6 supposed to be dead 10 years ago and I'm having one of  
7 the best days of my entire life?" But that's what this  
8 is all about. It's not about existing or existing a  
9 little better. It's making yourself be the best you  
10 you can be. And that's worth everything, okay?

11           Read the Atlantic article. You're going to be  
12 blown away by what Emanuel says. Thank you. Thanks  
13 for giving me the time.

14           DR. EGGERS: Yeah. Thanks. So, I think Fred  
15 has made a point that the folks in the room have  
16 traveled, some quite a distance, to come and give their  
17 input. And on that note -- unless, Rose, you have one  
18 quick thing?

19           MS. CHALASANI: I have a quick comment, and  
20 it's really in relation to women. I think a lot is  
21 also -- when women go through menopause, I think that  
22 ratchets them down a notch in terms of some of these

1 things. This is just -- you know, this is my peer  
2 group here. All the mothers I know, you know, going  
3 through this particular situation or over on the other  
4 side.

5 And so, I think people start to do less. Or  
6 they can't do as much as they used to do, and they used  
7 to have to do a lot every day, all day long, 5:30 in  
8 the morning till 9:30 at night. You just start to  
9 realize you can't do that anymore.

10 So, you know, it could be hormones that have  
11 an effect as well, on people, you know, loss of ability  
12 to do as much as they used to.

13 DR. EGGERS: Okay. All right. Thank you,  
14 Rose.

15 Well, this is the end of the facilitated  
16 discussion. On behalf of Meghana and myself and our  
17 team, and our FDA colleagues, a very sincere thank you.  
18 We asked you a tough job to come and talk about  
19 sarcopenia in a way that is pretty hard to think about  
20 it and to share your insight and to try to interpret  
21 our questions and answer them, and to ask your own  
22 questions and demonstrate what's important to you about

1 your condition, about what you think needs to be done  
2 to treat it, et cetera.

3 So with that, we're going to close. Please,  
4 everyone give our participants a round of applause for  
5 participating.

6 (Applause)

7 DR. EGGERS: And with that, I'm going to ask  
8 Pujita to come up and do the Open Public Comment  
9 session.

10 OPEN PUBLIC COMMENT

11 MS. VAIDYA: Hello, everyone. I'd like to  
12 thank you all for coming today. We're now moving into  
13 the Open Public Comment session.

14 And for those of you who are not aware, the  
15 main purpose of this session is to allow an opportunity  
16 for those who have not had a chance to speak on issues  
17 that are not related to our two main discussion topics  
18 that we covered today. This is an opportunity for  
19 folks who are not patients or patient representatives  
20 to comment.

21 Please keep in mind that we will not be  
22 responding to your comments, but they will be

1 transcribed and be part of the public record. Since we  
2 would like this to be a transparent process, we  
3 encourage you to note any financial interests that you  
4 have that are related to your comment.

5 If you do not have any such interest, you may  
6 state that for the record. And if you prefer not to  
7 provide this information, you can still go ahead and  
8 provide your comments.

9 So we have collected signup before the meeting  
10 and during the break. We have a total of six people  
11 who have signed up, and about a little less than 20  
12 minutes for this session. So please be respectful for  
13 your other colleagues here and other patients, and  
14 stick to the three-minute limit that we have for this  
15 session per person.

16 I will be keeping track of time up here. And  
17 when I see that you are reaching your three-minute  
18 mark, I will need to ask you to stop. If you do have  
19 additional points that you would like to say, I suggest  
20 submitting those to our public docket. That will be  
21 open to up to 60 days after this meeting today. So I  
22 strongly encourage you to submit your comments there.

1           So, right now I will run through the order of  
2 speakers. And I apologize in advance if I mispronounce  
3 your name. We will be starting off with Michael  
4 Thorner, then Adrian Fugh-Berman, Nicholas Mendola,  
5 Ronenn Roubenoff, Ram Miller, and then finally Cynthia  
6 Bens.

7           So first, could I have Michael Thorner? And  
8 we'll bring the mic to you.

9           DR. THORNER: Thank you. First of all, my  
10 name is Michael Thorner, and I'm an emeritus professor  
11 from the University of Virginia and the Founder and the  
12 Scientific Officer of Ammonett Pharma, which is  
13 developing a drug for sarcopenia. So that's my  
14 disclosure.

15           First of all, I'd like to thank the  
16 organization here and Dr. Guettier in particular, for  
17 holding this public forum, because I think this is a  
18 really important area.

19           I've been working in this field for over 20  
20 years. And there are two things that have really  
21 impeded progress, I believe. One is the recognition of  
22 sarcopenia as a medical condition. In general, only

1 conditions that are considered to be medical conditions  
2 are ones that are eligible for consideration for  
3 approval for pharmacological interventions.

4 And secondly, there's been no defined  
5 regulatory pathway for considering drugs for  
6 sarcopenia. And so, that's something that's been  
7 deficient.

8 Right now, we have a lot of work that's been  
9 done by many different disciplines, including the type  
10 of work that Fred described by Dr. Fielding and his  
11 colleagues, and others, in the exercise physiology  
12 intervention, nutrition, and in pharmacologic  
13 developments.

14 And also, there have been the FNIH and the  
15 discussions between the National Institute of Aging,  
16 FDA, and the pharmaceutical industry. And they've had  
17 several meetings, and there have been several position  
18 papers. So there is a great deal of information that's  
19 out there.

20 And I think this is a great opportunity for  
21 the FDA to show leadership in helping the field move  
22 forward in working together with academia and with the

1 public and with patients, work as a group to make an  
2 accelerated pathway so that treatments, which hopefully  
3 have a different profile from that last profile that  
4 was put up there, where my first thought was, "How was  
5 that ever approved?"

6 (Laughter)

7 DR. THORNER: Well, we could have therapies  
8 that are, first of all, not harmful; most importantly,  
9 that would be beneficial; and finally, as I can see the  
10 clong (phonetic) is about to cling, that not only would  
11 deal with improving sarcopenia, but in fact preventing  
12 sarcopenia from getting worse.

13 As an example, people have mentioned when  
14 people get sick, particularly old people when they get  
15 sick, they lose muscle mass at a tremendous rate. If  
16 you could just prevent that, that would be beneficial  
17 in itself. Thank you.

18 MS. VAIDYA: Thank you, Michael.

19 Next we have Adrian.

20 MS. FUGH-BERMAN: Hi. I'm Adrian Fugh-Berman,  
21 and I'm the Director of PharmedOut at Georgetown  
22 University Medical Center. We're a research and

1 education project that does research on how the  
2 pharmaceutical industry affects therapeutic choices.

3 I've also been a paid expert witness in  
4 litigation regarding pharmaceutical marketing  
5 practices.

6 This meeting is very different from other  
7 patient-focused drug meetings that I've been at mainly  
8 because of the lack of patients pushing for drug  
9 treatments for their conditions. I think the stories  
10 we've heard here are very inspiring.

11 But I just want to defend the FDA a little.  
12 You know, they think this is a really important  
13 condition because that's what they hear in the medical  
14 literature. That's what they're hearing at medical  
15 meetings.

16 Sarcopenia exists, but it's not actually a  
17 real disease. The selling of sarcopenia as a disease  
18 is a clear example of industry control over medical  
19 discourse, the subject of the conference we're holding  
20 at Georgetown in June.

21 Normal aging's pandemic, so a drug treatment  
22 for normal manifestations of aging has a large

1 potential customer base. There have been a lot of  
2 articles in the medical literature in an attempt to  
3 link sarcopenia with real medical diseases and real  
4 diseases. And this is easy to do because real diseases  
5 can limit mobility, and limited mobility causes loss of  
6 muscle mass.

7 Ten years ago, in 2006, sarcopenia was  
8 mentioned in Medline Index Abstracts 98 times. In  
9 2016, there were 1,021 mentions of sarcopenia. And I  
10 hope you can see my little graphic here. But this is  
11 how sarcopenia has gone up in the medical literature.

12 There have been a lot of efforts made to scare  
13 consumers. It's not clear if these efforts have been  
14 successful; I'd say from today that they really haven't  
15 been. There's an industry-funded website, Aging in  
16 Motion, funded by Novartis, Astellas, Abbot Nutrition,  
17 and other industry partners, that exaggerates the  
18 effects of sarcopenia and rather boldly states that its  
19 goal is to manipulate regulators.

20 Quote: "A lack of action at the regulatory  
21 level further impedes progress in research, innovation,  
22 and development of therapies to effectively treat or

1 manage sarcopenia." Aging in Motion tried to drum up  
2 patients to come to this meeting. They had a webinar.  
3 They actually offered to pay transportation. Is there  
4 anyone here whose transportation was paid by Aging in  
5 Motion or by industry to be here, that will admit it?

6 (Pause)

7 MS. FUGH-BERMAN: Interesting. Okay. So,  
8 they apparently weren't very successful.

9 Perhaps the -- but anyway. Some of the things  
10 they say on the website, I won't read all of this, but  
11 "Sarcopenia leaves millions of aging Americans  
12 vulnerable to falls and fractures, hospitalization,  
13 loss of mobility, frailty, institutionalization, and  
14 death. The direct U.S. health care costs of sarcopenia  
15 are estimated at over \$18 billion a year." They go on  
16 to say it's actually hundreds of billions.

17 Fightsarcopenia.com, sponsored by Abbott,  
18 conflate sarcopenia and malnutrition. Even if you  
19 don't have sarcopenia, by the way, you can't escape a  
20 diagnosis. You have, many people in this room, I have  
21 this -- pre-sarcopenia, which is characterized by  
22 reduced muscle mass, no reduction in muscle strength or

1 physical performance. Well, that applies to every  
2 elder who's not diagnosed with sarcopenia.

3 Perhaps the difficulties inherent in  
4 portraying low muscle mass as a silent killer led drug  
5 and supplement manufacturers to obfuscate the issue by  
6 linking the term "sarcopenia" to frailty, osteoporosis,  
7 and cachexia whenever possible.

8 MS. VAIDYA: Thank you, Adrian. I would like  
9 to ask if you would like to wrap up. And then we'll  
10 move on to the next person.

11 MS. FUGH-BERMAN: Okay. All right.

12 There's been a lot of drugs being developed,  
13 including myostatin antagonists, which have risks.  
14 Androgens and selective androgen receptor modulators  
15 also have risks. There haven't been any drug  
16 treatments for age-related sarcopenia that have been  
17 successful, which hasn't been for lack of trying.

18 Sarcopenia has been called "the next  
19 osteoporosis." Several Novartis researchers wrote,  
20 "Muscle is the last un-drugged organ system." I  
21 personally want to die with at least one un-drugged  
22 organ system. Sarcopenia's not a disease. It should

1 not be a medical diagnosis. And it does not need drug  
2 treatment. Thank you.

3 MS. VAIDYA: Thank you, Adrian.

4 Next we have Nicholas Mendola.

5 MR. MENDOLA: Hi. My name's Nick Mendola.

6 I'm a public health student at the Milka Institute  
7 School of Public Health at the George Washington  
8 University. And I'm transitioning from exercise  
9 physiology to the public health field.

10 And as a younger person who has not  
11 experienced this, I really appreciate everyone that's  
12 in this meeting that's shared their story.

13 One of the biggest things I wanted to talk  
14 about from an exercise science perspective is really  
15 pushing the exercise and nutritional treatment of this,  
16 which was really well stated by our panel and several  
17 of our guests here. There's a lot of studies talking  
18 about use of nutrition and vitamin D supplementation,  
19 proper protein intake, and using that to really combat  
20 sarcopenia and loss of muscle mass.

21 And there's a big problem with malnutrition,  
22 as stated by our RD over there. About 15 percent of

1 individuals above the age of 60 consume less than 75  
2 percent of the recommended daily amount of protein.  
3 And when they do consume protein, it's oftentimes in  
4 very confined time frames, usually at one meal. And it  
5 needs to be spread out much over the entire day.

6 And a lot of it just needs to be consistent  
7 regulated exercise programming, which is challenging as  
8 we get older, but obviously needs to be done to  
9 regulate not-loss of muscle mass.

10 And just using that to really emphasize the  
11 use of a drug treatment with a usually heavily  
12 medicated population has the potential for interference  
13 and other side effects, where exercise and nutrition  
14 and proper diet and management of lifestyle does not  
15 have anywhere near the same adverse side effects.

16 MS. VAIDYA: Thank you, Nicholas.

17 Next we have Ronenn Roubenoff.

18 DR. ROUBENOFF: Thank you. I'm Ronenn  
19 Roubenoff from Novartis. I'm also a professor of  
20 medicine and nutrition at Tuft's University. And I've  
21 been working in this field since 1989, which is the  
22 year that my then-boss coined the term "sarcopenia."

1 I wanted to get to a bit of confusion that I  
2 think is very common here. And it gets to the  
3 definition, which is what Dr. Sharretts presented  
4 earlier. The definition of sarcopenia has bounced  
5 around for a long time. But in 2010, we had a  
6 conference with people from FDA, and they told us, "We  
7 need a clear definition. We need scientific community  
8 assessment and consensus on what this is before we can  
9 go further."

10 And over the past seven years now, I think we  
11 have achieved a lot of that, so that we now have had  
12 three clear international definitions of sarcopenia,  
13 which are all essentially the same. They've gotten  
14 away from the concept of just the body mass change,  
15 muscle mass change, to function change as well.

16 And when you do that, you clearly make a  
17 distinction between sarcopenia as a process, which is  
18 universal. Everybody loses muscle as they get older.  
19 Starts in their 30s, has to do with all sorts of  
20 changes in the nervous system and the hormones and so  
21 on that support muscle growth. But that's not a  
22 disease. I agree with that.

1           What is a disease is when that causes  
2           disability and loss of muscle strength to the point  
3           that people can't function. And that, according to  
4           data now from the 25,000-patient NIH-funded study, is  
5           somewhere between 2 and 5 percent of elderly people. I  
6           think that's a real population where exercise and diet  
7           are necessary, but not sufficient for the treatment.

8           I think that's where the focus can be. And  
9           then I think there really is consensus in the  
10          scientific community now around this. And now, with  
11          the ICD-10 Code, as people have said, there's a chance  
12          for recognition in the clinical world, which is only  
13          just beginning.

14          I think that's part of the reason that it's  
15          hard to find patients. People have this, but they  
16          don't know they have it and their doctors don't know  
17          they have it.

18          So I think this is where the next generation  
19          of treatments is going to be.

20          But I really do think that there are people  
21          for whom diet and exercise alone are not enough, and if  
22          a drug were developed and was sufficiently safe and

1 effective, it could be a real benefit. Thank you.

2 MS. VAIDYA: Thank you, Ronenn.

3 Next we have Ram Miller.

4 DR. MILLER: Thank you. Ram Miller. I'm also  
5 from Novartis. But I'm speaking more from the context,  
6 I'm also a geriatrician by training. And in my  
7 clinical practice I deal with sarcopenic older people  
8 all the time.

9 So, in that context, I want to just comment on  
10 one of the things that was raised earlier, which is the  
11 importance of chronic disease. I know many people have  
12 mentioned many of the chronic diseases. But I think,  
13 as Ronenn was alluding to, one of the things that we  
14 recognize as geriatricians is that sarcopenia coexists  
15 with chronic disease.

16 And if you look at the list of chronic  
17 diseases that the people in this room reported, those  
18 are the ones that any clinician who takes care of older  
19 people would have guessed would be the ones that most  
20 people would have reported -- you know, arthritis,  
21 cardiovascular disease.

22 But clinically, we recognize, as

1 geriatricians, that they may be correlated, but we  
2 don't believe that sarcopenia is caused by these  
3 chronic diseases. So, sarcopenia, as Ronenn alluded  
4 to, is part of these other age-associated responses.

5 I think it's also important that, clinically  
6 as geriatricians, we deal with -- we're confronted with  
7 ageism and therapeutic nihilism all the time. And this  
8 is one of the things that we have to fight against.  
9 And I've heard some themes about that here, as well as  
10 that this is just a part of aging, this is normal, you  
11 know.

12 And as geriatricians, we have always fought  
13 against that. And we get that all the time. And, you  
14 know, the earlier examples are we don't have to treat  
15 high blood pressure in older people; that's just  
16 normal. And then we have to show that, well, yes, we  
17 can treat it. We can treat it safely. And if we do  
18 so, it improves the outcomes.

19 And I think we're dealing with the same thing  
20 here, because I think everyone will recognize that the  
21 consequences of sarcopenia are significant. Whether  
22 it's functional decline, social isolation, loss of

1 productivity, decreased resilience to acute illness and  
2 hospitalization, those consequences are serious and  
3 real.

4 So I think we have to prove that it's possible  
5 to treat those people who are at risk, safely. And we  
6 need to avoid the therapeutic nihilism and the results  
7 from the ageism that these things aren't a disease and  
8 they need not be treated.

9 I think one of the things we have to recognize  
10 is most of the chronic diseases that most people are  
11 familiar with have been around for a very long time.  
12 It's only recently that life expectancy has increased  
13 to the point that people are living long enough to  
14 experience some of these age-associated syndromes that  
15 we haven't encountered hitherto.

16 And I think there needs to be a paradigm shift  
17 in the way we think about these things. The old  
18 paradigms may not apply.

19 MS. VAIDYA: Thank you, Ram.

20 And finally, we have Cynthia Bens.

21 MS. BENS: Hi, everyone. I'm Cynthia Bens,  
22 and I'm Vice President of Public Policy at the Alliance

1 for Aging Research. And I also serve as Executive  
2 Director of the Aging in Motion Coalition that you all  
3 heard about earlier.

4 We do receive support from Astellas  
5 Pharmaceuticals, Novartis Pharmaceuticals, Avid  
6 Nutrition, Nutricia, as well as GE Health Care and  
7 Hologic. And we're very transparent about the funding  
8 we receive from industry.

9 But I wanted to use my time, even though I  
10 didn't have prepared remarks, to just applaud the FDA  
11 for having this meeting.

12 Most of the patient-focused drug development  
13 meetings that have been held so far have been on  
14 diseases that were recognized. And when you all  
15 selected sarcopenia as the disease to focus on, it had  
16 not yet been recognized by the CDC as a condition. So  
17 it takes a lot of courage to devote the resources and  
18 time of your staff to bring patients and caregivers  
19 here.

20 I would also note that you did hear from a  
21 number of people today for which nutrition and exercise  
22 was effective in targeting their condition. But there

1 are a number of other people, who couldn't make it here  
2 today, whose nutrition and physical activity was not  
3 enough to treat them. And that is a primary concern of  
4 our coalition.

5 And that's why we've been working with the FDA  
6 not just to engage in conversations about it, but we're  
7 actually pursuing the development of an endpoint that  
8 can be used in clinical trials, where we're working to  
9 develop data for people who are immobile, to try to get  
10 a sense from them of what's going to be important to  
11 them to recover from their inactivity and their  
12 immobility.

13 So those are the types of activities that we  
14 engage in through our coalition.

15 I'm not going to take three minutes. We're  
16 actually going to submit some comments for the record.  
17 But again, thank you to FDA for having this meeting  
18 today.

19 MS. VAIDYA: Thank you, Cynthia.

20 (Applause)

21 MS. VAIDYA: And that wraps up our Open Public  
22 Comments period.

1                   Now, finally, I would like to ask Dr. Jean-  
2 Marc to come to the stand for his closing.

3   CLOSING REMARKS

4                   DR. GUETTIER: So, I want to thank, first and  
5 foremost, the patients, the patient representative that  
6 came today to testify about their personal experience  
7 living with loss of muscle mass, weakness, and strength  
8 related to aging. And I think that the testimony took  
9 a lot of courage. You're talking to the FDA.

10                   I want to thank the people online that also  
11 testified and participated in the polling questions.  
12 So thank you very much for making it here and for  
13 actively engaging with us. I want to thank the people  
14 in the Office of Strategic Programs, who really planned  
15 this meeting and ran the meeting. They're real  
16 professionals, and it was a pleasure working with them.

17                   So, thank you all for coming. And look at the  
18 website, because everything will be on the website.  
19 Thank you.

20                   (Applause)

21                   (Whereupon, at 5:01 p.m., the meeting was  
22 concluded.)

1  
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CERTIFICATE OF NOTARY PUBLIC

I, MICHAEL FARKAS, the officer before whom the foregoing proceeding was taken, do hereby certify that the proceedings were recorded by me and thereafter reduced to typewriting under my direction; that said proceedings are a true and accurate record to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.



MICHAEL FARKAS

Notary Public in and for the  
District of Columbia

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CERTIFICATE OF TRANSCRIBER

I, ELLEN SANDERS, do hereby certify that this transcript was prepared from audio to the best of my ability.

I am neither counsel for, related to, nor employed by any of the parties to this action, nor financially or otherwise interested in the outcome of this action.

April 18, 2017

Ellen Sanders

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