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

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C O N T E N T S

P R O C E E D I N G S

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

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

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

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

their role within the Agency.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

OPENING REMARKS

DR. GUETTIER: So, good afternoon. Again my

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

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

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

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

We understand that sarcopenia may have

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

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

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

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

I know we also have representation from

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

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

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

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

involved in developing drugs to treat this condition.

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

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

OVERVIEW OF SARCOPENIA AND CURRENT TREATMENT OPTIONS

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

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

Sarcopenia is a word that's derived from

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

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

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

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

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

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

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

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

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

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

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

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

But with a lot of things that are identified

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

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

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

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

effects, and others have not.

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

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

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

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

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

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

OVERVIEW OF PATIENT-FOCUSED DRUG DEVELOPMENT MEETING

DR. EGGERS: Thank you, John.

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

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

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

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

participants talk today.

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

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

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

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

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

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

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

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

engage with people who have lived with conditions.

After each meeting, we publish a Voice of the Patient Report. And it's available on our website. And what is does is summarize the input and perspectives we hear today in the meeting with the input we get over the webcast and the input that the public can continually submit for the next two months through our website. I'll give some information on that in a minute.

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

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

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

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

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

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

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

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

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

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

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

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

And on the web, feel free to answer the

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

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

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

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

So there are a few ground rules we've learned

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(Pause)

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

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

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

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

(Pause)

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

(Show of hands)

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

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

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

DR. EGGERS: Okay.

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

MR. THOMPSON: Similar to that in the room.

DR. EGGERS: Okay.

(Pause)

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

I think that is our last polling question.

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

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

SETTING THE CONTEXT ON PATIENTS' EXPERIENCES AND PERSPECTIVES

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

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

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

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

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

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

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

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

poor hostess at my own party.

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

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

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

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

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

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

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

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

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

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

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

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

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

better enables muscle development.

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

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

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

So, while we wait for new drugs to be

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

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

DR. EGGERS: Thank you so much, Greta.

(Applause)

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

(Applause)

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

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

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

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

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

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

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

part of the literature.

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

(Laughter)

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

(Laughter)

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. EGGERS: Thank you, Fred.

(Applause)

DR. EGGERS: And now we have Rose.

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

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

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

My team and I work directly with older adults

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

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

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

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

Unintentional weight loss and physical frailty

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

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

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

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

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

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

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

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

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

natural cheeses.

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

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

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

Thank you very much.

DR. EGGERS: Thank you very much, Rose.

(Applause)

DR. EGGERS: And finally, we have Ray.

MR. LIPICKY: It’s hard to know where to

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

(Laughter)

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

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

(Laughter)

MR. LIPICKY: We'll see.

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

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

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

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

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

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

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

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

isn’t any deep-water exercising in Tampa.

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

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

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

DR. EGGERS: Thanks a lot, Ray.

(Applause)

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

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

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

(Applause)

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

LARGE-GROUP FACILITATED DISCUSSION

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

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

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

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

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

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

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

(No audible response)

(Pause)

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

(Inaudible comment)

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

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

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

(Inaudible comment)

DR. EGGERS: Chronic, yeah.

(Pause)

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

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

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

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

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

(Pause)

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

Graham, are we getting any responses on the web?

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

DR. EGGERS: Okay. All right.

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

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

(Inaudible comment)

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

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

with Fernando?

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

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

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

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

(Pause)

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

DR. EGGERS: Um-hm.

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

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

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

DR. EGGERS: Okay. Can you describe why?

PRU: Because my lower leg muscles aren't

strong enough.

DR. EGGERS: Okay.

PRU: Pru.

DR. EGGERS: Thanks, Pru.

All right. So more ideas about what "weakness" means?

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

Ray, were you going to say something?

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

DR. EGGERS: Okay.

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

DR. EGGERS: What question was --

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

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

MR. LIPICKY: Not these.

DR. EGGERS: Okay.

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

DR. EGGERS: Okay.

(Cross-talk)

MR. BARTLIT: Questions people ask --

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

MS. GEPHARDT: Okay. Um-hm.

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

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

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

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

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

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

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

DR. EGGERS: Okay. All right.

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

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

Then we'll go over here to Steve.

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

DR. EGGERS: Okay.

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

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

That would be very helpful.

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

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

(Laughter)

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

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

DR. EGGERS: Okay.

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

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

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

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

DR. EGGERS: Yep.

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

DR. EGGERS: Okay.

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

DR. EGGERS: Um-hm. All right.

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

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

(Laughter)

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

So, any other thoughts?

MS. CHALASANI: I think Greta wanted to speak.

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

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

DR. EGGERS: Okay.

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

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

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

DR. EGGERS: Um-hm.

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

DR. EGGERS: All right.

Yes, Jean-Marc.

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

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

feeling aspect.

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

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

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

MS. CLIFFORD: Can I make a comment?

DR. EGGERS: Sure. Yes, Rose.

MS. CLIFFORD: So, as a health professional

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

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

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

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

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

DR. EGGERS: Okay. Thank you, Rose.

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

DR. EGGERS: Thank you, Rose.

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

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

(Pause)

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

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

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

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

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

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

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

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

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

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

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

(Pause)

DR. EGGERS: Okay.

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

DR. EGGERS: Yeah, yeah, yeah.

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

MALE VOICE: That's right.

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

DR. EGGERS: Okay. Okay.

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

(Laughter)

DR. EGGERS: Anyone else?

(No audible response)

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

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

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

MS. CHALASANI: Um-hm.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(Cross-talk)

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

DR. EGGERS: Wow.

MR. LIPICKY: Good. That answers my question.

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

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

DR. GUETTIER: We have our experts here.

MR. LIPICKY: You're ducking.

(Cross-talk)

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

(Cross-talk)

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

DR. EGGERS: So, I think --

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

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

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

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

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

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

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

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

Thank you.

DR. EGGERS: Thank you

Yes. Silvana.

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

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

But there's another aspect that is more

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

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

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

So we need to know, what is it that sarcopenia

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

DR. EGGERS: Great.

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

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

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

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

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

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

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

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

MS. CHALASANI: It's closed.

DR. EGGERS: Closed?

(Laughter)

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

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

DR. EGGERS: So it might be reopened.

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

LARGE-GROUP FACILITATED DISCUSSION (Cont'd)

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

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

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

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

MS. CHALASANI: Your hobbies, um-hm.

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

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

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

(Pause)

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

(Pause)

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

(Pause)

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

MS. CHALASANI: Okay. So --

DR. EGGERS: Work and hobbies.

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

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

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

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

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

MS. CHALASANI: Why? Why have you then?

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

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

FEMALE VOICE: Well, one was more physical,

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

(Laughter)

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

DR. EGGERS: Okay. Anyone else? Anyone?

(No audible response)

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

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

DR. EGGERS: I think Fernando.

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

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

In matters of dignity loss, it's another one

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

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

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

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

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

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

MR. CRUZ-VILLALBA: Got worse.

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

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

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

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

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

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

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

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

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

DR. EGGERS: Thank you very much, Fernando.

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

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

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

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

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

MS. CHALASANI: Okay. Maybe we can switch

gears a little bit now --

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

(Pause)

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

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

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

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

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

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

became a big factor.

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

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

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

(Pause)

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

(Pause)

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

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

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

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

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

benefit for you, the most meaningful benefit?

So would you rather have a reduction in pain? Click A. If you'd rather have a reduction in fatigue and lack of energy so you'd have more energy, pick B. If you'd like to work on balance, have improved balance, you'd pick C. More endurance during your physical activity, D.

Increased mobility, walking across the room, getting out of a chair, going up and down the steps, that would be E. And then just generally improved muscle strength or muscle weakness as a feeling of those, that would be F.

And if we missed something and there's something else that you think a medicine, you wish a medicine, would treat for you, then you would pick G.

(Pause)

DR. EGGERS: So we'll give you a few minutes to think about this because it's a different way of thinking.

(Pause)

MR. BARTLIT: You know, there is peer-reviewed research saying that the thing that is most correlated

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

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

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

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

exercise and caused me to be in bed more.

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

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

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

muscle weakness, and address it then.

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

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

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

(Inaudible comments)

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

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

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

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

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

(Laughter)

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

Oh, Fernando.

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

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

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

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

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

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

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

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

Had a tremendously complicated protocol,

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

(Laughter)

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

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

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

And when you start to move as a young person,

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

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

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

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

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

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

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

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

I also got bilateral carpal tunnel syndrome.

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

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

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

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

because of that particular situation.

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

(Laughter)

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

MS. CHALASANI: Thank you. Thank you.

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

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

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

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

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

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

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

So, what first questions would you have, do

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

(Laughter)

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

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

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

Others? First thought?

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

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

Okay. Back there, Fernando.

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

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

Other questions? Steve.

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

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

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

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

STEVE: Oh, it's cheap.

DR. EGGERS: Okay.

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

DR. EGGERS: Oh, those types of benefits.

Okay. Okay.

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

DR. EGGERS: Okay. Yes, Rose.

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

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

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

DR. EGGERS: Okay.

So, Greta, please.

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

DR. EGGERS: Okay.

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

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

(No audible response)

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

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

Yes, Wen-Hung.

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

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

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

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

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

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

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

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

Can I make one more point about medical science?

DR. EGGERS: You can.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(Applause)

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

OPEN PUBLIC COMMENT

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(Laughter)

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

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

MS. VAIDYA: Thank you, Michael.

Next we have Adrian.

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

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

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

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

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

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

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

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

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

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

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

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

(Pause)

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

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

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

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

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

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

MS. FUGH-BERMAN: Okay. All right.

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

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

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

MS. VAIDYA: Thank you, Adrian.

Next we have Nicholas Mendola.

MR. MENDOLA: Hi. My name's Nick Mendola. I'm a public health student at the Milka Institute School of Public Health at the George Washington University. And I'm transitioning from exercise physiology to the public health field.

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

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

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

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

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

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

MS. VAIDYA: Thank you, Nicholas.

Next we have Ronenn Roubenoff.

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

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

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

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

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

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

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

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

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

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

MS. VAIDYA: Thank you, Ronenn.

Next we have Ram Miller.

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

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

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

But clinically, we recognize, as

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

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

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

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

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

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

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

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

MS. VAIDYA: Thank you, Ram.

And finally, we have Cynthia Bens.

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

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

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

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

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

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

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

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

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

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

MS. VAIDYA: Thank you, Cynthia.

(Applause)

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

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

CLOSING REMARKS

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

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

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

(Applause)

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

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

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

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April 18, 2017 Ellen Sanders

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