

FOOD AND DRUG ADMINISTRATION (FDA)

PUBLIC MEETING ON IDIOPATHIC PULMONARY FIBROSIS
PATIENT-FOCUSED DRUG DEVELOPMENT

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Food and Drug Administration
White Oak Campus
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1 P R O C E E D I N G S

2 MS. GIAMBONE: Good afternoon, everyone.

3 If you could start making your way over to your
4 seat. My name is Soujanya Giambone, and I am with
5 the FDA's Center for Drug Evaluation and Research,
6 Office of Strategic Programs. And on behalf of
7 all of my FDA colleagues, I'd like to thank you
8 and welcome you to our tenth Patient-Focused Drug
9 Development Meeting.

10 So today's meeting is on idiopathic
11 pulmonary fibrosis, IPF, and we are just so
12 thankful that you're here. We have a lot to learn
13 from you today, and we hope that you share all of
14 your experiences with us, and we're looking
15 forward to a great day of discussion.

16 So I'll be the facilitator for the
17 meeting, and what I'd like to do is just spend a
18 few minutes going over the agenda and a few
19 housekeeping items, and we'll get things started.
20 And you should all have a copy of the agenda. It
21 was available on the registration desk. But if
22 you don't, just feel free to get one, or just

1 raise your hand and one of my FDA colleagues will
2 be happy to help.

3 Okay. So we're going to start off today
4 with three presentations from my FDA colleagues.
5 They will provide some opening remarks, provide an
6 overview of the Patient-Focused Drug Development
7 Initiative, and also they'll provide a background
8 on IPF and current therapeutic options.

9 Then I'll come back and go over the
10 discussion format. We have two topics for today,
11 so we're going to have a panel discussion followed
12 by a group discussion for each of those topics.
13 So Topic 1 is on the most significant symptoms of
14 IPF and how they impact your daily life. Topic 2
15 is on your perspectives -- patient perspectives on
16 current treatment approaches to IPF.

17 So that'll take us towards the end of
18 the day, and we have the last half-hour of the day
19 reserved for open public comment, and I know many
20 of you have signed up for that. So what open
21 public comment is, is if anybody in the room, not
22 just patients or patient representatives, but if

1 anybody in the room wants to share additional
2 thoughts or comments outside the scope of Topic 1
3 or Topic 2, we'll encourage you to sign up for
4 open public comment.

5 And we'll take sign-up for public
6 comment during break time, so we'll see how many
7 people have signed up and how much time each
8 speaker will have at that point. And then we'll
9 have some closing remarks, and that will wrap up
10 the day. So it's a full day, but, as I mentioned,
11 we're just so thankful and excited to get this
12 meeting going and look forward to learning so much
13 from you.

14 So just a few housekeeping and logistics
15 items. First thing, we do have oxygen available
16 for anyone that needs it during the meeting. We
17 have oxygen support systems, and they set up a
18 table right outside this doorway, and you can feel
19 free -- please get up if you need to go and, you
20 know, get additional oxygen. You can -- they'll
21 be happy to help you.

22 And restrooms are back out into the

1 lobby area, and if you make a right and go all the
2 way down the hallway, you'll find the restrooms
3 there. And last, but not least, we do have a
4 kiosk out there that serves basic sandwiches and
5 snacks and beverages for purchase.

6 So we want you to know that this is a
7 more informal meeting. We want you to be
8 comfortable. If you need to get up and stretch,
9 if you have to take a break, please feel free to
10 do so. Okay?

11 And before we get started with our FDA
12 presentations, can I have each one of you
13 introduce yourselves?

14 DR. MCCLAIN: Lydia Gilbert McClain,
15 Deputy Division Director, Division of Pulmonary,
16 Allergy, Rheumatology Products.

17 DR. KARIMI-SHAH: Good afternoon. My
18 name's Banu Karimi-Shah. I'm a Clinical Team
19 Leader in the Division of Pulmonary, Allergy, and
20 Rheumatology Products.

21 DR. MULLIN: Good afternoon. I'm
22 Theresa Mullin, and I direct the Office of

1 Strategic Programs in the Center for Drugs.

2 DR. SLAGLE: Good afternoon. I'm Ashley
3 Slagle from the Office of New Drugs, Study
4 Endpoints.

5 MS. GIAMBONE: Great. Thank you. And
6 we have some FDA colleagues here.

7 MS. VAIDYA: Hello. I'm Pujita Vaidya
8 from the Office of Strategic Programs.

9 MR. GRAHAM THOMPSON: Graham Thompson,
10 same office.

11 MS. STARK: Grace Stark, same office.

12 MS. GIAMBONE: Great. Thank you. Okay.
13 So and just one additional item. This meeting is
14 being recorded and transcribed, so we'll have the
15 recording and the transcript available shortly
16 after the meeting on our website. And with that,
17 I'd like to turn it over to Lydia for your
18 remarks.

19 DR. MCCLAIN: Thank you very much. Good
20 afternoon, and welcome again. We are delighted to
21 have you here at this Patient-Focused Development
22 Meeting on Idiopathic Pulmonary Fibrosis. Again,

1 my name is Lydia Gilbert McClain, and I'm the
2 Deputy Division Director in the Division of
3 Pulmonary, Allergy, and Rheumatology Products, and
4 that is the division that's tasked with evaluating
5 and reviewing programs for IPF.

6 We are very happy to be holding this
7 meeting today. I think it is very important, and
8 we are very interested to hear from you, the
9 patients, about your experiences with IPF. We
10 recognize the disease is characterized by symptoms
11 that can have a significant and devastating impact
12 on the day-to-day lives of patients, and so it is
13 good to see so many of you here today. I also
14 understand that there are several hundred people
15 participating on the Web, and we welcome you, and
16 we're thankful that you are able to participate.

17 Today's meeting is one in a series of
18 what is called FDA Patient-Focused Drug
19 Development Meetings. In a few minutes, my
20 colleague, Theresa Mullin, from the Office of
21 Strategic Programs, will provide you some more
22 information about the Patient- Focused Initiative.

1 IPF, as we all know, is a very serious,
2 debilitating condition that is progressive and
3 often life-threatening, and the causes of IPF are
4 unknown. So this makes it very important, from our
5 standpoint, to hear from you and to hear your
6 perspectives about how you, as patients and
7 patient advocates, experience IPF.

8 In a couple minutes, one of our clinical
9 team leaders, Dr. Banu Karimi-Shah, will provide
10 some brief clinical background about IPF. But we
11 think it is very important for us to hear directly
12 from you:

13 how do you experience the different
14 symptoms of IPF, how it affects your daily lives,
15 what you value in treatment for IPF, and what you
16 would like to see in future IPF development
17 programs.

18 Having this kind of dialogue is
19 extremely valuable to us, and your input during
20 this meeting can help us understand how patients
21 view benefits and risks of treating IPF. Giving
22 us a better appreciation of your needs as patients

1 from your perspective in a disease that is
2 associated with symptoms that impact your lives on
3 a daily basis can be very valuable to us in
4 understanding what clinical benefits could be
5 meaningful to patients in a clinical trial.

6 While we, the FDA, play a critical role
7 in drug development, remember that we are just one
8 part of the process. We do not develop the drugs,
9 we do not conduct the clinical trials, but instead
10 our task of protecting and promoting public health
11 is based on the evaluation of the data for safety
12 and efficacy of these new therapies, and we work
13 with drug companies, researchers, patient
14 communities. They're the ones who conduct the
15 clinical trials and submit applications of new
16 drugs for us.

17 We work closely with the companies
18 throughout the drug development program, initially
19 from the early stages of R&D development all the
20 way up through completion of the program and the
21 submission of the New Drug Application.

22 We recognize that there is

1 representation from industry, academia, and others
2 in the room and on the Web today, and we are very
3 glad to see that there is such a high level of
4 interest from those of you who play an important
5 part in drug development.

6 So we thank you again for being here.
7 We thank you for being part of this meeting. We
8 look forward to hearing from you, so we welcome
9 you again. And so I'll turn the podium now over to
10 my colleague, Theresa Mullin, who will share some
11 broader points on the Patient-Focused Drug
12 Development at FDA. Welcome.

13 DR. MULLIN: Thank you, Lydia. And,
14 again, I'm Theresa Mullin, and thanks for coming
15 today to White Oak to our campus, and thank you
16 very much for those of you who've joined us on the
17 webcast.

18 This is just to give you some background
19 on this overall program. FDA, as Lydia was
20 describing, greatly values and needs patient input
21 and understanding of the patient perspective,
22 really, throughout the process of development and

1 then beyond.

2 But we've initiated this program, and I
3 just want to give you the sort of background on
4 this, what we're calling Patient-Focused Drug
5 Development Program. We've developed this in
6 recognition that we didn't really have a way to
7 systematically collect information and
8 perspectives from a wide range of patients.

9 We had a patient representative program,
10 which is extremely valuable, but really were only
11 able to have a few participants or representatives
12 in any given disease area, and we have to put
13 those folks through a great deal of screening,
14 because they're going to be participating in
15 discussions related to a particular matter that
16 has to do, usually, with a particular drug product
17 in development or decisions on particular matters,
18 and we need to screen for conflict of interest and
19 so on, and that sort of limits how much
20 participation and the range of perspectives that
21 we're able to get.

22 And so we needed another format, and

1 this is really one that we committed to do under
2 this reauthorization of the Product Drug User Fee
3 Act, the five-year reauthorization that was put in
4 place by Congress in 2012. And it allows us to
5 try to get better input, because patients, we
6 recognize, are really the most important
7 perspective. They're the ones suffering from the
8 disease. They're the ones who are going to
9 experience any benefit there is to be gotten from
10 the drug, and they're the ones who are going to
11 experience the risks. And so it's quite critical
12 that we understand their views.

13 And so this approach allows us to really
14 step back out of the context with any particular
15 drug and go in and ask about questions at the
16 disease level, and it enables us to get a much
17 more -- much larger and wide-ranging views in
18 patients who have that disease.

19 We began this process of trying to
20 identify because we agreed to do 20 -- at least 20
21 different diseases over the five years of this
22 five-year program. And so we put out a rather

1 long list, asked for public comment. We got over
2 4,500 comments from the public on the list that we
3 published. We took that input into consideration,
4 and the diseases that were identified by the
5 public, in addition to the ones I reviewed,
6 conditions (ph) identified as ones that they felt
7 would be particularly helpful to them.

8 Putting that together, we identified a
9 list of diseases for the first three years of the
10 program, so 16 diseases, we identified for the
11 first three years of the program, and then we're
12 going to be coming out and doing another Public
13 Federal Register Notice very soon on our proposed
14 disease areas for the final two years of this
15 program.

16 We really view this as a sort of pilot
17 to learn how to do this as effectively as
18 possible, with the idea that we'll be continuing
19 it beyond, of course, those five years, and we've
20 been talking with patient groups about ways to
21 extend it beyond -- not just having FDA be
22 convened around (ph) such meetings; how can we

1 also have -- and other groups are already doing
2 this, beginning to convene meetings, trying to
3 locate them where FDA can easily show up and
4 participate and listen. And so I think that we
5 want to not -- we want to try to figure out how to
6 expand and sustain this effort going forward and
7 build on it.

8 Here are the diseases that we have --
9 are undertaking for meetings for 2013, fiscal year
10 2013 through '15. That's the first three years of
11 the five years. And those on the left, you can
12 see we've already done the list, chronic fatigue
13 syndrome, HIV, lung cancer, and narcolepsy, in our
14 fiscal year 2013, which ended last September. And
15 then in 2014, so far, we've had meetings on sickle
16 cell disease, fibromyalgia, pulmonary arterial
17 hypertension, inborn errors of metabolism, a
18 meeting on bleeding disorders earlier this week,
19 actually, and then today's meeting on idiopathic
20 pulmonary fibrosis.

21 And I shall note we have a next -- the
22 next meeting we have scheduled will be on female

1 sexual dysfunction, and that's a two-day meeting,
2 one day devoted to getting public input, or,
3 rather, patient input, and the second day, a
4 scientific meeting on sexual -- female sexual
5 dysfunction. And as you can see, the other
6 diseases there will be covered in the coming year.

7 Now, each of these meetings has some
8 similar -- similarity to this format. We -- as
9 Soujanya was mentioning earlier, we have panels
10 that are structured around the two key areas that
11 we want to talk about, and particularly here, your
12 perspectives on -- so those are the questions
13 around what it's like for you to live with the
14 condition, your -- what are the symptoms that are
15 most impactful on you and your family or
16 caregivers, and then what your experiences is with
17 the treatments that you're using for the disease.

18 We also have questions that we tailor
19 that the review divisions may particularly want to
20 probe and understand better while they have the
21 opportunity, the sort of great opportunity that
22 you're here and they can ask those questions.

1 The other thing I'll say about these two
2 areas, the severity of the disease and the -- what
3 it's like to live with the disease and how well
4 the available treatments work are components that
5 fit right into FDA's risk-benefit approach in
6 looking at assessing drugs. We really need to
7 understand the severity of the condition and the
8 degree to which drugs meet the needs of the
9 patient to determine the context -- what we call
10 the clinical context in which we evaluate the
11 benefits that are found through the clinical
12 trials and whatever harms have been identified in
13 the trials. It's a critical context for our
14 decision-making around whether or not something
15 should be approved for marketing or stay on the
16 market.

17 So the questions that are being probed
18 today are essential to setting the stage for our
19 decision- making about drugs to treat the disease.
20 And so we're extremely happy to have you here
21 today to help us with this.

22 And so these outcomes of these meetings

1 help us to identify future topics that we need to
2 address or issues that may need to be addressed in
3 drug development, and the participation and the
4 level of participation and engagement that we get
5 from you is critical and, really, the key to the
6 success of this meeting.

7 I have to keep Regina (ph) here to find
8 the space bar. Okay. The final thing I want to
9 mention is we produce a report. After we have --
10 in addition to the webcast and the comments that
11 you give us today, we have a docket that we open
12 for several weeks at least to try to get any other
13 public input information that patients may want to
14 submit, something that you may not think of today
15 you want to send us later, either your own
16 comments, something you want us to be aware of,
17 that electronic docket is open for that purpose.

18 And so the report that we produce tries
19 to faithfully capture what we hear today just the
20 way we've heard it in the words that the patients
21 have used to convey that to us, similarly capture
22 what we hear in the webcast, in addition to what

1 we hear in the room and what we might get through
2 the docket. And those sources of information are
3 put into the summary report. We have a series
4 that we're calling Voice of the Patient, and
5 that's available on our website, and it's there
6 for your use, for our use, for our use in future
7 work. For example, Ashley Slagle's here today.
8 She's part of our team in the Center for Drugs
9 that worked on patient-reported outcome tools, and
10 her group may look at ways we can further
11 formalize developing a tool to collect this kind
12 of information in clinical trials. So that's one
13 way that this information could move forward and
14 be further enriched later and help us with our
15 clinical studies in the future.

16 And so with that, I'll end, and I'll
17 turn it over to Banu, who's going to talk about
18 the disease.

19 DR. KARIMI-SHAH: Afternoon, everyone.
20 Again, I'd like to echo the welcome that you heard
21 from the previous panelists. I'd like to welcome
22 you here to White Oak today, and I really look

1 forward to this discussion. My presentation's
2 very brief and probably nothing that's new to
3 anyone in this room, so I will go through quickly,
4 because I really do want to have you spend time --
5 us spend the time hearing from you today.

6 So as we all know in this room, IPF is a
7 rare, chronic, and progressive interstitial lung
8 disease of unknown etiology, affecting about five
9 million patients worldwide. It affects males
10 greater than females, and the diagnosis usually
11 occurs between the fifth and seventh decades of
12 life.

13 Progression of disease is variable among
14 individuals, and this is one of those things that
15 makes it very difficult to study IPF. Progressive
16 fibrosis, or scarring of the lungs, leads
17 ultimately to death, with a median survival of
18 three to five years after diagnosis.

19 The signs and symptoms are shortness of
20 breath, or dyspnea, which can occur as --
21 manifesting as rapid or shallow breathing or also
22 with exertion. A nonproductive, or dry cough, is a

1 very bothersome symptom to many patients with this
2 disease, and I know that we'll probably hear a lot
3 more about these today, and we look forward to
4 hearing your characterization of these symptoms.

5 Some patients experience gradual, unintended
6 weight loss; feeling very tired; and also a change
7 in the shape of their fingers and toes from the
8 lack of oxygen delivered to their body.

9 As with many diseases, the goals for the
10 treatment of IPF are to reduce the symptoms and
11 signs, improve patient quality of life, slow or
12 halt disease progression, and increase survival.
13 We know that current therapeutic options are
14 limited. Lung transplantation is an option for
15 those who qualify, but there are no recommended or
16 approved therapies specifically to treat IPF. And
17 one of the reasons that a session like this is so
18 important is because we have been using therapies
19 over the past years that now, as we're studying
20 them, and we've considered them the standard of
21 care in the past, have actually shown to have been
22 harmful to patients when studying clinical trials.

1 So we realize that even those things that were the
2 standard of care in the past may not be helpful to
3 patients, and hearing from you as patients is very
4 valuable to us.

5 There are multiple challenges in drug
6 development with IPF. We have a small patient
7 population. We have diverse phenotypes, or
8 disease characteristics. As I mentioned before,
9 different people progress through this disease
10 differently and at different paces, so it's very
11 difficult to study patients in a large clinical
12 trial when everybody's so heterogeneous.

13 And there are multiple, multiple
14 unanswered questions that are important here, and
15 I have some of them listed here, but these are not
16 likely to be all the questions. But some of them
17 are: what signs and symptoms should be measured,
18 and how should we measure them? Do the disease
19 symptoms progress in a time course that can be
20 captured adequately in a clinical trial? And do
21 biomarkers exist, certain measures that indicate
22 disease, and do they have relevance as an endpoint

1 in clinical trials?

2 So for conditions like IPF which are not
3 fully understood, we realized that input from
4 patients is especially important, and that's why
5 we place such value on this session today.
6 Patient-reported outcomes, or PROs, can represent
7 direct measures of treatment benefit, how a
8 patient feels or functions. And this is of utmost
9 importance. All measurements need to be
10 evaluated, however, in adequate and well-
11 controlled randomized trials, so we hope to take
12 the input that you give us today and, as Dr.
13 Gilbert McClain said, we don't design the clinical
14 trials, but we do provide input to companies
15 regarding the clinical trials.

16 So this really helps us to guide the
17 companies as to what kind of endpoints, what kind
18 of patient-reported outcomes, how to develop their
19 patient-reported outcomes. And patient input such
20 as yours is essential to capture important and
21 clinically relevant disease symptoms for these
22 patient-reported outcomes.

1 So with that, my remarks are finished.

2 I welcome you again, and I'd like to turn the
3 podium back over to Soujanya.

4 MS. GIAMBONE: Thank you to my FDA
5 colleagues for all of your comments. So what I'd
6 like to do now is go over the discussion format
7 and let you know what to expect with our kind of
8 discussion.

9 As I mentioned before, this is probably
10 very different from other public meetings you may
11 have intended. This is more informal. It's more
12 talk show style. Again, I want to just reiterate,
13 please feel comfortable to take a break, get up
14 and stretch if you need to, go and get the
15 additional oxygen. Please feel free to do those
16 things.

17 So we have two topics today. Topic 1 is
18 on the most significant symptoms of IPF and how
19 they impact your daily life. So what we're
20 listening for here is what are those symptoms that
21 really impact what you can do on a day-to-day
22 basis? Are there certain activities that you

1 can't do at all or maybe not as fully as you would
2 like because of those symptoms. Also, talk to us
3 about how your symptoms have changed or evolved
4 over time, and, if you can, tell us what an
5 average day looks like versus a more severe day of
6 symptoms.

7 The second topic is on patient
8 perspectives and current treatment options for
9 IPF. So here what we're listening for is what is
10 your current treatment regimen? Is it working for
11 you, and how do you know it's working for you?
12 Can you point to specific examples? And on the
13 flipside, what is not working for you? What are
14 the downsides to those treatments? And, again,
15 give us those specific examples on what those
16 downsides are and how you know it's not working
17 for you.

18 We also want to hear from you on what
19 you're looking for in an ideal treatment. Next
20 slide, please. So what we're going to do is first
21 hear from a panel of patients and caregivers, and
22 with that, could I have my Topic 1 panelists come

1 on up and take your seat. And if you could bring
2 your name card with you.

3 So I have had the privilege of working
4 with our panelists for the last two weeks or so,
5 and I just -- I can't thank you all enough for
6 preparing these summaries and taking the time to
7 share these stories with us. So we sincerely
8 appreciate it.

9 So our panel reflects a range of
10 experiences with IPF, and they've each prepared
11 about five minutes of remarks. And what we'll do
12 after we hear from our panel is then we'll broaden
13 the dialogue, and we will invite more patients and
14 caregivers and patient representatives in the
15 audience to share your experiences. And we want
16 to hear from you, for those of you in the
17 audience, what resonated with you? What are
18 similar experiences that you shared? And, also,
19 what may be different for you? Build on what
20 you've heard from the panel, and periodically,
21 we'll ask questions. I'll ask some follow-up
22 questions. I'll also look to the FDA panel

1 periodically. And we look forward to hearing what
2 you have to say.

3 And we have mic runners around the room.
4 Some of my FDA colleagues will be here, and
5 they'll have a microphone. And if you're
6 comfortable to do so, just raise your hand, and
7 they'll come to you. And if you could state your
8 first name before answering, that would be very
9 helpful.

10 And so we have a few other ways that we
11 are going to learn from you today. One of those
12 ways is that we're going to have polling questions
13 along the way, and with that, can we have the
14 clickers passed out? And we're going to test this
15 out in just a bit. But the polling questions, it's
16 a way for us at the FDA to learn more about the
17 perspectives in the room and also those that are
18 on the webcast. So we're going to pass out these
19 clickers, and we will do these -- you know, we'll
20 do an example in just a bit. And so for the in-
21 person participants, use your clickers to respond
22 to the questions, and for those of you joining us

1 on the Web, you can also answer the polling
2 questions via the webcast.

3 So the polling questions are entirely
4 voluntary. They're -- it's not a scientific
5 survey, but it's very beneficial for us to learn
6 more about the perspectives in the room and on the
7 Web. We do ask that, for those of you responding,
8 that only patients and patient representatives
9 respond, please.

10 And as I just mentioned, we have over a
11 hundred people joining us on the Web today, so
12 thank you so much to all of you joining us on the
13 webcast. We can't see you, but it's very important
14 and so beneficial for us that you're here. Your
15 voice is being heard. We will be checking in with
16 the webcast periodically throughout the meeting,
17 and we'll also take some time to have a few of you
18 on the Web join us by phone so you can share your
19 experiences with us.

20 Okay? And another way -- another
21 critical way that we learn from you, and I believe
22 one of my FDA colleagues mentioned this also, is

1 that we have a public docket that will be open for
2 two months after the meeting, so it'll be open
3 until November 26th. And what this is is a
4 website. You can see it up on the slide. And you
5 can go there for two months after the meeting and
6 continue to share your experiences, continue to
7 share additional thoughts and comments that you
8 have. They're very, very important to us to read,
9 and they will be summarized and incorporated into
10 the summary report that gets published after the
11 meeting.

12 Anybody is welcome to comment in the
13 open public comment -- or, I'm sorry, in the
14 public docket. So, please, we will encourage you -
15 - and I will encourage you throughout the meeting
16 to continue submitting our comments to the public
17 docket.

18 Okay? So we do have a few ground rules
19 for the day. First and foremost, we encourage
20 patients and caregivers to contribute to the
21 dialogue. Caregivers, as I mentioned, and
22 advocates are welcome too, so it's very important

1 for us to hear as much as we can from those of you
2 sharing these experiences, patients and caregivers
3 and advocates.

4 We understand -- we know that there's
5 industry here and academia and other government
6 agencies. We sincerely appreciate that you're all
7 here. We think this meeting will be very helpful
8 for you too. We just ask that you stay in
9 listening mode. Similarly, FDA is here to listen
10 also.

11 Our discussion is going to focus on
12 symptoms and treatments. And these are the
13 questions -- the questions that you've all
14 responded to -- the topic questions are -- they're
15 very beneficial for us to hear about and to learn
16 about, so we understand that there's many
17 different aspects and many different factors and
18 considerations to IPF. We're going to do our best
19 to stay on topic, but if there are things that you
20 would like to share outside the scope of Topic 1
21 or Topic 2, again, we encourage you to sign up for
22 open public comment or submit your -- submit

1 additional thoughts to the public docket.

2 The views expressed today are personal
3 opinions, and, on that note, respect for one
4 another is paramount. And, last but not least,
5 let us know how the meeting went today. We have
6 evaluation forms out on the registration desk, and
7 we'll also pass them out towards the end of the
8 meeting. And they're very important to us. It
9 helps us to see what went well today for you and
10 what you think we can improve on.

11 Okay? Great. So next slide. Okay. So
12 we are going to -- we're going to start off with a
13 polling question. Does everybody have your
14 clicker? Okay, great. All right. Curt, we have a
15 -- you can look right on the screen up front.

16 MR. CURTIS THOMPSON: I can't see it
17 (ph).

18 MS. GIAMBONE: No problem. Okay. So
19 let's do our first polling question. Where do you
20 live? Press A for within the D.C. Metro Area or B
21 for outside the D.C. Metro Area. Okay. So many
22 of you have traveled to come here. We appreciate

1 it so much. We know that travel is not always
2 easy, so we appreciate the time and the effort for
3 all of you to be here.

4 Okay. Have you ever been diagnosed as
5 having IPF? Press A for yes or B for no. Okay.
6 So it looks like we have a little over a third of
7 you in the room that have been diagnosed with IPF,
8 so we look forward to hearing all of the
9 experiences that you have to share.

10 Okay. Next question. And so here we
11 ask, again, patients and patient representatives
12 only. What is your age or your loved one's age?
13 A, younger than 30; B, 31 to 40; C, 41 to 50; D,
14 51 to 60; E, 61 to 70; F, 71 to 80; or G, 81 or
15 greater. Okay. So it looks like we have a very
16 good distribution here. The majority of you are in
17 the 61 to 70 range, and we also have many of you
18 between that 41 to 80 range. And let me check in
19 with our Web real quick. How do the results look?

20 MR. GRAHAM THOMPSON: It's a very even
21 distribution on the Web, pretty much equal in all
22 group, with a little bit heavier towards the older

1 population. And for the previous questions, we
2 had about 95 percent outside of the D.C. area, as
3 you would expect, and about 60 percent saying they
4 received a diagnosis of IPF and 40 percent saying
5 they hadn't.

6 MS. GIAMBONE: All right. Great. Thank
7 you. So we have a few more questions. Are you,
8 or is your loved one, A, male or B, female? Okay.
9 So two- thirds of you are male in the room, and B,
10 we have about a third of you female. Okay?

11 MR. GRAHAM THOMPSON: And on the Web,
12 it's a even split, with about 48 percent male and
13 51 percent female.

14 MS. GIAMBONE: Okay. Okay. And this is
15 our last question before we get to the panel.f So
16 what is the length of time since your diagnosis?
17 A, less than one year ago; B, one to three years
18 ago; C, three to five years ago, or D, more than
19 five years ago. Okay. So here's what we have in
20 the room. We have about a third of you, more of a
21 recent diagnosis, one to three years ago, and then
22 we also have a large portion of you that have been

1 diagnosed more than five years ago. And then
2 pretty much an even split for some of the newly
3 diagnosed, less than one year ago, and about 17
4 percent three to five years ago. On the Web?

5 MR. GRAHAM THOMPSON: Very similar on
6 the Web: 17 percent less than one year; 30 percent
7 one to three years; 17 percent, again, three to
8 five years; and 35 percent for more than five
9 years.

10 MS. GIAMBONE: Okay. Thank you. Okay.
11 So that will be the polling questions for now.
12 We're going to come back to the polling questions
13 in just a bit, but now I'd like to turn it over to
14 our panelists to share your comments with us. And
15 if we could go to the next slide. So it looks
16 like we have Curt sitting closest to me, so you'll
17 get started, if that's okay. So what you'll do is
18 you'll press the red button to

19 MR. CURTIS THOMPSON: Okay.

20 MS. GIAMBONE: All right.

21 MR. CURTIS THOMPSON: Hi. I'm Curt
22 Thompson. My wife's name was Joy, and she was

1 quite a joy. We were married 42 years and a day.
2 She died the day after our 42nd wedding
3 anniversary. She's been gone a little over four
4 years, and we have three children and five
5 grandchildren.

6 She was the -- she had an identical twin
7 sister who also died of pulmonary fibrosis, age of
8 48. And I'm going to pretty much keep my remarks
9 to my wife. If you have some questions -- because
10 they were very much identical twins, and I say
11 that -- you'll see me grin a little bit. The
12 first month I met them, I think I may have had a
13 date with her sister one time, but I'm never real
14 sure about that, and they'd never tell me. But I
15 promise you, years later, that my heart could tell
16 the difference (ph).

17 She was 62 years old when she died. She
18 was diagnosed in July of 2005. She lived four and
19 a half years, and she died on July 20th of 2010.
20 We're from Jackson, Mississippi. Now, that word
21 usually will bring out the (inaudible), can you
22 tell I'm from Mississippi? We were referred to

1 the University of Alabama at Birmingham. Research
2 -- there was a lot of research being done on
3 pulmonary fibrosis. Very few people in Jackson,
4 Mississippi even knew what it was.

5 Joy participated in three different
6 studies at UAB, three different drug studies. She
7 was in the pirfenidone study, which we're going to
8 talk about some today. That was the last study
9 she was in, and we never knew -- of course, when
10 you're in the studies, you don't know whether
11 you're on the placebo or the real medication, so
12 we never knew.

13 Hold on. I have prepared notes. I'm
14 not used to working from prepared notes, but I'm
15 working against (ph) a time deadline here, so I'm
16 trying to stay on topic. The first thing I
17 remember about her, and the first thing I noticed
18 that started the process, was the cough. The
19 cough. It just starts -- it's kind of like this
20 dry cough. It goes -- of course, her sister had
21 had it, so it's not like we'd never heard that
22 before. About a year or so, it got more intense.

1 She couldn't catch her breath. She couldn't stop
2 coughing. Her clothes would just be soaking wet.
3 She would sweat. The fatigue. It was just -- you
4 know, it just built over a period of years. It
5 just -- it's just one of those things. You watch.
6 The doctor was very, very helpful to us.
7 I feel like I'm switching gears here,
8 but I'm going to talk some about her cough
9 medicine. She took -- I made a D in chemistry
10 also. I'm a business major, so if this -- if I
11 butcher this name -- there's an exotic -- a very
12 good cough medicine that helped that cough, and
13 it's Tussionex. I could walk into a drugstore and
14 tell them I wanted Tussionex. And it's called
15 Pennkinetic, but if there was a doctor here that
16 knows how to pronounce it properly, I'm always
17 welcome to be corrected. It would help the cough,
18 and as things progressed, she would take that, and
19 then like in intervals between that, she would
20 take an over-the-counter cough medicine. That's
21 what she took to help her stop coughing. And the
22 side effects of that, that's what I'm trying to

1 get at, is with that much cough medicine, that
2 much codeine, she had a lot of side symptoms.

3 And I also was a business major. I need
4 to tell you this. One bottle -- one eight-ounce
5 bottle of the Tussionex cost about 380 bucks.
6 It's not covered by the insurance. And in her
7 last year, she took two bottles, so that was about
8 \$900 a month, close to \$9,000 a year. It's not
9 covered under Medicare. She was eventually under
10 Medicare, and it's just not a covered cost to us.
11 So we were fortunate that we could afford that.

12 I took an early retirement to take care
13 of her. I took an early retirement to spend time
14 with her. But she was about halfway into the
15 illness. She had to go on to oxygen. That limits
16 what she can do. You know, flying is a -- you
17 know, there are portable oxygen machines, but for
18 her, they would not produce the liter amount that
19 she needed. We pretty much depended on the one we
20 got from the oxygen company in the bottles. I
21 would always have a trunk full of bottles. I
22 always had the big bottles, the little bottles,

1 and I had the machine with me. I would move --
2 just haul it with me wherever I went.

3 But the side effects of that -- she had
4 acid reflux. I'm not trying to be graphic, but it
5 -- she was very constipated. She had headaches,
6 joint pain, weight gain, and the fatigue. And she
7 was depressed. There's a lot to say about the
8 identical twin sisters. If I had time, I could
9 tell you a story about it, but they would very
10 much share a lot of emotions and knew a lot about
11 each other, so she was very depressed when her
12 sister died, and, of course, there's just -- when
13 you meet the doctor and talk to him, there's just
14 not a lot of things to look forward to.

15 I would be wandering around the
16 drugstore sometimes at midnight, looking for
17 things like enemas and cough medicine and cough
18 drops and everything. I mean, you just would get
19 everything. You do what you got to do. You do
20 what you got to do. And she took so much
21 medicine, I mean, we tried to manage it, we tried
22 to stock it.

1 One day, I walked in the kitchen, and
2 she was crying, and I looked, and there was that
3 medicine laying on the counter. And she just
4 swooped her hand and knocked it over. And she was
5 just crying because it was so hard to get. It was
6 just so hard. So it's just one of those little
7 side things I wanted to mention to you.

8 In our house, the doctor recommended
9 that we make the environment as clean as possible
10 for air, so I got down, and I got me a razor
11 cutter, and I cut every piece of carpet in the
12 house up, and I installed a laminate floor. I
13 must say, if you didn't know where the mistakes
14 were, you won't find them. They're behind the
15 doors and in the closets. But I got that sucker
16 down.

17 And so we have all laminate. There's no
18 carpet anywhere. And we did that -- she also --
19 when she slept at night, she had an overhead fan.
20 She had a fan by her head. She had two
21 oscillating fans, and we have a window air-
22 conditioning unit. So air was moving. I mean, it

1 was just something to help some -- it was some
2 psychological. It was some -- helped her breathe
3 better. And we did -- and we painted the room
4 real dark, we put dark curtains in it, because
5 when she wanted to sleep, she slept.

6 I had a housekeeper. I'm not a real
7 good housekeeper, but I do pretty good. Not a
8 real good cook, but I do all right. If you look
9 at me, you can tell I don't -- well, I eat out a
10 lot. Thought I'd tell you the truth to get that
11 over with.

12 The progression -- that last study,
13 though, the pirfenidone -- the doctor and I had
14 this conversation one day where he told me, he
15 says, "I have no way of knowing whether she's on
16 the placebo or the real thing." He said, "But I
17 can see -- I feel -- I sense some important going
18 here." He said, "I don't -- I mean, it's not
19 going away. It's not going to ever go away, but,"
20 he says, "she's holding her own for a little while
21 here."

22 She would -- she would kind of come --

1 I'm going to tell you something that she did,
2 because in this process -- about the third year,
3 we started talking to a transplant unit in the
4 University of Alabama at Birmingham. We had a
5 number of visits with them. And they did not want
6 to transplant her lungs until they could
7 deteriorate to a point. As a doctor put it,
8 "You're swapping one set of issues with another
9 set of issues." So her lungs -- her lung capacity
10 was holding pretty well. We were pushing it, we
11 were pushing it, we were pushing it. This is no
12 lie. They told her to go home. This is in the
13 third year now, so her progression was pretty bad.
14 Told her that she needed to get her weight to a
15 height limit (ph), in shape. She needed to get in
16 as good of physical shape as she could get.

17 She lost 30 pounds in 6 months. She
18 went to aerobics. She went to aerobics at a
19 church by our house, and the people couldn't
20 believe it when she walked in there with that
21 oxygen bottle and that cannula hooked up. And she
22 -- she was an athlete in high school. She played

1 basketball and ran track, so she was a very
2 athletic person. And she would get up there and
3 do the aerobics for about six or seven months.
4 And we talked back and forth with the transplant
5 unit, and it just never happened. We just ran out
6 of time.

7 One other thing I would tell you about
8 the oxygen machine, we didn't go anywhere without
9 the machine. I mean, I lived in Jackson,
10 Mississippi. Birmingham, Alabama is a four-hour
11 drive. I counted, in over a five-year period, we
12 probably drove almost a hundred times back and
13 forth. That's a lot of time. Some days, we would
14 make the trip, we'd have tests, we'd come home.
15 She'd sleep. She'd sleep over, she'd sleep coming
16 back. We'd use oxygen bottles for that.

17 The guys at the hotel -- after a while,
18 we stayed at the hotel, when we knew we'd be there
19 long enough for more testing. A couple of guys
20 there that knew more about oxygen machines than
21 the oxygen company. I could pull in -- they
22 looked like a pit crew coming out for a NASCAR

1 race. I'd go to the trunk. Out would come the
2 oxygen machine, out would come all of our clothes,
3 and before I could check in and get to the room,
4 they had the machine running, they had a 50-foot
5 cannula and cord running, and she was ready to go.

6 And they all -- my wife was a hugging,
7 kissing person, and she hugged them all, and every
8 time we'd leave, she'd hug them all, and I got
9 loads (ph) of it. Normally, you would see me in a
10 white shirt, and usually there was lipstick
11 somewhere, because I was going to get a kiss every
12 morning before I went to work, so -- she was just
13 that type of person, but --

14 MS. GIAMBONE: Thank you, Curtis. Do
15 you have any other final remarks?

16 MR. CURTIS THOMPSON: That's enough.
17 I'll pass it on.

18 MS. GIAMBONE: Thank you, Curt. Thank
19 you so much. Okay. So we have Faye next.

20 MS. MACINNIS: Hi. Faye MacInnis. Can
21 you hear me okay? Actually, myself and my husband
22 were diagnosed with two very deadly diseases the

1 summer of 2012. My husband Phil was diagnosed in
2 June with IPF, and I was diagnosed in July with
3 breast cancer. We were both -- it was a scary
4 diagnosis, obviously. Forty thousand people die a
5 year from IPF and breast cancer, so we knew we
6 were in serious trouble.

7 However, what I want to bring -- part of
8 what I want to bring to light is the fact that
9 from that moment on, from the diagnosis, we had
10 two entirely different experiences. We were at
11 two opposite ends of the spectrum.

12 When I was diagnosed with breast cancer,
13 my doctor held my hand and said everything was
14 going to be fine, I was going to be okay. She
15 told me I would have a team of doctors. She would
16 be my surgeon, I'd have a radiation oncologist,
17 and then I would have a medical oncologist.

18 After she left the room, talking to me
19 for a few minutes, her physician assistant came
20 in. She sat down. She handed me this binder
21 that's called "My Personal Treatment Journal."
22 And inside it, it already came with a bunch of

1 business cards from people that are associated in
2 the medical community with this disease. All
3 throughout this book, it ranges anywhere from a
4 financial navigator program, nutrition, body,
5 mind, spirit wellness, nurse navigator support,
6 pain and symptom management, pastoral care,
7 psychological counseling, social worker, all of
8 it, right in here. You kept it with you, took it
9 to all your appointments, to everything.

10 When Phil was given his diagnosis by the
11 local pulmonologist, he was given four sheets of
12 paper. The first two just described pulmonary
13 nodule. The last two sheets are the only thing
14 that talked about IPF, and all's it gave him were
15 some of the diagnosis about it, some of the
16 causes, treatment, which was there was no
17 treatment. The doctor said, "I can't do anything
18 for you. You need to go to a specialist," either
19 -- we live in Delaware, so either Temple or Penn
20 or Johns Hopkins. The pulmonologist told him,
21 "Pick one." So he picked Temple. Talking to a
22 couple of his other doctors, they thought Temple

1 might be good. So he made a phone call in June.

2 And, of course, the first appointment he could get
3 was in September, three months later.

4 So during the summer of 2012, I ended up
5 having surgery, a lumpectomy, in August. Then I
6 had to go back. A little more tissue had to be
7 taken out. That was done in September. In
8 October, I had radiation. In November, I was put
9 on a cancer medication, tamoxifen. So I remember,
10 I was cancer free. I was on -- I had finished a
11 surgery, my radiation, and I was on a medication
12 that I would have to stay on for several years.

13 During summer of 2012 for Phil, he
14 waited. There was no treatment. The pulmonologist
15 didn't tell him anything about anything. So he
16 went about most of his regular activities,
17 although whenever he would mow the grass, I would
18 look out, and I would see -- it was a push mower,
19 and I'd see him stop with his hands on it,
20 breathing, trying to breathe, and he looked all
21 white and pasty, and I kept thinking he was going
22 to pass out.

1 And I would talk to him, and, of course,
2 he was a man, so he explained to me, "No, no, no,
3 I'm fine. It's just really hot out. I should
4 have mowed the grass earlier in the morning." And
5 that's how it always was. We would always ride
6 bikes, and when we rode our bike, he always was
7 faster than me. He would -- he, in previous
8 years, would be in different cycling events. One
9 was Bike to the Bay in Delaware, 75 miles each
10 way. No problem, he could do that. He would ride
11 50-mile biking events.

12 So this summer, we'd go out, and we'd
13 ride in our neighborhood and go around, and I'm
14 beating him. I thought it was kind of funny at
15 first, but then I -- then it wasn't funny. Then
16 we went out a second time, and I realized he
17 really can't breathe. And then that's when I --
18 and this -- I'm getting -- but that's when I
19 really threw a fit and actually made him go to the
20 doctor, to a local pulmonologist, which is how he
21 got his diagnosis.

22 For me, I got my diagnosis going in for

1 a mammogram. That's how I ended up at the doctor.
2 But for him, it actually took me noticing him,
3 that he couldn't do things as well as he did
4 before. Again, he downplayed it. He didn't tell
5 me what pulmonary fibrosis was. I, unfortunately,
6 did not go on the Internet and look. I just took
7 him at his word, and he just said, "Oh, no, it's
8 no problem. Some problems with my lung. It's
9 taken care of."

10 So I watched him during the summer and
11 realized he always made excuses so we didn't go
12 bike- riding. I watched him when he mowed the
13 lawn and had trouble getting through that. He was
14 still able to go to work. He still did projects
15 around the house. He was a little bit slower with
16 it, but he always had an excuse for why he was
17 that way.

18 So since I was out for surgery with
19 breast cancer, I was able to go with him in
20 September to Temple to see the pulmonologist
21 there. And through discussions with her, she felt
22 that he should go on oxygen with exertion, but he

1 wouldn't need it at any other time. She was very
2 friendly. He was very friendly, my husband,
3 talking. Everything seemed okay. I got no red
4 flags. Okay, so he needs oxygen to help him until
5 they work on this, and everything was fine.

6 She said, "You want to come back
7 November, because you had your pulmonology test --
8 breathing test in June with your other doctor.
9 You want to do a six-month test." Okay. That's
10 fine. We continue on -- we continue on, then,
11 during the fall, and then I noticed that, you
12 know, he still had more trouble, but he was still
13 doing okay.

14 And then we went back in just a couple
15 months later, in November. They did more tests,
16 and then she told him that he had lost 10 percent
17 of his lung capacity in 6 months. And then she
18 said, "You have to go -- from the test results,
19 you have to go on oxygen all the time, even when
20 you're sleeping." So 24/7. So even from
21 September, somehow, to the end of November, he
22 went from just needing oxygen during -- from

1 exertion to all the time.

2 And then that's when I started to really
3 see a difference in him. That's when he -- going
4 up the steps, that's when he would -- even with
5 his oxygen, he would take one step, and then have
6 to rest and breathe, take another step and
7 breathe. So instead of running up the steps or
8 even walking up the steps, it now became a 20-
9 minute ordeal, just for him to get upstairs and to
10 get into bed.

11 Getting dressed in the morning, that
12 became an hour-and-a-half struggle, because it
13 took him so long to walk to the closet, to get the
14 clothes, then he had to sit down, then he had to
15 rest after each piece of article that he put on.

16 In January, at that point, he had to
17 quit work. It was just really too difficult for
18 him for all the -- for transportation. Also in
19 January, that's when he stopped driving. I would
20 get to drive him wherever we were going. So I
21 took him to all his doctor's appointments and to
22 other things.

1 Getting back to the oxygen, that's back
2 in September when we got the oxygen, our whole
3 lives became wrapped around that. He couldn't
4 take a trip, go to the doctor's, we couldn't go to
5 visit family, we couldn't take a day trip
6 anywhere, without making sure we had enough oxygen
7 to be there. The worst thing that could happen
8 would be to be stuck and not have oxygen. He
9 could end up at the emergency room, passing out,
10 and maybe even die. That was an extremely scary,
11 frightening time. I was always so scared we were
12 going to go someplace, and he was going to run out
13 of oxygen.

14 In January, then, that's when -- and
15 also too, when we would go to doctors'
16 appointments, they didn't have oxygen refills
17 there. They didn't have any -- you had to bring
18 everything with you. No one else is set up for
19 this if you have this disease. The only place was
20 when he went to the pulmonologist, where they
21 would have facilities there to take care of you.
22 Nothing else, public buildings, no place else,

1 nothing can help you (inaudible).

2 Finally, I noticed, when we went back
3 and saw her in December, when she put him on
4 oxygen all the time, she said -- actually, my
5 husband, again, very, very casually, and he sort
6 of whispered to her, "Do you think it's time we
7 should start talking about lung transplants?" And
8 that, quite honestly, was the first time that I --
9 "Lung transplant? Hey, what's going on here?" I
10 was so clueless. I'm ashamed of myself at this
11 point, but I was so clueless about this.

12 And she said, "Yeah, that would be some
13 treatment maybe further down the line." And then
14 I looked at her, and I said, "Well" -- I said,
15 "What do you mean, lung transplant? Can't this --
16 isn't this going to be fixed? Doesn't this get
17 better?" And she said, "Well, no, but most people
18 last two to three years after they're diagnosed."

19 And my jaw dropped, and I said, "You're
20 talking death?" I mean, I had no idea, and I was
21 just -- stunned silence. They're still happy with
22 each other, talking back and forth, doesn't seem

1 to be any urgency. Phil and I don't talk because
2 it's hard to say anything, you don't know what to
3 say. We're driving back home in the car, and then
4 tears -- I don't sob, but tears start coming out
5 of my eyes, and he looks at me, and he saw this.
6 He says, "Now, Faye," he says, "I'm not going to
7 bring you to any more doctors' appointments if you
8 start to cry." And I said, "I promise I won't
9 cry. I promise."

10 And from that point forward, then I went
11 home and actually looked it up on the Internet and
12 found a lot of things out I didn't want to know.
13 So I really was scared from that point forward,
14 and then that causes some friction, because he
15 would have a pulsometer (ph), oximeter (ph), and I
16 would always be asking what his readings were to
17 make sure they were at 90 or more, until finally,
18 at one point after this, he said, "Faye, you've
19 asked me three times in the last ten minutes."
20 And I started to cry, and I said, "I just want to
21 make sure that you're okay," and I started crying,
22 and he said, "Faye," he said, "I'm so sorry." He

1 said, "I know you're really scared, and I'm sorry
2 I've made you scared." And that's really pretty
3 much how we lived.

4 And in January, he was told that he
5 should try to get a biopsy to get into a clinical
6 trial. So they made an appointment. End of
7 January, we saw the doctor, Temple, everything was
8 good. It was set up for February 19th, but he
9 really wasn't doing very well. I think it was
10 more difficult for him to get around, as I said,
11 to go up the stairs. He really couldn't work, he
12 couldn't ride.

13 And I just noticed he was -- on a bad
14 night, he couldn't even make it all in one trip.
15 He'd get up from the armchair, have to sit down in
16 a chair in the kitchen, then make it to the
17 stairs, then get up to the landing, then sit down
18 for a couple minutes, then make it the rest of the
19 way up.

20 So called the doctor, and we went in and
21 saw her on February 12th, and she said, "No, it's
22 too risky for you to have this operation," so they

1 stopped the operation for the lung biopsy. And
2 she said, "You need to start being tested for lung
3 transplant." Unfortunately, he had Aetna, but we
4 found out at that last point that they covered for
5 management of IPF, but not for lung transplant.

6 So all the time he went to (ph) the
7 doctor meant nothing. He couldn't get a lung
8 transplant, the testing or -- so then she said,
9 "Well, Penn (ph) has a good -- let me call there."
10 Well, that was five weeks later until he would get
11 an appointment to see them.

12 Unfortunately, ten days later, on
13 February 28th at three in the morning, Phil
14 couldn't breathe at all. I had to carry -- he
15 went to the bathroom, and from that point on, I
16 had to carry him out of the bathroom into the bed.
17 And I called 911, and they came, and they had four
18 men with one stretcher and carried him out, and
19 they had to actually put him on a ventilator.
20 They had to sedate him and actually paralyze him.
21 And they told me he probably wouldn't survive the
22 night, but he did. He's a fighter, and he did.

1 And he spent 30 days on a ventilator, believing
2 that we could get him in for testing for a lung
3 transplant. And he hung on to that.

4 MS. GIAMBONE: I know this is hard,
5 Faye. I'm so sorry.

6 MS. MACINNIS: That's okay. Am I out of
7 time?

8 MS. GIAMBONE: Any final remarks?

9 MS. MACINNIS: Just that on March 28th
10 at three a.m., he died. Up until that last
11 moment, he thought that there was still hope, but
12 there wasn't, and maybe with drugs that are coming
13 out, they may have -- would have given him more
14 time that he might have been able to get tested,
15 because he was a good candidate for a lung
16 transplant, but he wasn't. So now, he's not here,
17 and all I have left are memories and pictures and
18 his wedding band on my necklace. And I want drugs
19 to come out that help to give people more time,
20 that they might have a chance. I'm sorry.

21 MS. GIAMBONE: No, no, don't be sorry.
22 Thank you so much for sharing that. It's -- thank

1 you. Thank you, Faye. Okay. Next we have Diane.

2 MS. REICHERT: That's something to
3 follow up, huh? Okay. Hi. My name is Diane
4 Reichert, and I am living with idiopathic
5 pulmonary fibrosis, also known as IPF. And I'd
6 like to thank my husband Curt (ph) for walking
7 this journey with me.

8 In August of 2013, at the age of 48, I
9 was diagnosed with IPF. This past year has been
10 an express train to a multitude of life-changing
11 decisions, with no time to think, to plan, or
12 prepare. The symptoms I think that affect me the
13 most are shortness of breath, fatigue, and I get
14 pain in my fingers, the tips of my fingers, my
15 toes, my lips, and my tongue. Not everybody has
16 that, but I do, unfortunately.

17 Early on in my diagnosis, I only needed
18 oxygen to sleep at night and possibly to walk my
19 dog, and I would be at two liters. Fast-forward
20 to where we are right now, I am on four liters
21 continuous flow, and it's increasing quickly, and
22 this was just within a year of diagnosis.

1 Although I experienced shortness of breath
2 initially at diagnosis, it's easy to blow off
3 because, you know, you're getting older, you're
4 overweight, out of shape, those types of things,
5 but as time passed, my shortness of breath
6 increased, and my need for supplemental oxygen
7 increased as well.

8 And along with the increase in shortness
9 of breath or the shortness of breath, the fatigue
10 really weighs on you. Your body works so hard to
11 be able to process the oxygen that you breathe in
12 that you're completely exhausted.

13 It required me, at the age of 49, to
14 take an early retirement from a profession that I
15 had done forever. I was a school teacher and then
16 became a learning consultant, which is someone who
17 diagnoses or tests students to see if they're
18 eligible or continue to be eligible for special
19 education services. I spent a great deal of time
20 working with emotionally disturbed children, so
21 this was a huge shock for them.

22 I loved horseback riding. It was my

1 peace, and I had to give that up. It's extremely
2 difficult to groom a horse and prepare a horse, to
3 get on him to ride him, let alone to actually be
4 able to sit on him and get him to move in any
5 direction. Believe it or not, it's a lot of
6 cardio work that I never thought of. I just
7 couldn't figure out why I couldn't breathe doing
8 it.

9 I'm a hobby photographer. I'm not able
10 to do that so much anymore for a couple of
11 reasons. One, a lot of times, my fingers hurt too
12 much to push down on the shutter, believe it or
13 not. And I also have a great deal of difficulty
14 walking, lugging the oxygen, lugging the camera,
15 going anywhere to be able to take pictures. It
16 would be great if the scenes would come to me, but
17 they don't, so I don't really do that too much
18 anymore.

19 It's difficult to keep my house clean.
20 Even with the oxygen, I get very tired, so it's
21 sweep the floor, sit down and rest for a long
22 time, and then maybe do something else and sit

1 down and rest. Laundry takes days to do, and not
2 just one day. The beach -- this is the first time
3 -- this summer was the first time, in all the
4 years that I've been alive on this earth, that I
5 have not been to the beach. I am a beach girl. I
6 can't go to the beach now. I can't walk in the
7 sand. I can't go in the water. I could sit on
8 the boardwalk, but that's not what a beach girl
9 does. And I didn't realize that until the end of
10 the summer, that I had not been.

11 On my very best days, I struggle to have
12 a good, long conversation with my friends, hang
13 out with my family. It's difficult. It's hard
14 talk. It's hard to talk and be able to breathe,
15 and it makes you very tired.

16 Shopping is hard. I'm not -- they don't
17 let me borrow the oxygen. I have a concentrator,
18 so you always have to worry about running out of
19 battery charge or run out of oxygen in your tank.
20 So everything is planned. Oh, I like to shop.
21 You can't really shop now.

22 On my worst days -- and this morning was

1 a rough morning -- coughing will wipe you out for
2 an entire day. Wake up in the morning and cough
3 so hard that you may actually throw up in your
4 mouth. And I'm sorry to say that, but it's the
5 truth. And it just literally wipes you out.
6 Physically, you're exhausted.

7 And if that's not bad enough, now you
8 have to get up and take a shower and then rest,
9 and then dry yourself off and rest, because you
10 can't get out of the shower and dry yourself off.
11 You have to rest in between. Everything is do a
12 little bit and rest. So, like you said, it's about
13 an hour and a half to two-hour production from the
14 time you get up in the morning until the time you
15 look as cute as I look right now.

16 So it's difficult. It's very difficult.
17 The headaches -- I get severe headaches that cause
18 me to just lay on the couch. And, again, the pain
19 in my fingers and toes are just tremendous.
20 Ideally for me, what I would like to see is a
21 medication to slow the progress of this disease,
22 eventually make it so people don't get this

1 disease at all.

2 Unfortunately for me, my disease has
3 progressed to the point where I probably won't
4 reap the benefits of this drug or any drug.
5 However, I want it for my PF warrior friends, my
6 people that live with idiopathic pulmonary
7 fibrosis every single day and know how hard it is
8 to breathe, know how hard it is to get up in the
9 morning and keep a smile on your face and to keep
10 going. I just want them to be able to live a
11 good, healthy quality of life with slow
12 progression of this disease, if that's at all
13 possible.

14 MS. GIAMBONE: Thank you so much, Diane.
15 Thank you. Okay. And then we have Laura.

16 MS. ROIX: Really, it's my turn? Can
17 you hear me? I want you to see that I've had to
18 do something that I normally never, never do
19 unless I have idiopathic pulmonary fibrosis, and
20 that's to set up my little station here with cough
21 drops, with water. Because of Diane, I have
22 Kleenex. And this little thing, which is called a

1 POC, or a portable oxygen concentrator, for those
2 of you that probably have never seen one and have
3 seen the little (inaudible) tanks that are behind
4 us.

5 It's very difficult still -- it's
6 getting better, but it's very difficult to be,
7 first, diagnosed with idiopathic pulmonary
8 fibrosis. In 2006, I was diagnosed with scarring,
9 and I used to get pneumonia all the time, so I had
10 gone to the pulmonary doctor to find out why. It
11 just didn't seem right. And he diagnosed me with
12 scarring. He said, "But don't worry about it.
13 It's just scarring. So come see me in two years."

14 So I went to see him in two years, and
15 he said, "You still have scarring. Don't worry
16 about it." It could have been -- I'm a baby
17 boomer, so my parents are -- were older than that,
18 so, you know, they were exposed to certain
19 environmental things, such as asbestos, which I
20 was exposed to as a child, because my father would
21 bring it home.

22 So, you know, the doctor didn't know

1 that maybe that might be the cause of my scarring
2 in my lungs. And fast-forward to 2012. When he
3 took another PET scan, he said, "Oops, it moved,
4 but don't worry about it. (Inaudible), but don't
5 worry about it." I can't cry. If I cry, I'll
6 start coughing. That's one of my major symptoms
7 that are really bad, other than my shortness of
8 breath. And I'm holding this because I'm trying
9 to do this without my oxygen.

10 So he still said, "Don't worry about
11 it." I tried in -- and I was a power-walker.
12 Thanks to prednisone, I gained 40 pounds, so it's
13 a little bit harder to do, but -- with the oxygen,
14 but I was a power-walker. I would do that all the
15 time on my lunch hour.

16 In the winter, instead of power-walking
17 outside at lunch -- and I live in Hartford,
18 Connecticut, and so we would go across the river
19 to power-walk, and we decided that we would try to
20 compete against each other, and we walked 15 to 22
21 flights of stairs at lunch instead of power-
22 walking in the middle of the winter. And I

1 started coughing, and I couldn't stop.

2 So I finally went and talked to another
3 doctor, another pulmonary doctor, who did a VATS
4 biopsy on me, and with the VATS biopsy, he said,
5 "You have a thing called idiopathic pulmonary
6 fibrosis. There's no treatment, and there's no
7 cure, but don't worry about it. I'll take care of
8 you." So I said, "That's not going to happen."

9 Then I went out onto the Internet, and I found
10 certain sites -- PatientsLikeMe was one of them --
11 that -- people out there who had IPF said, "Don't
12 settle for that. Go to a Center of Excellence,"
13 which I did do. I went to Yale-New Haven. And
14 Yale sent me on to my journey, which brought me to
15 transplant evaluation at Brigham and Women's
16 Hospital, and also I'm now going for evaluation at
17 Columbia so that I can hopefully, when the time
18 comes, be transplanted into either center in one
19 of the two regions.

20 I -- one of the things that I -- I loved
21 my job, and I can no longer work. I would go to
22 work, and I would cough so badly that there was

1 another person in the office who would sit there
2 and be able to gauge how my day was going because
3 it depended on how much I coughed.

4 And so I would bring a washcloth to work
5 with me so that I could muffle the sounds of my
6 cough so that I wasn't bothering other people,
7 because it would always be known that Laura was
8 coughing an awful lot today, so had to be a bad
9 day for her today.

10 This wonderful thing, this portable
11 concentrator, I also had at the time. I'm now
12 back to tanks, but I had this portable
13 concentrator, and it's hard for this -- like this
14 area, I would take a bus to work. You know, I
15 know a lot of you who live here probably take
16 trains.

17 And so in the middle of the winter, this
18 thing doesn't have four-wheel drive on it, so I
19 couldn't put it in the middle of the snow and try
20 to get it to move. So I'd be in the middle of the
21 street at five o'clock in the morning, in the
22 middle of the dark, hoping that a car wasn't

1 coming so I could get myself to that bus stop in
2 order to get on the bus. Not only that, but there
3 has to be sleeves made for these little pieces of
4 plastic, because once I got to the bus stop, I'd
5 have to then try to warm it up because it froze
6 solid, so I would have to try to warm it up in
7 order to use the oxygen in order to get to work.

8 And that's just the little things that
9 happen, you know. It's a very lonely disease.
10 It's a very lonely place to be, because it is
11 terminal. There's only one treatment currently out
12 there, and that one treatment is a lung
13 transplant. That's hard to take. It's hard to
14 take. And if I talk about it, my daughter tells
15 me I'm being negative, and so do all my friends.
16 And if I don't talk about it, then I'm inside
17 myself, and "What's the matter with you," you
18 know?

19 It's hard. It's very difficult. But
20 hopefully we'll come out with something. I'm
21 currently in a clinical trial. There's more
22 clinical trials coming out. There's two that

1 currently are here at the FDA that hopefully those
2 drugs will come out that have been promising in
3 stopping the process. And that's about all I can
4 do. They say that it's very rare. It's not as
5 rare as everyone thinks. My Godchild's mother has
6 the same disease. And I'm in a clinical trial
7 because I don't want my daughter to have to sit
8 here someday (inaudible) because her mother had
9 it. I don't want my daughter to have to do that
10 and say what her name is and that she has
11 idiopathic pulmonary fibrosis and there's no cure,
12 no treatment. So I think I'm up, right?

13 MS. GIAMBONE: Yes. Thank you --

14 MS. ROIX: Hopefully, so I don't have to
15 sit here and cry anymore. Thanks for listening to
16 me.

17 MS. GIAMBONE: Thank you. I would like
18 to ask can we give our panelists a round of
19 applause? It takes a lot of courage -- a lot of
20 courage and a lot of strength to sit up here and
21 share such personal experiences, and we can't
22 thank you enough. Thank you for sharing Joy's

1 story and for Phil's story and, Diane and Laura,
2 thank you so much for sharing your experiences
3 with us.

4 FEMALE SPEAKER: Thank you.

5 MS. GIAMBONE: All right. Thank you.
6 Yeah, you can stay up there. Stay up there.
7 You're not off the hook yet. Okay. So I want to
8 quickly recap some of the voice that we heard, and
9 if you're comfortable to do so, I want to do a
10 quick show of hands to see how their experiences
11 resonated with your experiences. So we heard Curt
12 share about his wife's dry cough, a cough that
13 would make her so sweaty because it was so
14 intense. Could we do a show of hands to see -- do
15 others experience that? Okay. So we have quite a
16 few hands raised, about five or six hands. Okay.

17 We also heard shortness of breath. Faye
18 mentioned that her husband would be so short of
19 breath that he would be white and pasty, as you
20 said. Shortness of breath to that intense level,
21 can we do a show of hands to see how many that
22 resonated with? Okay. I see about eight or ten

1 hands raised. Okay.

2 And then we heard about -- Diane was
3 sharing about the pain in the fingers and toes and
4 lips. How many of you also experienced that?

5 FEMALE SPEAKER: (Inaudible).

6 MS. GIAMBONE: Okay.

7 FEMALE SPEAKER: (Inaudible).

8 FEMALE SPEAKER: You're not alone.

9 FEMALE SPEAKER: Yeah.

10 MS. GIAMBONE: You're not alone. That's
11 right. You are not alone.

12 FEMALE SPEAKER: Yes. That's my
13 (inaudible).

14 MS. GIAMBONE: Yeah. Okay. And then
15 Laura mentioned quite a few of the impacts of
16 living with IPF. As she mentioned, she enjoyed
17 shopping and traveling. So how many of you did
18 that resonate with, that it impacts your -- some
19 of the hobbies and activities that you really
20 enjoy doing that are now limited? Quite a few
21 hands. Quite a few hands. So I think what that
22 shows is that your experiences resonated so much

1 with those of you in the audience and that you're
2 not alone, so thank you for sharing those
3 experiences with us.

4 So let's get our clickers out. We're
5 going to do another polling question. And those
6 of you on the panel, make sure you have your
7 clickers ready too. Okay. This one says, "Of all
8 the symptoms you have experienced because of IPF,
9 which do you consider to have the most significant
10 impact on your daily life?"

11 And you can choose up to three symptoms:
12 shortness of breath; B, fatigue or malaise; C,
13 coughing, especially dry or hacking coughs; D,
14 chest pain; E, gradual, unintended weight loss; F,
15 decreased appetite; G, clubbing; H, depression; or
16 I, other symptoms not mentioned. So take a few
17 moments to put in your responses.

18 And, again, the polling questions are
19 for patients, caregivers, patient representatives,
20 so make sure you respond on behalf of your loved
21 one. Okay. So it looks like shortness of breath
22 is the most prevalent -- or most significant

1 symptom for the majority of you in the room,
2 followed by coughing and the fatigue, and then it
3 looks like we also had depression come up, and
4 then a small percentage of some of the other
5 symptoms mentioned. So shortness of breath,
6 coughing, and fatigue were the top three symptoms.
7 And could we see what the results were on the Web?

8 MR. GRAHAM THOMPSON: On the Web, it was
9 very similar. We had about 60 (ph) percent
10 shortness of breath, and we had 50 percent fatigue
11 and 50 percent coughing, and then 14 percent
12 depression.

13 MS. GIAMBONE: Okay. Thank you. Okay.
14 So with that, I'd like to now open it up to other
15 patients and caregivers in the audience. Let's
16 start with shortness of breath. And would anybody
17 like to share how you or your loved one experience
18 the shortness of breath? Yes? And hang on just
19 one second. We'll have the microphone come over
20 to you.

21 MS. COATES-NANCE: My name is Martina
22 Coates-Nance, and I'm representing my husband

1 today, but, unfortunately, he couldn't be here
2 because for some strange reason -- we think our
3 daughter brought it home, but he got a cold. So
4 to talk about cough, I mean, it is that cough,
5 where he literally is like to the point of almost
6 throwing up.

7 The shortness of breath affects
8 everything, as, you know, we commented on the
9 questions there, but he can't do anything. I
10 mean, Douglas was a biker. He played tennis. I
11 mean, he'd throw a football a football field
12 length, so it affects everything.

13 To go up the stairs, he goes up the
14 stairs -- I remember Faye talking about, you know,
15 her husband going up the stairs. It's like, okay,
16 you get to the top of the steps, you have to stop,
17 pause. And what I didn't know, and what I've
18 learned, is that, you know, sometimes we don't
19 even realize it, but we hold our breath going up
20 the steps. And having to learn to remember to
21 breathe as you're doing different activities, so
22 that's -- like I said, it's impacted us so much.

1 Curt talked about, you know, having that
2 50- foot cord, and others have talked about -- we
3 don't travel. We -- the last time we actually did
4 take a trip was to go to California to his
5 father's funeral, and, yes, on the plane, with
6 portable oxygen, he ran out of oxygen. We're in
7 the air. He ran out of oxygen. So as soon as we
8 touched down, it's like we had to call. We're
9 getting ready to touch down. Somebody needs to be
10 at the airport with a tank. The TSA guy would not
11 let his brother get his tank to him. I'm like, "If
12 you don't let his tank get to him, he literally
13 will die on you right here." So it's -- you know,
14 it's your life, having those tanks with you all
15 the time.

16 As I mentioned to the folks here at the
17 table, you know, you plan a trip based upon how
18 much oxygen you have. You have to figure in that,
19 you know, okay, where do we have to go? How long
20 is it going to take to get here? Right now, he's
21 at rest, four liters. At exertion, it could be
22 anywhere from six to eight. So it's like, okay,

1 get there, and you're sitting right here. You
2 can't move too much. How long are we going to be
3 here to make sure we have air to get back home.
4 So, yeah, that shortness of breath, it literally
5 is a matter of life and death.

6 MS. GIAMBONE: Thank you, Martina.
7 Anyone else want to share -- yes?

8 MR. BOYER: My name is Bill Boyer.
9 Fortunately, I was able to retire from USDA, one
10 of your sister agencies, on January 1st, and I
11 like traveling, so in May, I took my sister to
12 visit friends in France that we've visited many
13 times. My condition at that point was I needed
14 oxygen for exertion and not really for sleeping or
15 sitting and things like that, so I took a
16 concentrator with me.

17 I had a little cold before I left, had a
18 little bit of a rattle, and by the time I got
19 there, you know, almost a day and a half, almost
20 two days of travel by plane and train and stations
21 and train and stations, I was pretty worn out. So
22 that night, I went to bed early, and I didn't have

1 an oxygen with me or turned on because I was
2 sleeping, and had a little coughing spell and got
3 out of breath, got shortness of breath, and
4 everybody else was asleep when I had this happen,
5 so I went down, hooked up the machine, and said --
6 got my breath again, and I said, "I've got to take
7 this up to bed."

8 So I took -- went back upstairs, got the
9 extra tubing, plugged that in, went back upstairs,
10 got back in bed, and thought I was going to die.
11 I mean, at that point, I really -- I came up with
12 two conclusions. One was having IPF and needing
13 oxygen is like being in jail. You're really boxed
14 in by having that oxygen need, you know, having to
15 always think about where it is, what you're doing,
16 what you're about to do. And the other thing was
17 it took me a while to calm down, but at that
18 moment, when it was the worst panic of part of the
19 moment, I suddenly knew what it was like to drown,
20 because I pulled out my oximeter at that point,
21 and I was at 59 percent, and I was scared to
22 death. So all I could do was just lay there and

1 keep saying, "Relax and breathe and relax and
2 breathe." And somehow I got through it, but then
3 I spent the next 3 -- 13 days in the hospital with
4 antibiotics, because it actually became a lung
5 infection. So that's the shortness of breath
6 story for me. Thanks.

7 MS. GIAMBONE: Bill, thank you. And I'm
8 not sure if you saw while you were speaking, but
9 there were several heads nodding as you talked
10 about some of the restrictions and the constraints
11 that you felt. Thank you.

12 Would anybody else like to share how
13 they experience shortness of breath, maybe on an
14 average day versus a more severe day? Yes?

15 MS. SNYDER: Hi. My name is Heather
16 Snyder. I'm a post-transplant -- I received a
17 transplant, so I'm going to tell you a story about
18 a couple years ago. But a lot of people will
19 describe this disease as having an elephant on
20 your chest. I'm not sure why I never felt like I
21 had an elephant on my chest. What I did feel was
22 a very tight noose around my neck. To climb one

1 step, I felt like I was hanging myself. It was
2 extremely difficult, and I kept scratching at my
3 throat, trying to pull that invisible noose off,
4 but it just never came off.

5 MS. GIAMBONE: Thank you for sharing
6 that. Anybody else? Okay. And FDA panel, do you
7 have any questions to follow up on the shortness
8 of breath? Okay. Great. And let's check in with
9 the Web to see what comments are coming in.

10 MR. GRAHAM THOMPSON: Many people are
11 writing in to talk about shortness of breath.
12 Most of the perspectives are very similar to what
13 we've been hearing in the room. There's also been
14 several people talking about coughing, including
15 one person talking about how severe coughing led
16 to hearing loss in one ear, and another person who
17 said that instead of dry or hacking cough, he has
18 more of a problem with a productive (sic) cough,
19 or, you know, a cough with thick and sticky mucous
20 stuck in his throat, resulting in hacking and
21 spitting and things like that.

22 And then, finally, we had one person

1 mention her father, who had difficulty with
2 shortness of breath after minimal exertion,
3 hypoxia after coughing attacks, and also pulmonary
4 hypertension and ulcers.

5 MS. GIAMBONE: Thank you, Graham. So I
6 think that can take us to the next symptom that
7 received a large response, which was coughing. So
8 I hear that, you know, from all that you've
9 shared, that the shortness of breath can also sort
10 of results from that coughing spell that you had.
11 So would anybody like to share that experience
12 with that coughing, that intense coughing or dry
13 cough? How do you experience it? Heather?

14 MS. SNYDER: I remember I had a dry
15 cough for years before I was really officially
16 diagnosed, and it sounded like a sneeze. So I
17 would have people say "God bless you" all the
18 time. I'm like, "Oh, it's really a cough." But
19 after a couple years, I just gave up and let them
20 think whatever they wanted to think. But I also
21 remember my cough was really so deep that it felt
22 like I broke my ribs, and my ribs became so

1 cramped that I couldn't even twist, so it caused a
2 problem driving, because you really can't twist to
3 see over your shoulder, see who's beside you. And
4 it's kind of scary because it's like a charley-
5 horse, almost, type thing, in your rib cage. And
6 when I used to get that, I had problems breathing
7 because I was having an anxiety attack on top of
8 that. So that was really hard for me.

9 MS. GIAMBONE: Thank you, Heather. Any
10 other comments that you'd like to share? Yes?

11 MR. BULGER: I'm Sam Bulger, and I just
12 -- my comment on coughing, because, to me, when it
13 came, I was -- it was so, so different. I was --
14 I remember exactly when it happened. We had
15 gotten off a ship, and it was the day we got off,
16 and I was embarrassed on the airplane going home
17 because I was coughing so much. And back in
18 reality, it was probably an early wake-up call,
19 because I tried home remedies for a couple months.
20 Finally, this -- so this was December, and in
21 March, I went to see my doctor. He had a chest X-
22 ray, and he said I have interstitial stuff in

1 there and put me on an antibiotic, which, of
2 course, it wasn't anything that needed the
3 antibiotic.

4 But then, a month later, I had a CAT
5 scan done, and it agreed with him, the chest X-
6 ray. But I went to a pulmonologist -- I live in
7 Denver, and I've been dealing with National
8 Jewish, and my doctor had worked there, and he put
9 me on this PharmaNac. And to me, it's a wonder
10 drug. And it's just an over-the-counter thing.

11 And, I mean -- oh, and the other major
12 side effect I had was unintended weight loss, and
13 so I lost about 12 pounds. And but those are the
14 two big things. And I've gone into a couple of
15 research things at National Jewish, and I'm not
16 saying that I've got this thing under control or
17 anything, but it seems like I'm still in the early
18 stages. And, actually, my lung capacity has
19 improved.

20 Now, this has been a year and a half
21 since the diagnosis, so I'm just wondering -- I
22 haven't heard that mentioned, PharmaNac, but it's

1 just an over-the-counter drug, and, to me, it's
2 been a wonder drug so far.

3 MS. GIAMBONE: Thank you, Sam. I do
4 remember -- I think it was -- let's see. Was it
5 Diane? You had talked about how the coughing was
6 -- it was more intense in the morning of -- you
7 said you would have that morning cough, which
8 would kind of make the rest of the day -- it would
9 kind of shape your day, almost.

10 MS. REICHERT: Correct.

11 MS. GIAMBONE: And I'm curious if others
12 have a similar experience of -- is there a time of
13 day, or is there a certain -- is there any sort of
14 pattern to that cough? Does it -- is there times
15 when it's worse than other times during the day?
16 Does anybody want to --

17 MR. VAN DEN ASSUM: It depends on the
18 weather.

19 MS. GIAMBONE: Yeah?

20 MR. VAN DEN ASSUM: It depends on the
21 weather very often.

22 MS. GIAMBONE: Hang on one second.

1 We're getting

2 MR. VAN DEN ASSUM: Hi. My name is
3 Peter Van Den Assum. For me, it depends on the
4 weather.

5 MS. GIAMBONE: Okay.

6 MR. VAN DEN ASSUM: Barometric pressure,
7 the moisture in the air, wind, dust in the air.
8 Basically, that's it. I do have it in the
9 morning, but I inhale MEK (ph), and that clears it
10 up usually for the whole day. But then, again, if
11 it's moist outside, hot -- high temperatures,
12 yeah, that's when it hits me.

13 MS. GIAMBONE: Okay.

14 MR. VAN DEN ASSUM: And I got diagnosed
15 by a regular doctor, and he said -- after a
16 regular checkup, and he just is like, "Do you
17 cough a lot?" And I go like, "No." And he says,
18 "Well, the fact that you do, even though you don't
19 know that you're doing it, makes me wonder. Take
20 off your shirt again." And that became an X-ray.
21 That became a CT scan, pulmonologist. Thank you.

22 MS. GIAMBONE: Okay. Thank you. So

1 weather-triggered cough. Okay. Yes?

2 MR. BOYER: Bill again. Mine comes with
3 exertion, and there's obvious exertions, like
4 walking up a flight of stairs. You know, I forget
5 to turn my oxygen up when I go upstairs, but
6 instead of going slowly or maybe even stopping, I
7 just walk right up like I used to always do, and
8 I'm so used to just having this on my nose all the
9 time, I forget about it sometimes. And I get up
10 at the top, and a minute later, I'm like
11 (Gasping). "Oh, my God." I start coughing.

12 And so there's obvious things like that,
13 exertion, but I think there's little exertions
14 too. Putting your clothes on, bending over and
15 tying your shoes, fixing something in the kitchen,
16 moving around. You don't really think about that
17 that, in itself, is a level of exertion, and all
18 of a sudden, I'm coughing, and that coughing seems
19 to come -- for me, in those circumstances, from
20 the chest, the lungs, I suppose, pulling for
21 oxygen. There's something that tightens in the
22 chest, and that the lung and the heart are working

1 hard to try to get more oxygen in there.

2 So there are little exertions a lot of
3 times that you don't even think about that trigger
4 that cough. And sometimes if you're not having a
5 good day or maybe there's more phlegm in your
6 throat than you realize, (inaudible) than you
7 realized, you can be coughing for minutes and
8 feeling like you're going to throw your guts up,
9 you know. But it's exertion, certainly.

10 MS. GIAMBONE: Thank you, Bill. So some
11 of the triggers we've heard are weather, exertions
12 -- little exertions in addition to maybe something
13 more intensive. Any other thoughts? Yes? Right
14 up here.

15 JEAN: Sometime -- Jean (ph). Sometimes
16 when Sam coughs, something is caught in his
17 throat. However, it seems like forever before the
18 cough ends. He -- it's like he's unable to finish
19 one cough. It's quite scary.

20 MS. GIAMBONE: Thank you, Jean. And we
21 can get one more.

22 MR. VAN DEN ASSUM: I've got one last

1 one. Laughing, and that's a very serious thing,
2 because if you have two boys who are very funny,
3 you can't laugh, because then you start to cough,
4 so they don't tell jokes anymore.

5 MS. GIAMBONE: And looks like we have
6 one more comment.

7 PHILLIP: My name is Phillip (ph), and I
8 would say this is for people who haven't been
9 diagnosed with IPF and don't have it. If you have
10 that unexplained cough for about ten years, you
11 should really get it checked out.

12 FEMALE SPEAKER: Maybe after a year.

13 MS. GIAMBONE: Thank you, Phil.

14 FEMALE SPEAKER: Or a month.

15 MS. GIAMBONE: Okay. So do we have any
16 more comments on the coughing? Okay. So let's
17 move on to the next symptom that we heard, which
18 is the fatigue. So would somebody like to share
19 what the fatigue looks like to you on a day-to-day
20 basis, and what do you do to sort of, you know,
21 manage the fatigue? So we have a few hands raised
22 here.

1 MS. KOCH: My name is Taleena, and I
2 took care of my mom. She was always very active
3 and, you know, was always up doing something;
4 didn't really spend a lot of time sitting down.
5 The biggest thing that she noticed with the
6 fatigue and when she noticed with it was that she
7 would sit down and immediately fall asleep. She
8 could not stay awake.

9 So for her, it was very difficult to
10 manage because when you're in late-stage pulmonary
11 fibrosis, you can't stay up all the time, so you
12 have to, you know -- you have to try to weigh
13 that. So she ended up spending a lot of time
14 sleeping, which she didn't like.

15 The other thing that she talked about
16 with regard to fatigue is that her legs always
17 felt like Jell-O. She just -- it wasn't that she
18 was physically tired or tired from lack of sleep.
19 It was that she just couldn't move, and it was
20 very difficult for her, just, you know, because
21 she was active and she wanted to move around, so
22 that was part of -- probably -- that and shortness

1 of breath were her worst things.

2 MS. GIAMBONE: Taleena, if I can ask,
3 when you described the fatigue that your mom felt,
4 was it that her muscles were fatigued and that's
5 why her legs felt that way, or was it more of a
6 general body -- full-body exhaustion and, you know
7

8 MS. KOCH: She did talk a lot about her
9 muscles in her legs just feeling really tired, you
10 know, and not really feeling like she could walk
11 across a room, but she just also had an overall
12 general fatigue, where she had no energy. You
13 know, like I said, she wasn't sleepy; she just had
14 no energy. And so as soon as she'd sit down,
15 she'd fall asleep. Her body just couldn't keep
16 up.

17 MS. GIAMBONE: Thank you, Taleena. So
18 let's do a quick show of hands here based on that
19 comment. How many of you also feel as if that
20 fatigue was -- you know, the sort of full
21 exhaustion where you have to sleep, or you sit
22 down to rest and sleep because you're just that

1 fatigued? Oh, many of you. Okay.

2 FAYE MACINNIS: If I could just -- if I
3 could add to that.

4 MS. GIAMBONE: Yes.

5 FAYE MACINNIS: If I could add to that,
6 one thing for me that I find extremely difficult
7 is physically, I'm exhausted. Physically, I'm
8 fatigued. My brain is not. So I will lay down to
9 rest, and I'm not able to rest. Physically, I can
10 rest, but my brain is going a million miles a
11 second. You know, I should be doing this, I want
12 to do that. Oh, I wonder what's going on outside,
13 all these other things, and I can't make my brain
14 shut down, which is frustrating because you can't
15 really rest then. That's it.

16 MS. GIAMBONE: Thank you. Yes?

17 MR. MCCENEY: I'm Jim McCeney. I was
18 diagnosed in January. I get up at 6:30, I fix my
19 own breakfast, I read the newspapers, and at 8:30,
20 I'm taking a nap.

21 MS. GIAMBONE: Thank you, Jim. So it
22 sounds like we've heard from the panel and also

1 now from hearing from those of you in the audience
2 that there's frequent resting that's required. I
3 know -- I recall hearing a lot of our panelists
4 sharing that when you're climbing the stairs, you
5 take a rest, and even just with daily activities,
6 showering, rest; dry off, rest. So, okay. Now,
7 are there -- yes, we have a hand back here.

8 MS. CLARICE WILLIAMS: I'm Clarice.

9 With the fatigue, I can relate to that. Excuse
10 me. When I wake up every morning, I have to -- I
11 usually go right to the computer, and I have to
12 sit there for at least five hours before I feel up
13 to doing something. So half of the morning, I'm
14 just exhausted. So I'll read the newspaper,
15 Internet, or I'll (inaudible) cereal, and I'll
16 look and want to vacuum, but I can't do it. Going
17 back and forth to the kitchen, I'm just exhausted.
18 So half of my day is just sitting, looking out the
19 window, until I feel like I can get up and do a
20 chore. And by then, I can move around a little
21 better as the evening progresses.

22 MS. GIAMBONE: Okay. Yes, Laura?

1 MS. ROIX: I'm sorry. I just wanted to
2 add, you know, it's very important that -- for me,
3 anyway, that I don't allow that to take me over,
4 because in order for me or any of us to -- you
5 know, prednisone added weight to me, and I have to
6 get it off. It's a catch-22 circle. In order to
7 get it off, I have to exercise in order to go for
8 a transplant.

9
10 I go to the gym, I'm the only one there
11 with oxygen, and I exercise. And then when I
12 leave the gym, I also go and walk the mall or go
13 grocery shopping. I do something so that --
14 because I know once I get home and I get in that
15 chair, I'm not getting back up for a couple hours.

16 So, you know, it really is hard for us
17 when that fatigue starts to take over. Like Diane
18 said, your brain goes a mile a minute, but you
19 know your body can't because it's lacking that
20 oxygen in your legs, but you have to try to keep
21 them to move, at least for me. Thanks.

22 MS. GIAMBONE: Thank you, Laura. So

1 what I'm going to do is for those of you joining
2 us on the webcast, we're going to be taking a few
3 phone calls in just a minute. So use this time
4 now to, you know, get your thoughts together and
5 dial in if you'd like to share over the phone.
6 And while we're doing that, I'd like to just ask
7 if -- what is it like to recover from one of these
8 symptoms, whether it's a very intense cough or a
9 day of fatigue or a very, you know, intense bout
10 of shortness of breath? What does it take to
11 recover from one of those on a day-to-day basis?
12 Would anybody like to -- how do you sort of manage
13 it as it happens? So with the fatigue, we heard
14 the rest. Yes?

15 MR. BOYER: Bill again. I think this
16 leads -- for me, it leads into your last -- number
17 four there, and that's depression or emotional
18 issues, because if you come back from a busy day
19 in the mall and shopping and whatever, keeping
20 yourself busy and active, and you sit down, you
21 lay down, and it's only two o'clock or three
22 o'clock, and you just slept for an hour or more,

1 you wake up, and you go, "Oh, shit, I still feel
2 like I need to sleep some more. Or you sleep
3 eight or nine or ten hours at night -- I sleep
4 nine to ten hours a night. Thankfully, I'm
5 retired. A lot of times, I'll sleep 30 or 60
6 minutes in the day.

7 So I think this needs to be mixed with a
8 discussion about depression, because you say
9 getting -- what does it feel like to get over that
10 or get out to the next phase? You've gotten
11 through that fatigue, you've got some rest, you
12 feel better, and yet sometimes the mind is going,
13 "Why am I even putting up with this? What's it
14 going to be like tomorrow? What's it going to be
15 like next month," and all those things that we
16 question as our health starts declining. It's
17 right there in front of your face all the time.

18 So it's -- coming out of it, it's good,
19 but I bet for most people, there's a certain
20 amount of -- you've got to identify that negative
21 cloud hanging in there too and say, "Get out of my
22 way. I'm busy," or recognize it for what it is

1 and move on, or let it take over your life.

2 MS. GIAMBONE: Thank you for raising
3 that important point, Bill. How many of you -- I
4 mean, you know, we saw that 23 percent of you in
5 the room shared that depression was a significant
6 symptom for you. So in terms of the emotional
7 impact, we've heard depression. We've heard
8 Heather mention panic attacks. Would anybody else
9 like to share this other impact of IPF that you
10 experience and how you experience it? Yes?

11 MS. COATES-NANCE: You know, kind of to
12 piggyback on what you were saying, but from a
13 caregivers' perspective, that depression, you
14 know, it -- you know, it affects you guys. Of
15 course it does. You're living with the disease.
16 But from a caregivers' perspective, especially as
17 a wife and -- you know, we have two of our four
18 kids still at home, so to see that person in that
19 condition and that helplessness that you have --
20 like this week, because Douglas is having a cold
21 and can't be here, and, you know, he's really
22 coughing, and it's like, you know, "What can I

1 do," and he's like, "Nothing," you know. "Do you
2 want some tea? You want

3 But so the depression does go a lot
4 with, you know, the fatigue, the coughing. He'll
5 come from rehab, but then he's tired. You know,
6 he's done really great at rehab and still wants to
7 do, but he can't. So that feeling of being boxed
8 in and, you know, just not being able to do, it
9 does impact your life. You get depressed. When
10 he -- you know, I know when it gets to him, he's
11 like, "I don't want to be sick. I don't like
12 being sick." I want to do things. I want to
13 travel. I want to -- you know, it is quite
14 depressing, and then for you as a caregiver, to
15 try to, you know, encourage them, but -- and I'm
16 so grateful for the groups, for the Coalition of
17 Pulmonary Fibrosis and, you know,
18 pulmonaryfibrosis.org, that I, as a caregiver, can
19 look to, to reach to.

20 I mean, the friends that I've made here
21 in this room, on Facebook, it helps me to hear
22 other stories and know what other loved ones are

1 going through as they are dealing with someone in
2 their family, a husband, a father, mom, you know,
3 that's dealing with a disease that there is no
4 cure for. It's not like the cancer. It's not, you
5 know, you go through an oncologist, and there's a
6 series of chemo and radiation. There is nothing,
7 so you wait to be transplanted, or you wait to get
8 into a clinical trial, and that waiting can be
9 depressing.

10 MS. GIAMBONE: Martina, thank you for
11 sharing that perspective. We'll take one more
12 comment.

13 MR. VAN DEN ASSUM: When I got
14 diagnosed, I was hit by a baseball bat. I was a
15 55-year-old, had two boys with girlfriends, so
16 what you want in life is like you want them to get
17 married and have kids so that you have
18 grandchildren, and that was taken away from me.
19 So I went back to work and thought that I could
20 manage on my own. And I talked it over with my
21 wife, and finally, I came to the conclusion that I
22 couldn't, so I went out, and I did seek

1 counseling. And -- because what hit me was there
2 are things in life, when you know you're having
3 this disease, you want to discuss it with your
4 caregiver or with your kids or with your friends
5 or with close family because that's you, and these
6 negative thoughts, you want to share with somebody
7 who can put them into something that makes it
8 livable.

9 So I went to a counselor, and she did
10 kids, so I was in the right place. And we've
11 talked about dying. We've talked about where do
12 you want to be buried. How are you feeling about
13 that? How are you thinking about like what it
14 will be with -- to run without air or the
15 struggling for breathing and all those kind of
16 things, exactly the things you don't want to talk
17 to your wife about. So she helped me to get out
18 of the depression, and I'll try to be positivity
19 (ph), so

20 MS. GIAMBONE: Thank you. Thank you for
21 sharing that. Okay. So let's take a minute, and
22 can we summarize some of the comments that have

1 been coming in from the Web? Have we heard
2 anything different from what we've been hearing in
3 the room?

4 MR. GRAHAM THOMPSON: We are hearing a
5 lot of very similar perspectives on the Web with
6 result to -- with respect to depression and the
7 impact on caregivers, or people whose caregivers
8 have been hospitalized for major depression,
9 anxiety, or have had to deal with it because
10 people say that you always have to be positive
11 when you're treating with patients, and they can't
12 express any of this, and that makes it harder for
13 them.

14 In addition to this, there's burden
15 because, going back to the fatigue and coughing
16 mentioned before, a lot of that has been tied to
17 sleep disturbances, both for the patients and for
18 their caregivers, and that's a big burden on
19 everyone. I think that's about it.

20 MS. GIAMBONE: Okay. Thank you. Let's
21 do a quick show of hands here with regards to the
22 sleep disturbances. How many of you also

1 experience sleep disturbances as a symptom? Okay.

2 So we see about five or six hands raised. And
3 let's actually take some of the phone calls that
4 are coming in now.

5 OPERATOR: This is the operator. Our
6 first comment comes from Karen Lane. Your line is
7 open.

8 MS. LANE: Hi. This is Karen Lane, and
9 I'm calling just to kind of share, you know, my
10 observations from my husband. He was diagnosed
11 last fall. And one of the biggest symptoms,
12 really, of that cough is the feeling of -- there's
13 an isolation component to it. He could clear a
14 crowd. We were in line to go to the Red Sox games
15 for the World Series, and the look that people
16 gave him for coughing, that -- thinking that he
17 was, you know, a contagious person. People don't
18 understand the cough of PF.

19 And what people do when they're smoking
20 -- so the secondhand smoke that we can't avoid
21 would put him into this coughing fit, and it's the
22 smokers that would make him feel that he's

1 intruding on their space. And so it's just
2 really, really difficult to explain to people, you
3 know, what this is, that there really is no
4 treatment for it, and that the medication, that
5 cough syrup, while it might dull the cough, puts -
6 - you know, it puts them into that really just
7 intoxicated state. It's a depressant. And so
8 it's difficult to take that and try to still be
9 active and be engaged in the community.

10 MS. GIAMBONE: Karen, thank you so much
11 for sharing that with us. Operator, do we have
12 another caller on the line?

13 OPERATOR: We have four commenters in
14 the queue. Our next commenter is Mr. Peter
15 Kaiser. Sir, your line is open.

16 MR. KAISER: The biggest issue that I'm
17 having to deal with was the cough in sleep. I
18 have to sleep sitting up. And you're in my
19 naptime right now, so I'm doing okay, but -- and
20 the only solution I have for the cough with the
21 medication is I chew ice, and that seems to help a
22 lot, but I can only sleep at any given time for

1 maybe an hour and a half or two hours before I
2 have to get up and cough and go back to bed. So
3 that's my biggest deal is sleep. Thank you.

4 MS. GIAMBONE: Thank you for sharing
5 that. And there were several heads nodding as you
6 were sleeping, so thank you for sharing that.
7 Next caller, please, operator?

8 OPERATOR: Our next commenter is Mr.
9 John Myers (ph). Sir, your line is open.

10 MR. MYERS: Thank you so much. I just
11 wanted to say that it's so obvious to me, with
12 regards to the disease, which I've been diagnosed
13 with now for going on three years in November --
14 it's so obvious that we don't all experience the
15 same thing at the same time with the same
16 intensity. And specifically what I deal with on a
17 day-to-day basis is shortness of breath. I get
18 tired. I don't have a lot of cough, thankfully,
19 and I'm so thankful for that. And I don't
20 experience a lot of depression, just by virtue of
21 the fact that I have a phenomenal caregiver, my
22 wife. And -- but I think that what is really

1 obvious to me too is -- and what I've seen with
2 regards to, you know, going for rehab, talking to
3 other patients that might have IPF, is that they
4 don't understand the disease at all.

5 And, for example, you know, when the
6 diagnosis came in and diagnosed me, he said,
7 "John," he said, "You have pulmonary fibrosis."
8 And it was like, "Oh, thank you," and -- you know,
9 without knowing or understanding really how
10 serious this disease is. And then the only other
11 comment that I want to make is that as I've talked
12 to other patients and -- or people or friends or
13 whatever, they look at me, and they say, "John,
14 you look great." And, you know, all I have that
15 shows that I really have this disease is a cannula
16 in my nose, and it's really hard for them to
17 understand how serious this disease is. But also,
18 I just want to say thank you for the opportunity
19 to participate today. It's been a pleasure.

20 MS. GIAMBONE: John, thank you for
21 sharing your experiences with us. There were a
22 lot of people that were agreeing with the comments

1 that you just shared. Next caller, please?

2 OPERATOR: We have three more
3 commenters, if time allows. Our next commenter is
4 Leann Storch (ph). Your line is open.

5 MS. STORCH: Hello?

6 MS. GIAMBONE: Yes, Leann.

7 MS. STORCH: Yes, hi. Thank you for
8 this. This has been very, very good. I just
9 wanted to just reiterate about the lack of sleep.
10 So many people that I've talked to have
11 experienced the sleeping. And if people could get
12 their sleep at night, then they'd probably have
13 better days, because, you know, it affects
14 everything that you do. So -- and I also -- I
15 actually was diagnosed in 2003, and then in
16 January 2014, I received a left lung transplant,
17 so I'm actually going back through my experience,
18 and I've had a lot of experience with the
19 pulmonary fibrosis community. And I was one of
20 the people that really got hurt with the
21 depression and the anxiety. And I don't know that
22 that -- I mean, some people don't have it, as

1 previous callers just said, and some people -- I
2 had issues growing up, but I didn't realize the
3 impact the disease was going to have on my
4 depression. And I almost was too late in getting
5 help because I didn't -- where I was working, it
6 was just a lot of things that kind of came out at
7 once. And I was working at the Pulmonary Fibrosis
8 Foundation, and I felt like it was very hard to
9 share that with people because I was very much an
10 inspiration, because I had started the foundation
11 in 2004.

12 And it was hard to share that part of my
13 journey because I didn't want to let the people
14 down, you know, that this was just part of it, but
15 now I know that I should have gotten more help and
16 been more vocal about it. But it's -- you don't
17 want to -- I'm always trying to look at the good
18 side of things and trying to be happy and
19 positive, and so I was always trying to look at it
20 that way and be as positive as I could, and
21 towards the end, you know, after living with it
22 for so long, I just -- it just kind of all hit me.

1 And so I'm hoping that there will be -- you know,
2 people will be more apt to look for help and also
3 the (inaudible) sleeping very well at all, and it
4 really affected everything too, because with the
5 cough --

6 MS. GIAMBONE: Thank you, Leann.

7 MS. STORCH: Okay, sorry.

8 MS. GIAMBONE: Oh, no, no. That's okay.

9 No, thank you for sharing your comments with us.

10 MS. STORCH: And thank you for all of
11 this. We appreciate it very much.

12 MS. GIAMBONE: Okay. So I know that
13 we've run into our break time a little bit, but
14 there's been such a great discussion, and I think
15 we have learned so much from you on the symptoms
16 and the impacts of living with IPF, so thank you
17 for sharing all of those experiences with us.
18 Let's take a ten-minute break and look at that and
19 get started with Topic 2.

20 (Whereupon, a brief recess was taken.)

21 MS. GIAMBONE: Okay. So we are going to
22 get started. Okay. Well, let's get started with

1 our next discussion topic. What I'd like to just
2 say, you know, with the topic that we just
3 finished, and hearing about the symptoms and the
4 experiences, not only from the patients, but from
5 the caregivers, we really appreciate that you've
6 all spoken so much about this. It's challenging
7 and such a personal experience to be sharing with
8 many people that you don't know, but it's really
9 been so helpful and valuable and beneficial to us,
10 so thank you for sharing all of those experiences.

11 I would like to ask -- I know that we
12 have some advocacy groups in the room -- and maybe
13 just with a quick show of hands for those of you
14 here on behalf of the advocacy group, do you feel
15 that what we heard during the first topic session
16 -- do you feel that that also represents the many
17 thousands of patients and caregivers in your
18 advocacy groups? Do you feel like that was a good
19 representation? Yeah? Okay, good. I'm glad to
20 see your heads nodding in agreement, so that's
21 good.

22 Okay. So we are going to get started

1 with Discussion Topic 2. And, once again,
2 Discussion Topic 2 is on current treatment
3 approaches to IPF. And just to remind everyone
4 again, here we're listening for what is your
5 current treatment regimen, what -- for the patient
6 or for the caregiver, if you can let us know the
7 treatment regimen that your loved one is going
8 through or has experienced. And if you can give
9 us very specific examples on, you know, what are
10 the benefits of it? How do you know -- if it is
11 working, you know, how do you know it's working?
12 And then on the flipside, what are the downsides,
13 and what are the side effects that you feel, and
14 what is not working for you? And then towards --
15 you know, the later part of the conversation will
16 also talk about the ideal treatment.

17 So let's have our Topic 2 panelists come
18 on up, and if you could bring your name cards with
19 you and have a seat at the panel table. And, once
20 again, I just want to thank our panelists in
21 advance for preparing your summary statements, and
22 you worked very hard over the last two weeks.

1 What's that? You don't have to. Just whichever
2 way, and then we'll just make sure we go in --
3 okay. And remember to press the red button when
4 it's your turn to speak. And with that, let's get
5 started with Mike.

6 MR. HENDERSON: Okay. I'm Mike
7 Henderson. I'm from Portland, Oregon. And I was
8 diagnosed with IPF in June of 2004 and received a
9 double lung transplant in March of 2006. Since
10 then, I've facilitated two pulmonary fibrosis
11 support groups in the Northwest and a lung
12 transplant group there. So I can share my own
13 experience, but I can also related to those --
14 about 200 other patients who have been through the
15 same process that I've met through that
16 experience.

17 And I'm very lucky ones. Even today,
18 the only treatment to extend the lives of IPF
19 patients is a lung transplant, and it's not a
20 trivial operation. I hope that changes sooner and
21 that there are some therapies approved, but as of
22 today, that's (inaudible). And that's a tradeoff

1 (ph) of a deadly disease for a really difficult,
2 chronic condition, which extends the life for most
3 people in the neighborhood of five years.

4 Less than one percent of IPF patients
5 will receive a lung transplant, so it's a very
6 rare thing, and I'm very appreciative that I got
7 one. But we desperately need new therapies for
8 IPF to improve both the quality and the quantity
9 of life for these patients.

10 As I said, I was diagnosed in 2004 with
11 kind of shortness of breath at elevation at that
12 time, and within 12 months, I was on oxygen 24/7.
13 So it progressed fairly quickly for me. As I was
14 going through that, I would have gone anywhere for
15 treatment for this disease. My only options at
16 the time were pirfenidone, which was available in
17 Japan (ph) at that time; a clinical trial for
18 Gleevec, which was a cancer drug, at the Mayo
19 Clinic; the IPF cocktail of prednisone,
20 azathioprine, and NAC; and either a trial or off-
21 label prescription for (inaudible).

22 I decided that was -- I had to decide

1 whether to move someplace, try an unproven
2 cocktail, or try (inaudible), and I decided on the
3 latter, with, you know -- (inaudible) for an off-
4 label prescription, because I wanted the real
5 thing. And I think every patient, as they look at
6 options of clinical trial versus the real deal,
7 they want the real deal. I was certainly one.
8 But I promised my doctor that I would give back at
9 some point, somehow (inaudible), so this is one of
10 those things. This is (inaudible).

11 Did it work? No. (Inaudible) trial
12 failed just about three months after I went on the
13 drug, so I switched to the IPF cocktail, and just
14 two years ago, they discovered that that cocktail
15 did more harm than good for patients, so I don't
16 know if that impacted me or not.

17 But I was blessed to receive a double
18 lung transplant in 2006, and this is my new
19 treatment regimen. So this is the extreme
20 treatment for IPF. This is one day's worth of
21 pills, 34 a day. They're not all for IPF, but by
22 far, the majority are. Half of them do something,

1 and half of them undo the side effects of the ones
2 that do something. So it's a job just to manage
3 that.

4 So this, along with diet and exercise,
5 are the treatment that keeps me alive. Lots of
6 side effects, daily GI upset, bone and muscle
7 wasting, skin cancer. I've had nine skin cancer
8 surgeries already. Tremors, constant risk of
9 rejection and infection that we have to be careful
10 for. But, hey, it works, and I'm living life
11 pretty much the way I did, with a few limitations,
12 but it's not a good solution. One percent of all
13 these patients, that is not getting the job done.

14 So what did I want out of a treatment?
15 I wanted to be able to breathe without using
16 supplemental oxygen. I wanted to be able to take
17 a walk, go fishing, travel, just get across the
18 room without getting short of breath and gasping;
19 be able to go up a flight of stairs without
20 gasping. I wanted to stop the incessant clearing
21 of my throat and the cough that came with it. I
22 wanted to be untethered more than anything. To be

1 attached to that machine or to a tank is not a
2 pleasant experience. I wanted to have energy back
3 that I used to have. I wanted to live longer,
4 better, and to let my family know that I was going
5 to be there for them and with them.

6 Patients are dying every day of IPF, and
7 it's a terrible way to die. And I've actually
8 been there at the end for a number of patients,
9 and it is not a pleasant experience. So we need
10 treatments that can stop the progression, at least
11 improve the quality of life, both in prolonged
12 life, without requiring a lung transplant. We
13 need to develop a system where promising therapies
14 can be tried by desperate patients once they've
15 passed a safety test. We need to rethink the
16 clinical trial guidelines and consider ways to get
17 more drugs in the pipeline and promising drugs to
18 patients much sooner than they are today.

19 Patients are willing to take some risk.
20 When your life is slipping away, which -- you're
21 very likely to take the risk. It seems to make
22 sense. And only you can shorten this approval

1 cycle by developing new clinical trial designs
2 that could take us more aggressively towards these
3 goals.

4 So I thank you for listening, and -- to
5 all of us this afternoon, and for all of you that
6 keep us healthy and safe.

7 MS. GIAMBONE: Mike, thank you so much.
8 Okay. We have Heather next.

9 MR. GRAHAM THOMPSON: Just a quick
10 reminder.

11 MS. GIAMBONE: Yes?

12 MR. GRAHAM THOMPSON: Feel free to pull
13 those mics close to your mouth so the people on
14 the Web can hear you. Thank you.

15 MS. SNYDER: Can you hear me? My name's
16 Heather. I'm from Pennsylvania, around the
17 Harrisburg area. Like Mike, I'm a transplant
18 patient, but I'm going to tell a different story
19 (inaudible) wanted to. This disease is genetic in
20 my family. My father was diagnosed with pulmonary
21 fibrosis by the National Institute of Health in
22 the late 1970s.

1 He participated in one drug study. He
2 felt he had more energy. I don't think he lasted
3 much more than a month on that study. He came
4 down to Bethesda, Maryland, to get some
5 medication. I don't know what it was, because I
6 was really young, so I don't remember everything,
7 but I do remember that he was on a high dose of
8 prednisone, and he had severe acne on his back,
9 and I remember it was constantly red, and it
10 looked extremely painful. But he just wanted a
11 transplant, and it didn't happen, so he died in
12 1981. He was only 49 years old, and I was 9 at the
13 time.

14 In the mid-20s, I was diagnosed with
15 asthma. I had symptoms of tightness of the chest.
16 I was wheezing with exercising. I tried to run.
17 Really didn't work out very well for me. The
18 drugs I was given were inhalers, rescue inhalers
19 and daily (ph) inhalers, prednisone tapers, and
20 anxiety medication. And I did this for years, on
21 and off constantly. They'd never work. Nothing
22 ever helped. Nothing ever took that tightness in

1 my chest away, and I never had an asthma attack,
2 so I never could breathe better after I inhaled
3 the steroids.

4 It got very frustrating, but about ten
5 years or of this, I asked for my own (ph) chest X-
6 ray. I was being monitored by three different
7 doctors. I had clubbed fingernails. I was out of
8 breath, and I couldn't do a flight of steps
9 without being out of breath. And I just finally
10 said, "Enough is enough." I learned how to be my
11 own advocate and asked for a chest X-ray.

12 At the time, I was -- I had a hacking
13 (ph) cough. Like I said earlier, it sounded like
14 a sneeze more than a cough. Probably had that for
15 maybe eight years. I had severe clubbing of the
16 fingernails, and I remember a doctor specifically
17 looking at my fingernails; never said a word at
18 all. I didn't even know.

19 And I had cramping up of my ribcage so
20 much. And I already discussed this a little
21 earlier, so I'm not going to go into that much,
22 but I was prescribed cough medicine, muscle

1 relaxers, and (inaudible). When I was diagnosed, I
2 was sent to a transplant hospital, and what they
3 put me on was prednisone and acetylcysteine. So
4 when you take acetylcysteine, it's awful. It
5 smells awful, and it tastes awful, so you put it
6 in fruit juice, fruit juice to mask everything.
7 And I think twice a day, if I remember correctly.
8 Well, the combination of the fruit juice and the
9 prednisone blew me up like 30 pounds within a
10 matter of weeks -- I mean, two months. And that
11 was kind of in an opposite direction I needed to
12 go, because I needed a transplant, so gaining
13 weight was not going to help me at all. I needed
14 to lose it.

15 So I finally transferred to a different
16 hospital, and the doctor put me -- took me off
17 everything. He said, "This is not going to help
18 you. It's going to hurt you more than it's helping
19 you." Although I did feel good -- my knees felt
20 good, my joints felt good. Now, I was eating way
21 too much. Sorry, my mouth is really dry from all
22 my medication.

1 I had the double lung transplant in
2 2011. I was 39 years old. It was a very
3 complicated transplant. I was on VA ECMO machine.
4 I was put on that as an emergency surgery. I was
5 on VA ECMO machine for five days. I had colon
6 (ph) issues. My colon (ph) died. I had to get a
7 colonectomy (ph). And then I got the (inaudible)
8 virus, so was in quarantine for ten days after
9 that. So it was pretty tough. I know the
10 doctors. I joke with my doctor, "You couldn't
11 kill me if you tried," but, I mean, they could
12 have.

13 But I really don't know how I made it
14 through all that. The doctor said, you know, "You
15 have age on your side," and that's what he told my
16 mom -- my family, because he's like, "I'm not -- I
17 don't think she's going to live, but she does have
18 age on her side."

19 So, you know, as you know, (inaudible)
20 discussed there's plenty of downsides to lung
21 transplant. There's plenty of good sides, but I'm
22 going to talk about the downsides a little bit

1 more. Like I said, you take medication all the
2 time. You take it every 12 hours. And,
3 obviously, many of us know that statistics of
4 receiving a lung transplant for pulmonary fibrosis
5 is extremely small. Most of us are not qualified
6 to even be listed because of age, comorbidity (ph)
7 issues, financial reasons, medical insurance
8 premiums, and pharmaceutical coverage. If you --
9 you can't even -- if you don't have any of that,
10 you don't even get an evaluation.

11 For those that are lucky enough to be
12 listed, the wait is tremendously stressful. We
13 need to be prepared for that call and leave at a
14 moment's notice. Everything we do is based on the
15 fact that the hospital will call any second, so
16 that's a pact. You stay close to home and have all
17 loose ends tied up. I personally was told to have
18 Plan A, B, C, and D. I had multiple plans in
19 place, but I could not prepare for what I really
20 went through, which was lifeline (ph). I wasn't
21 prepared for that.

22 I went into respiratory failure. I had

1 pulmonary hypertension as well as a secondary
2 disease because this disease was not caught in
3 time. I needed oxygen five years before was --
4 actually tried oxygen, so I had pulmonary
5 hypertension.

6 So I was in -- I was preparing for a
7 transplant in a snow and ice storm, so, like I
8 said, I was (inaudible) to a hospital, where I was
9 put on an emergency VA ECMO machine. I know I'm a
10 miracle. I know I'm alive for a reason, and I am
11 so blessed to have a second chance at life, but
12 there were -- you know, there were definitely
13 downsides that we really need to remember.

14 A transplant is given -- was given to me
15 to extend my life, but I do realize that I
16 probably will not live until retirement. I will
17 be working full-time the rest of my life to keep
18 myself alive. I take anti-rejection medication
19 every 12 hours. The medication have their own
20 side effects that I deal with on a daily basis,
21 such as memory loss, tremors, confusion,
22 migraines, sensitivity to sun, thinning hair,

1 chronic fatigue, depression, anxiety, flu-like
2 symptoms, et cetera. I am lucky enough to have an
3 employer that has helped me with some work
4 modifications, because I still have major sleeping
5 (ph) issues, but I know if I don't have that job,
6 it's going to be very hard to find a new one, and
7 I have met many patients that, you know, they
8 couldn't keep their job because they were in a
9 hospital (inaudible) they're a great working age.
10 They're only in their 40s, (inaudible). So that's
11 really tough. (Inaudible) really work? No one
12 wants to hire you.

13 Okay. I take a lot of my vacation time
14 for doctors' visits instead of going on vacation,
15 which I would love (ph) to do, but, I mean, I've
16 seen a lot of doctors. I see pulmonology,
17 obviously, neurology, psychology, rheumatology,
18 dermatology, sleep medicine, family physician,
19 and, of course, our monthly bloodwork.

20 As a patient -- I know it's been
21 discussed -- I do feel very, very alone, even
22 after transplant. You think you're going to be

1 somewhat normal, and you're just not normal. And
2 one thing I've realized, you know, when I was sick
3 and I looked so awful when I was on oxygen, people
4 would open the door for me. Like, "Oh, my gosh,
5 she's on oxygen. She's dying." And then after my
6 transplant, I must have looked really good,
7 because doors were slamming in my face. And then I
8 became like this hidden disease (inaudible) I
9 still had it -- well, like no one could see it,
10 because I was getting the color back (inaudible).

11 But because I choose to be an advocate,
12 I have a very heavy heart for all the patients
13 that have passed. A support for them started in
14 Hershey, Pennsylvania in 2009. Since then,
15 everybody's passed but two patients. I have been
16 emotionally devastated, and sometimes I --
17 (inaudible) -- sorry. This disease (inaudible).
18 My father died at age 41. When I was diagnosed at
19 28 years of age, a treatment still didn't exist.
20 It was hard to grasp the idea that we were so
21 advanced in cancer and HIV, which was devastating
22 in the '80s (ph). We still don't have anything

1 for pulmonary fibrosis.

2 MS. GIAMBONE: Thank you, Heather. Do
3 you have any final remarks?

4 MS. SNYDER: No, (inaudible).

5 MS. GIAMBONE: Thank you, Heather.
6 Taleena?

7 MS. KOCH: First I want to thank the FDA
8 for having these hearings and allowing patients
9 and families affected by IPF to have a voice. My
10 name is Taleena Koch, and I was a caregiver for my
11 mom after she was diagnosed with advanced IPF in
12 2003. She had a diffusing capacity of 27 percent
13 at diagnosis. She passed away six years later
14 from respiratory arrest on September 27th, 2009.

15 Two years prior to her diagnosis -- or
16 two years prior to 2003, she had been diagnosed
17 with emphysema. She was already using
18 supplemental oxygen and on prednisone when she was
19 correctly diagnosed with IPF. At that time, her
20 supplemental oxygen liter flow was increased, as
21 was her prednisone, and she was also prescribed
22 azathioprine, NAC, and interferon. Her

1 pulmonologist saw her every few months for updated
2 pulmonary function tests and a six-minute walk
3 test to watch her progression and see if any of
4 the medication was working.

5 After some months, she was taken off the
6 azathioprine because her PFTs were not
7 stabilizing. She was later taken off the
8 interferon, again, because her PFTs were not
9 stabilizing. She continued the prednisone at a
10 lower dose, continued the NAC and the supplemental
11 oxygen.

12 After the first nine months to a year,
13 her PFTs had stabilized, so the medication she was
14 taking continued. The oxygen would be titrated up
15 to a higher liter flow (inaudible) as her IPF
16 progressed. She was already on an osteoporosis
17 medication to combat bone loss from long-term
18 prednisone use. She was also on medication for
19 other conditions, like hypothyroidism, elevated
20 cholesterol, and essential tremors.

21 My mom was really good about maintaining
22 a healthy diet and staying as active as possible.

1 She took vitamins regularly, she got her flu shot
2 every year, but her activity at this point was
3 going for walks around her apartment building or
4 at the beach, cooking her own meals, or doing her
5 own shopping.

6 As her PFTs finally stabilized, she
7 wasn't seeing her pulmonologist as often. Most of
8 her day- to-day medical care was handled by her
9 primary doctor. At this point, she was not in a
10 drug trial, and there were no real medications to
11 treat IPF itself, so her medical care was all
12 about managing other conditions caused by the IPF
13 and learning to live with it.

14 For instance, her heart was in very good
15 condition upon diagnosis in 2003, but over the
16 years, the IPF took its toll, causing her heart to
17 work harder to make up for the work her lungs
18 could no longer do. She started having ongoing
19 fluid retention, which was treated with Lasix.
20 She was also prescribed a high-dose potassium to
21 combat the side effect of Lasix because it strips
22 the body of potassium.

1 A few years past her diagnosis, she fell
2 below an ejection fraction of 30 percent. Her
3 heart was not pumping blood out fast enough. She
4 was then put on Enalapril (ph) and (inaudible) to
5 assist her heart in doing its job.

6 Sometime in 2008, she started developing
7 a rash along her shins (ph). The rash started
8 spreading, and she saw many doctors. It was
9 diagnosed as cellulitis at one point, and she was
10 prescribed antibiotics. The rash never did clear,
11 continued to worsen and spread, and eventually,
12 she had open sores on both legs. None of the
13 doctors ever figured it out. She was treated with
14 topical creams, none of which worked. We never
15 officially knew what caused the rash.

16 Over the years, she was prescribed
17 antibiotics a number of times for a pneumonia,
18 which is very common for someone with PF. One of
19 the last medications she was prescribed before she
20 passed away was a narcotic cough syrup. Most
21 with pulmonary fibrosis have problems with coughs.
22 Some are severe right away, others are not. Her

1 cough wasn't worsening until the summer of 2009.

2 At that time, she needed better cough control, as
3 her cough was quite bad. The narcotic cough syrup
4 helped.

5 Her supplemental oxygen needs increased
6 over the years as her acne had progressed. As her
7 PFTs worsened and her oxygen liter flow went up,
8 her shortness of breath also increased. Even
9 though her PFTs were staying fairly stable, she
10 wasn't taking a quick speed decline. She had
11 developed a small mass on each lung. Because her
12 IPF was so advanced, a biopsy of those masses was
13 too risky. They had to be watched by CT scan to
14 look for changes.

15 For more than a year, there were no
16 changes in either one of those masses. Finally,
17 in February of 2009, she had a sudden onset of
18 shortness of breath, and a CT scan showed that
19 both masses had doubled in size. With her
20 diffusing capacity now at 13 percent, her oxygen
21 liter flow was increased dramatically, from 8
22 liters per minute to 12 liters per minute. This

1 meant the need for (inaudible) configuration of
2 oxygen equipment to give her more than ten liters
3 of oxygen.

4 It was also determined that the low dose
5 of prednisone she was on was not really doing much
6 for her, so it was discontinued. The Lasix she
7 was taking for water retention was helping less
8 and less. She had to spend a lot more time laying
9 down, with her feet elevated above her heart, to
10 help with fluid retention. All of this was making
11 her less independent and less active.

12 Losing her independence through the
13 oxygen needs and the inability to get up and move
14 around when she wanted made her depressed. Early
15 on in her PF, she was very positive, and she was
16 willing to fight this disease and live with IPF as
17 long as possible. As she neared the end of her
18 life, she became more depressed and was willing to
19 give in to the disease and let it take its course.
20 There was no treatment, and there still isn't in
21 our country, and the oxygen and medications she
22 was taking weren't helping as much as they had

1 been earlier on. She felt very defeated.

2 An ideal treatment would be something
3 that stops the progression of the disease in its
4 tracks. Since lung fibrosis cannot yet be
5 reversed, the damage is already done. However,
6 having no new damage in the future would be a
7 positive. Knowing that someone can live a normal
8 life without progression of the disease, even
9 supplemental oxygen as needed, would be helpful.
10 Knowing there is a medication to try, or more than
11 one, would give patients hope where they have
12 none. Quality of life counts.

13 MS. GIAMBONE: Thank you so much,
14 Taleena. And now we have Teresa?

15 MS. BARNES: Hi. My name's Teresa
16 Barnes. I want to thank the FDA for, just like
17 Taleena did, in including the patient voice in
18 drug development, not just here today, but on your
19 panels when drugs and devices are being reviewed,
20 it's so important to have the patient voice as
21 part of that.

22 I look around the room, and it's like a

1 reunion, in a way. There's almost nobody I
2 haven't seen before or met before or don't know
3 very well. And I pray that this room does not
4 catch on fire, because if it does, we're in
5 serious trouble. We'll probably never find a
6 treatment. Many of the people here, including the
7 advocates, the patient foundations, the
8 physicians, the researchers, these sponsors, and
9 you, are the reason that change is coming.

10 Many of the people here are patients and
11 family members, and on behalf of those patients,
12 family members, and advocates, I would
13 respectfully ask that the patient voice be
14 included earlier in the drug development process.
15 The opportunity to provide valuable input and
16 insight into each individual drug development
17 project begins before treatment trials are
18 designed, before they're developed, and before
19 they're launched.

20 I would suggest consideration of three-
21 way communications between pharmaceutical and
22 device companies, the FDA, and patients and

1 patient advocacy groups, beginning upon the
2 initial planning for a clinical trial, so 10 to 15
3 years (inaudible).

4 I'm a patient family member of five now-
5 deceased IPF patients. I serve as a patient
6 advocate for patients as Vice-President of the
7 Coalition for Pulmonary Fibrosis. I was a
8 founding board member of the organization back in
9 2001. I serve as a patient for the American
10 Thoracic Society. Some of my colleagues are here,
11 and I'm pleased to see a patient (inaudible).

12 I work with key IPF scientists and the
13 ATS to bring together researchers a couple of
14 years ago in the First Fibrosis Across Organs
15 effort. That included heart, lung, liver, kidney,
16 and skin. And we kind of like to say we want to
17 get to the lung of the matter.

18 I also helped scientists with -- and the
19 Westie Foundation of America develop the first
20 Fibrosis Across Species, meaning bringing together
21 pulmonary scientists and veterinary scientists for
22 comparative research efforts, looking at naturally

1 occurring IPF in dogs, horses, cats, donkeys, and
2 other species of domestic animals that share our
3 environment. I served on an FDA panel several
4 months ago for a device that has now been approved
5 for lung transplant.

6 I work every day to improve the options
7 for this disease. I worry about the future. Will
8 my twin sister, my brother, and me have to worry
9 about this disease? Will my cousins and our
10 children have to worry? It's kind of like walking
11 a tightrope, and you're scared of heights.

12 My father was the first person in my
13 family diagnosed with IPF. It's likely, however,
14 that his father and his uncle also had the disease
15 decades earlier and were diagnosed with other
16 conditions. My father was diagnosed in 1994 and
17 died after a failed lung transplant in 1996.

18 In 2001, my father's brother was
19 diagnosed. He died within a year of that
20 diagnosis. It was then that the many members of
21 my family, including me, joined the genetic
22 research efforts in the disease. Through a

1 research project, my aunt was diagnosed with IPF
2 the same year that we joined the study. She died
3 after surgical complications that exacerbated her
4 disease in 2003. That same year, another uncle
5 was diagnosed with IPF. He died in 2005. In
6 2005, another uncle was diagnosed with IPF. He
7 died in 2007. I saw the writing on the wall, and
8 I talked to the advocacy group, and I decided that
9 I should spend my life working on this.

10 So my family, an entire generation, five
11 siblings, is gone, (inaudible), yet each of these
12 patients actually had different experiences, even
13 though they also had the same experience. From
14 the time my father died in '96 and through the
15 deaths of all of his siblings, nothing changed, at
16 least not from a treatment perspective. And
17 today, I see how treatment options have not yet
18 changed. My father's treatment began six months
19 before he was diagnosed with IPF, because he was
20 treated symptomatically for cough and for
21 shortness of breath with inhalers, and a lot of
22 people have talked about those, like albuterol,

1 that had absolutely no effect on his symptoms.

2 It was the lack of response to the
3 therapy that led him to seek a second opinion at a
4 major IPF research center. He was quickly
5 diagnosed with IPF at that center, and he was told
6 there was no FDA-approved therapy and that he had
7 a very short time to live. He was also told that
8 there were no clinical trials in the disease.
9 This was 1996.

10 He was immediately placed on prednisone
11 and prescribed oxygen during exertion. The
12 prednisone, as some people mentioned, made him
13 gain a little bit of weight, but the most
14 concerning response was the change in his demeanor
15 and his level of tolerance. He had always been a
16 really kind and reasonable person, but on
17 prednisone, he became irritable and argumentative,
18 and on one very memorable occasion, he punched out
19 the next-door neighbor in front of a police
20 officer. Not a good idea, and after bailing him
21 out of jail, I made a phone call to his
22 pulmonologist and begged him to take him off the

1 drug. He said, "Oh, it's -- in a minority of
2 cases, that's a side effect." My father seemed to
3 grow more fragile on the steroid use, but clearly
4 his left hook was not one of his problems.

5 He also experienced trouble with his
6 teeth that he felt was caused by the prednisone
7 and eventually caused him to have to have many of
8 his teeth removed. I actually married a dentist
9 just in case, for the future.

10 Over a period of months, as my father
11 began being evaluated for a lung transplant, he
12 was placed on Cytoxan, an immunosuppressant. It
13 was difficult to tell if the drug caused any
14 problems that he had, but he felt as though his
15 condition was changing. The shortness of breath
16 was increasing, as was his level of anxiety.

17 Now, this was a really calm man for most
18 -- I mean, all of his life up to this point, and
19 he was never nervous or anxious, but it seemed as
20 though these shakes and tremors, almost like he
21 was physically shivering, were happening more and
22 more. He was never given medication for anxiety,

1 nor did he ever ask for it.

2 He coped with it by drinking coffee -- I
3 think -- and, actually, lots of it, all day long,
4 every day. And, actually, maybe it made things
5 worse, maybe it didn't, but it warmed him up
6 physically. He wore sweaters, even in the summer,
7 when he was sick because he said that breathing --
8 he felt like the oxygen made him cold. And he
9 complained that it gave him headaches too. Now,
10 he had had headaches throughout his life, but they
11 just got worse when he started using supplemental
12 oxygen.

13 He also had problems with his lips
14 drying out and his nose constantly being irritated
15 and red because of the cannulas. He used lip
16 gloss and creams to alleviate the symptoms, but it
17 was really difficult to control because he had to
18 wear the oxygen.

19 He used oxygen almost from the start of
20 his diagnosis. At first, he was just using a
21 liter or two, but it increased over time. He
22 complained that the bulkiness of the tank was a

1 problem, but he found ways to incorporate it into
2 his life, and he actually bought a golf cart to
3 drive around the neighborhood with his tanks.

4 He was able to use a concentrator when
5 he left his house, and it seemed to give him what
6 he needed to remain active for at least another
7 year or so. Eventually, he was limited to a
8 tethered oxygen machine at his home, and getting
9 outside was pretty much impossible.

10 His cough was often debilitating. He
11 would have what he called coughing fits, and when
12 he would have such violent coughs that he couldn't
13 catch his breath, then he would have to calm
14 himself afterwards. Even though he tried cough
15 drops, he had cough syrups, they, you know,
16 suggested breathing techniques, but nothing seemed
17 to impact the cough. He usually kept hard candy
18 in his pocket, tried to cope with the coughing
19 episodes.

20 Sometimes the cough was so violent that
21 he couldn't stand upright, and if he were in
22 public, he'd have to quickly sit down until he was

1 able to recover and compose himself. He found
2 that having a large cloth with him that he could
3 cough into would help his embarrassment, but it
4 would also help muffle the noise that someone else
5 mentioned. It was one of his most difficult and
6 embarrassing issues.

7 He suffered what I now know as a couple
8 of acute exacerbations. He was hospitalized both
9 times and given antibiotics and increased oxygen
10 levels. He was treated for an unexplained fever
11 and for low blood pressure, but the reason for the
12 sudden worsening was never explained. He
13 recovered from both exacerbations, but with each,
14 his condition worsened noticeably. He became weak
15 and fragile.

16 I don't think I mentioned that he was in
17 his 50s when he was diagnosed. He had been asked
18 to lose weight to be placed on this transplant
19 list, but even though he was not a very large man
20 -- he's not given guidelines for losing weight, by
21 the way, and patients still today are not given
22 guidelines to help them lose weight. But he

1 followed a restricted diet for a few months
2 (inaudible) he lost the weight, and he felt like
3 he could breathe better because his diaphragm was
4 a little bit freer, but the weight loss actually
5 seemed to weaken him more.

6 He waited 17 months on the transplant
7 list in North Carolina, and this was in 1996, when
8 the transplant list was based on how long you
9 waited, not how sick you were. Thankfully that's
10 changed, but my father got a call for transplant
11 six times in six months, and each time, the organ
12 was not usable. Ironically, the device I just was
13 part of a panel on, maybe families will not
14 experience that as much.

15 MS. GIAMBONE: Thank you, Taleena (sic).
16 Any final remarks?

17 MS. BARNES: Yes, I just -- you know,
18 patients and their lifestyle is really important.
19 Lifestyle drugs are important. So if we -- you
20 know, if we can't solve this problem today, let's
21 do something that improves patient symptoms, that
22 improves their quality of life, that can help them

1 to move forward, at least for a little bit of time
2 with their families, so that they're not faced
3 with all these issues that these patients have
4 mentioned, so that they have some options, and
5 then let's move quicker through the transplant
6 process, if that's available, and then throughout
7 the talk about the process, it's really important
8 that we include the patient voice there.

9 And also, you know, I have a four-year-
10 old daughter. My goal is to make sure that by the
11 time she's older, that she says, "Pulmonary
12 fibrosis is something that killed people in the
13 old days, and people don't die of it anymore."

14 MS. GIAMBONE: Thank you, Teresa. I
15 apologize. I said Taleena. I meant to say
16 Teresa.

17 MS. BARNES: That's okay.

18 MS. GIAMBONE: But thank you very much.

19 MS. BARNES: I'll answer to whatever.

20 MS. GIAMBONE: So let's give our
21 panelists a round of applause. Just as with the
22 previous discussion, I know it's not easy -- we

1 appreciate so much -- it's not easy to come and
2 talk about your experiences or your loved ones'
3 experiences, but we sincerely appreciate that you
4 did. Thank you.

5 Okay. So let's -- just to quickly
6 summarize some of the high points that we -- or
7 some of the major points that we heard from our
8 panel, and I'd like to do another show of hands,
9 if you can. We heard about the range of
10 treatments and many of the downsides of those
11 treatments, but Mike had mentioned -- Mike
12 received a transplant, and he mentioned that he
13 had this IPF cocktail and taking this range of
14 medications on a daily basis.

15 Heather, you mentioned some of the
16 downsides, not only that your dad experienced on
17 prednisone, but also you experienced. You
18 mentioned the acne that your dad -- as a side
19 effect that he had, and you've talked about the
20 weight gain and the tremors.

21 Taleena, you talked about -- for your
22 mom, you talked about the increasing oxygen needs

1 as the disease progressed and how even with the
2 treatments, the symptoms weren't stabilizing.
3 And, finally, Teresa, you talked about some of the
4 headaches and the cold, dry lips from the oxygen
5 that your dad had to use.

6 And I'm curious, did that resonate with
7 those of you in the audience? I know I saw a lot
8 of heads nodding as the panelists were speaking,
9 but did some of those treatments and also the
10 downsides, did those resonate with you? If so,
11 can you raise your hand and show us? Okay. Okay,
12 great.

13 And also another interesting point that
14 I'd like to do another show of hands for is we
15 heard mention on the panel and even in the
16 previous discussion that there was a time when,
17 early on, it appeared that some of the patients or
18 the caregivers, that they were misdiagnosed, you
19 know, whether it was asthma or pneumonia. How
20 many of you does that resonate with? Looks like
21 the majority of you. Okay.

22 And FDA panel, do you have any questions

1 that you'd like to ask before we get started with
2 Topic 2? Okay, great. Okay. So let's get our
3 clickers out, and we're going to do a polling
4 question. And everybody on the panel have your
5 clickers ready? Okay.

6 So the question is have you ever used
7 any of the following drug therapies to help reduce
8 the symptoms of IPF? And you can check all that
9 apply. A, pulmonary rehabilitation; B,
10 corticosteroids; C, immunosuppressants; D, N-
11 acetylcysteine; E, investigational therapy; F,
12 other prescription medications, such as the acid
13 reflux therapy or inhalers; or, G, I'm not sure.

14 So take a minute and -- okay. So it
15 looks like the majority of you have taken other
16 prescription medications, and then we have --
17 again, a large portion of you did pulmonary rehab
18 and also are taking corticosteroids. And then we
19 also have the N-acetylcysteine. Let's see. We
20 have some of you that took the immunosuppressants
21 and tried investigational therapies, and other
22 said that they're not sure. So what do the Web

1 results look like?

2 MR. GRAHAM THOMPSON: We have about 70
3 percent say pulmonary rehabilitation, 60 percent
4 corticosteroids, 22 percent immunosuppressants, 61
5 percent NAC, 22 percent investigational therapy,
6 and 78 percent say another prescription medicine.

7 MS. GIAMBONE: Okay. So let's -- being
8 that this was the majority on the Web and also in
9 person, let's start with some of the other
10 prescription medications that you're taking, that,
11 you know, the majority of you have said that
12 you're taking. So would anybody like to start off
13 by telling us what it is that you take to manage
14 the symptoms, and then, again, be as specific as
15 possible on how that does or does not work for
16 you. Yes?

17 MS. ROIX: Thank you. For me -- and
18 this is just my opinion, you know. These -- some
19 of these things here are like -- to me, they're
20 not really treatments as much as trying to see
21 what may or may not work. I don't know. I don't
22 -- because they don't -- some of them don't work.

1 I do -- pulmonary rehab is the biggest thing for
2 me that is number one that works on that list to
3 help us to try to strengthen our bodies and our
4 lungs.

5 I do take NAC. It has been proven
6 through a clinical study that it doesn't help for
7 some of us, and I'm one of them. I still take it,
8 thinking that maybe it does help with some of the
9 breathing and the cough, and you get to where
10 you're afraid not to.

11 And I do take an acid reflux. I do that
12 because acid reflux can -- reflux back into your
13 lungs, so that's more of a preventative for me,
14 and so the doctor has given me that, and I think
15 it works.

16 MS. GIAMBONE: Okay. Thank you, Laura.
17 Yes?

18 MR. BOYER: Bill again. The pulmonary
19 rehabilitation was very helpful for me because it
20 helped me in that state of mind to feel like
21 you're at least getting up and doing something,
22 trying something, finding out how much you can

1 exercise, and then adjusting your oxygen. You're
2 learning about those kind of things, so it's
3 trying to learn how to live with the condition and
4 get out and do something as opposed to sitting
5 around. And the other thing is the acid reflux,
6 they put me on that just to make sure that I don't
7 have any irritation of the throat or the larynx.
8 That was right -- the two right there -- they both
9 are kind of -- esophagus, I guess -- so that, you
10 know, you're not getting any of that acid reflux
11 going back down in the lung area.

12 And I'm sure that it helped some.
13 Haven't seen a big difference because I think in
14 the cough, the biggest thing that I noticed is
15 sometimes it's a different kind of tickle in
16 different places in the chest. Sometimes it's a
17 feel, a wheeze, a crackle, a vibration when you
18 breathe, and those kind of things kind of make you
19 want to cough too. So if acid reflux were
20 exacerbating that, then it's good to try to
21 eliminate that.

22 MS. GIAMBONE: Okay. Thank you, Bill.

1 So we've heard so far that pulmonary rehab
2 addressing the symptom -- just sort of managing
3 how to increase your breathing capacity, it sounds
4 like, and managing that. And then we're hearing
5 with the acid reflux, to help manage the coughing
6 symptom, that seems to help with that. Okay. And
7 -- yes, let's take a comment up here, and then
8 we'll get back there.

9 MALE SPEAKER: Okay. Thank you. My
10 name's (inaudible).

11 MS. GIAMBONE: Could you hold your
12 microphone up a little bit, please?

13 MALE SPEAKER: (Inaudible) this program
14 to gather some information, actually, about the
15 patients (inaudible) involved with, and the --
16 about the medication issue you were inquiring, we
17 have been using pirfenidone for patients in the
18 past two years, and there's been (inaudible) has
19 stabilized these situation (inaudible) physical
20 therapy, but on two occasions, (inaudible). It
21 was kind of a -- you know, (inaudible), but one
22 thing for sure we have observed is the effect of

1 pirfenidone (ph) (inaudible). Thank you.

2 MS. GIAMBONE: Thank you very much for
3 sharing that. And we had a comment back here?

4 MR. VAN DEN ASSUM: I keep hearing that
5 NAC was -- in the PANTHER-IPF trial, was like,
6 "Forget it, it doesn't work." But then again, a
7 few years ago, we had the IFIGENIA trial in
8 Europe, which said that it did work, and that's
9 actually the reason why we're all on NAC. I take
10 inhaled NAC, and it's all cheap, and it works for
11 me, because if I don't take it a few days, I
12 really start to cough a lot, and my kids will tell
13 me, "You go back in the kitchen and take your
14 inhaled NAC."

15 Pulmonary rehabilitation has the limit
16 of like your funding or your -- how do you call
17 it? Your insurance. And I would suggest
18 everybody go to a gym afterwards, and please do
19 it, because it works. And it -- I compare it to
20 an engine. If the engine runs great, everything
21 goes a lot easier. And I'm also on acid reflux
22 and all the other kind of things. So thank you.

1 MS. GIAMBONE: Thank you. Now, you
2 bring up a good point, which I'd like to ask to
3 the group, is do you feel the -- say -- you know,
4 do you feel the effect of your medications, that
5 if you didn't take it, you -- that symptom comes
6 back, and does it come back in a different way if
7 -- you know, if you've tried a medication and,
8 say, you don't take it, what do you feel when --
9 yes?

10 MS. REICHERT: This is Diane. I had a
11 VATS procedure done back in March, and I had to
12 get off of the steroids that I was on, and as I
13 was being weaned off of the steroids, my breathing
14 became extremely difficult, to the point where I
15 really wondered sometimes if I was going to be
16 able to breathe.

17 When I saw my doctor again, he moved up
18 the VATS procedure so I could get back on the
19 steroids just to help me with breathing. If I
20 don't take my acid reflux medicine, I'm miserable.
21 It makes that much of a difference. I'm also on
22 immunosuppressant drugs, and (inaudible).

1 MS. GIAMBONE: Thank you. Thank you for
2 sharing that, Diane. Any other comments? Let's
3 go to the Web and see what we're hearing on the
4 Web.

5 MS. STARK: Sorry. We're hearing a lot
6 of the same type of comments on the Web. There's
7 mixed results about the effectiveness of NAC.
8 People are also a bit mixed on prednisone. Some
9 say it works, some say it doesn't, but pretty much
10 all recognize the bad side effects that come from
11 it. Lots of folks on acid reflux medication as
12 well; immunosuppressants for those with
13 transplants.

14 MS. GIAMBONE: Okay. Thank you. Does
15 anybody want to share additional thoughts on some
16 of the treatments that you're specifically taking
17 or, as a caregiver, that your loved one has taken?
18 Yes, Martina?

19 MS. COATES-NANCE: It's interesting. As
20 you, you know, have these questions, how many do
21 you have to click on to, you know, respond, but
22 I'll just say for Douglas, I notice a difference,

1 and he notices it too, when he does go to his
2 pulmonary rehabilitation treatment. I think he's
3 able to do some things a lot longer as he's going
4 through his rehab treatment. He's tried the NAC,
5 but it really didn't work for him.

6 Thankfully, in being diagnosed with PF,
7 he had some acid reflux issues, but with the
8 prescription of the pantoprazole, it definitely
9 helps him, and when he doesn't take it, it has an
10 -- he can feel that effect immediately.

11 He also takes Adcirca, which is another
12 medication, and that's being clocked, actually, by
13 the regularly. They call when they know he's
14 getting down to that last week of medication, so
15 that's being closely monitored as well.

16 MS. GIAMBONE: So as a follow-up
17 question, you mentioned that the pulmonary rehab
18 is helping and that he's able to do more things.
19 What is he able to do now that you know that it's
20 working?

21 MS. COATES-NANCE: I just notice his, I
22 would just say stamina, or his ability to kind of

1 walk around and do things, he's not as -- getting
2 back to some of the Topic 1 questions, not as
3 fatigued. You know, I was mentioning to Mishka
4 (ph) that, you know, he's at a place where he's
5 lifting 25 pounds, you know, during his rehab
6 session; that, you know, he's almost at the full
7 capacity of what they can do for him, which is a
8 good thing, as they're now getting ready to prep
9 him for -- to go to the committee for transplant.

10 MS. GIAMBONE: Okay. Yes. Thank you
11 very much, Martina.

12 MS. OKUN: Thank you so much. I'm Sally
13 from PatientsLikeMe. I'm interested because of
14 the way the question is written, that we're
15 talking about drug therapies, and yet one of the
16 most effective things seems to be pulmonary rehab.
17 And so I was just wondering, others in the room,
18 if they have other experiences with non-drug
19 therapies or interventions that they use that are
20 actually quite effective.

21 The other concern I have, it a couple of
22 times came up, and I know it's not FDA's doing,

1 but it really is a shame that someone can get a
2 lot of benefit of pulmonary rehab, or any other
3 physical therapy, for example, reach the maximum
4 goals that are set, and then may be no longer
5 eligible for it.

6 So it just speaks for the feeling and
7 function of how do we have PROs that actually are
8 telling us a bit more about what the real
9 experience is, and sometimes it may be that we
10 need some things that are non-drug therapies that
11 are in combination with the clinical trial
12 experiences of PROs, see how do those in
13 combination help affect overall quality of life
14 and actually how the patients are doing. So I
15 would just like to know if there's other
16 interventions beyond that non-drug therapy (ph)
17 that people are talking about.

18 MS. GIAMBONE: And thank you, Sally.
19 And you bring up a great point, and we will be
20 getting to the non-drug therapies. That's coming
21 up right after we complete the discussion on the
22 drug therapies, but you bring up an excellent

1 point. Thank you.

2 So does anybody want to comment
3 additionally on some of, you know, the -- for
4 example, the corticosteroids, taking them, what
5 did you see as a benefit? Did you see a benefit,
6 and then did you see a downside?

7 MS. STEINBERG: My name's Lesli
8 Steinberg. My mom was on -- she did pulmonary
9 rehab, she did the steroids also, the
10 investigational therapy. None of them worked
11 except for the steroids. However, the steroids
12 would work for a limited time, and she would, of
13 course, feel awful, and she would go on them and
14 off them again and on them and off of them, and
15 over time, they stopped working altogether.

16 MS. GIAMBONE: Thank you, Lesli.
17 Anybody else? So let me ask a question, as Lesli
18 brought up the time as a factor. So speaking of
19 time, how long do you normally give a treatment to
20 decide that this is working or it's not working
21 before you go back to your doctor or make the
22 decision to have to try something else? Does

1 anybody want to comment on that? Yes, right up
2 here?

3 MR. MCCENEY: Jim McCeney again. I'm on
4 like four different things, and I can't tell
5 whether any of them are working or not, but I keep
6 on using them.

7 MS. GIAMBONE: So what are you using,
8 Jim, if you don't mind me asking?

9 MR. MCCENEY: I'm using the acid reflux
10 thing, a cough medicine, an allergy for a runny
11 nose, and pirfenidone (ph).

12 MS. GIAMBONE: Okay. So let's do a
13 quick show of hands before we move on to our next
14 polling question. How many of you does that
15 resonate with, that you're taking something, and
16 you're not sure if it's working, but you're going
17 to keep taking it, you know, not knowing whether
18 that particularly is working? Okay. So we have
19 about six hands that were raised.

20 Okay. So let's get our clickers out and
21 move to the next polling question. And, Sally,
22 this gets to your point. Okay. So besides your

1 drug therapies, what else are you doing to help
2 reduce your symptoms of IPF? Again, check all
3 that apply. Oxygen therapy; surgery, such as lung
4 transplantation; C, lifestyle changes, such as
5 limit activity or changes to your home; D, other
6 therapies not mentioned; or, E, I am not doing or
7 taking any therapies to treat symptoms.

8 Okay. So we see that the majority of
9 you that are -- or the majority of patients or
10 caregivers responding on behalf of their loved
11 ones, that oxygen therapy is really one of the
12 most -- you know, it's come up the most as
13 something that you're doing to reduce symptoms,
14 followed by lifestyle changes, limiting activity
15 or changes to your home.

16 We also have some of you that have had
17 surgery, and then other therapies not mentioned,
18 and we'll certainly hear some of those too.

19 How about on the Web? What are we
20 seeing there?

21 MR. GRAHAM THOMPSON: Eighty-seven
22 percent oxygen therapy, 20 percent surgery.

1 Everyone who responded on the Web, 100 percent
2 said lifestyle changes, and 27 percent said other
3 therapies not mentioned.

4 MS. GIAMBONE: Okay. Thank you. So
5 we'll get to the lifestyle changes in just a
6 minute, but can you -- we've heard some comments
7 on how oxygen therapy -- that you've had to
8 increase the oxygen, the dose of oxygen that you
9 needed as the disease progressed. Could somebody
10 share your experiences on taking oxygen therapy
11 and how that has evolved for you over time, or if
12 you're speaking on behalf of a loved one, how did
13 that evolve for them? Anybody want to share some
14 -- yes, Taleena?

15 MS. KOCH: When my mom was first
16 diagnosed -- well, like I said, she had already
17 been on oxygen for her misdiagnosis of emphysema,
18 and she was on two liters pulse, so she was able
19 to run around with a real small container that fit
20 on a belt that went on her waist, and she could go
21 for hours on that one container of oxygen.

22 When she was finally diagnosed correctly

1 with IPF, she went immediately to four liters
2 continuous. So at that point, when you're talking
3 about needing four liters continuous, a POC would
4 not work, which, you know, we didn't even have
5 access to that back in 2003.

6 As it progressed, she ended up -- before
7 she passed away, she ended up on 12 liters, and
8 honestly -- what she passed away from was a septic
9 infection and went into respiratory arrest, but
10 had she continued to live out the duration of her
11 IPF to the very, very end, she would have ended up
12 on a lot more. I know patients through support
13 groups that are on 35 and 40 liters of oxygen and
14 using, you know, two cannulas and a mask from
15 various different machines, just to get that much
16 oxygen flow.

17 Oxygen is probably the most overlooked
18 therapy, and everyone needs oxygen to survive, so
19 it's something that needs heavily (ph) looked at.
20 And I don't know if that's something that the FDA
21 looks at or who looks at that, but it is a
22 progressive disease, and it will progress to where

1 most patients will need a very high level of
2 oxygen, so it is a definite problem.

3 MS. GIAMBONE: Thank you, Taleena. Yes,
4 Bill?

5 MR. BOYER: A couple points about oxygen
6 therapy that I would offer is I think that the
7 doctors -- I'm working with a very good heart and
8 lung transplant center, and I have nothing but
9 good things to say about my experience with the
10 doctors and other staff there, but I think there
11 needs to be better -- you know, those people
12 aren't with me every day. They don't watch me go
13 up and down the stairs or when I get out of the
14 shower and I'm panting for breath just by toweling
15 off or whatever.

16 And they can ask those questions, and I
17 can tell them, but I think there needs to be a
18 better system for them to know when to change our
19 prescriptions (inaudible) goes to the oxygen
20 company, they accommodate us by bringing the right
21 new tank or a new concentrator or something that
22 has more oxygen level in it, that type of thing.

1 The other comment that I would make --
2 and you asked at the beginning of this whole
3 session is, "What do you need?" One innovative
4 thing that I need about oxygen is a way to adjust
5 the oxygen as I do things. For example, I'm in
6 the house, and I'm sitting down, I'm looking at
7 Facebook on my little laptop, I don't need much
8 oxygen. I could sit there at two liters per
9 minute. Now, if I get up and get coffee and move
10 around, get my cereal, I need to be at four or
11 five. And I walk upstairs to take a shower, I
12 need to be at seven and, you know, so forth.

13 So it would be great to have an app --
14 because there's an app for everything -- that --
15 you know, that communicates with your oxygen
16 concentrator to make those adjustments as you do -
17 - go about the house, wherever you are, visiting
18 friends at a party or whatever, so you don't have
19 to be there, next to it, because if I turn it up
20 to seven or eight when I go upstairs, and then I
21 lay down in the bed, I've got to have somebody
22 else turn it down, or I've got to go back

1 downstairs to turn it down and go back upstairs
2 and hope that I survive.

3 MS. GIAMBONE: Thank you, Bill. I saw a
4 lot of heads nodding. So let's get a show of
5 hands here. How many think it would be -- as part
6 of an ideal treatment, that it would be beneficial
7 to have oxygen therapy that sort of, you know,
8 changes for -- based on what activity that you're
9 doing, to be able to have that control on that
10 therapy? The majority of you. And I'd be
11 interested to ask those on the Web that question
12 too and see how they respond. Okay?

13 MS. REICHERT: If I could just comment -
14 -

15 MS. GIAMBONE: Yes?

16 MS. REICHERT: -- on that point, though,
17 I think the one things that patients are concerned
18 with -- and I've always been like, "Well, forget
19 it" -- if I need more oxygen, I'm cranking it up,
20 and if I don't need as much right then, then I'm
21 turning it down. For some people, some patients,
22 they're afraid if -- if the prescription right now

1 says two liters, they won't go beyond two liters
2 with their concentrator or anything. We have that
3 ability to change the number.

4 MS. GIAMBONE: Okay.

5 MS. REICHERT: And it's important that
6 we do that and let our doctors know. I'm sorry,
7 doctors, if that's not the right information, but
8 as patients, it's helpful, and I think that people
9 need to remember that.

10 MS. GIAMBONE: Thank you, Diane. Okay.
11 So how about -- we did hear some downsides on the
12 oxygen therapy. As I mentioned before, Teresa,
13 you had mentioned your father had the dry lips, he
14 felt very cold taking the oxygen. Does anybody
15 want to talk about the downsides? We've also
16 heard that it's hard to kind of, you know, take
17 with you when you're traveling. But any downsides
18 that you'd like to talk about, specifically to the
19 oxygen therapy? Yes? Let's hear from Heather.

20 MS. SNYDER: When I was first diagnosed,
21 when I was put on oxygen, I was put on liquid, and
22 I had no idea there was other options out there.

1 And I hated liquid oxygen. I felt like I had a
2 brain freeze all the time. And it dissipated, so
3 I was still trying to work eight-hour days, and I
4 didn't need it while I was sitting down, but by
5 the time I'd go into work and come back out, it
6 was gone, whether I used it or not. So it was
7 impossible to have an active life with liquid
8 oxygen. So I eventually turned to the gas and got
9 backpacks and strapped it on and just started
10 going. So (inaudible), but

11 MS. GIAMBONE: Thank you. So I'm going
12 to let those of you on the Web know that we'll be
13 taking phone calls in just a bit, so if you could
14 get your thoughts together for that. In the
15 meantime, I'd like to ask you -- many of you also
16 mentioned that you've made lifestyle changes. And
17 earlier on, we had heard from Curt, I remember,
18 saying that you made some changes in your home.
19 You got rid of the carpet. Can somebody share
20 with us some of the lifestyle changes that you've
21 made? Yes?

22 MS. ROIX: I'm Laura, and the change

1 that I had to make was very drastic, and I know
2 that some others have been in the same position
3 that I'm in. The -- we have cords or tubes that
4 will go 50 feet, and anything beyond that, really,
5 isn't -- doesn't give you much for oxygen because
6 it has to go through that. So keeping that in
7 mind, I had to give up my home. I had a condo,
8 and I had five levels. No gasp, please. I had
9 five levels, and in order for me to go from what I
10 used to call my nosebleed section back downstairs
11 to do laundry in the basement, I didn't have
12 enough tubing for that, nor did I have enough
13 breath for that.

14 So the major lifestyle change I had to
15 do was to get rid of my home that I lived in. And
16 I now live with my daughter, who's 34 and single.
17 I don't recommend that to anyone, the two o'clock
18 in the morning, you know, coming in. But with
19 (inaudible) that, that is a major thing. You
20 know, my daughter had said to me, "I want you to
21 live with me. I don't want you to get another
22 home on one level. I want you to be with me."

1 And as a parent, I don't want my child to take
2 care of me.

3 Of course, I had a choice between her
4 and her brother, and he told me what goes around
5 comes around and I have to be home by ten, so I
6 thought that she was the better choice, because
7 sometimes she doesn't get home until two, so I
8 could creep in at quarter of.

9 MS. GIAMBONE: Thank you. And then --

10 MS. ROIX: But that is hard.

11 MS. GIAMBONE: Thank you. Okay. And
12 then we also heard some diet and exercise was used
13 to manage some of your symptoms (inaudible). So
14 would somebody like to share some comments on how
15 you've changed your diet or how you've
16 incorporated exercise? Did -- how about let's do a
17 show of hands? We did -- oh, yes, I'm sorry.

18 MR. VAN DEN ASSUM: After physical --
19 after pulmonary rehab, I decided to go to the gym.
20 Actually, I was going to the gym, and it was not a
21 good gym. So I selected another gym. And when
22 I'm in the gym, I'm always asked, like, "Why don't

1 you go with me?" or "Why don't you do this with
2 us?" or so forth, and I was like, "No, I do it my
3 way."

4 So we're -- I see the young kids come in
5 and do their thing in half an hour, three quarters
6 of an hour. I'll take two hours. Right? And
7 that's actually the only gym point (ph).

8 MS. GIAMBONE: Thank you very much.

9 Okay. So we're just going to do a few more show of
10 hands, and then we'll go to the phone line. How
11 many of you feel -- and, caregivers, you know, if
12 you can also respond on behalf of your loved ones,
13 how many of you feel that based on your current
14 therapy, that your symptoms are well-managed at
15 this time? Okay. We do have one. So I imagine
16 I'm going to see more hands for this next
17 question, which is how many of you feel that,
18 given your current treatment regimen or the
19 treatment regimen that your loved ones are taking,
20 how many of you feel that it's not really under
21 control? Okay. The majority of you. Okay.

22 All right. So let's go to the phone

1 lines. And, operator, could we have the first
2 caller?

3 OPERATOR: The first call comes from
4 Christine Williams. You may ask your question.

5 MS. CHRISTINE WILLIAMS: Hi. Can you
6 hear me?

7 MS. GIAMBONE: Yes, Christine.

8 MS. CHRISTINE WILLIAMS: Okay. My name
9 is Christine Williams, and I was diagnosed with
10 pulmonary fibrosis -- idiopathic pulmonary
11 fibrosis in May of 2009, and I was diagnosed with
12 pulmonary hypertension secondary to it in October
13 of 2013. And I just mainly have a couple of
14 comments.

15 First of all, I'd just like to thank the
16 FDA and everyone that have put this forum
17 together. This is probably one of the most
18 important things that I have ever attended, and
19 it's so full of education, and I'm all about
20 advocacy and awareness.

21 The second thing is, I wanted to
22 acknowledge three people that are there that are

1 on your panel: Taleena, Doris (ph), and Laura. I
2 only know them through Facebook. However, I feel
3 that I can call them my friends, and I do call
4 them my friends. And I want not just you to know,
5 but all of you to know how brave and courageous
6 you are for sharing your story and being
7 vulnerable and allowing others into your world,
8 because I know how tough that is.

9 I tend to isolate myself, and I was in a
10 very, very dark place, and when I found these
11 groups, I just knew I wasn't alone, even when I
12 thought I was alone. And I just want to thank
13 them especially. We have come together by our
14 disease, unfortunately, but I'm so very glad that
15 God decided to put them in my life.

16 And whether you think you are or not,
17 you are a huge, huge inspiration to me, and I want
18 you to know that I love you all, and I thank you
19 for your participation in this event today.

20 MS. GIAMBONE: Thank you so much. Thank
21 you for sharing those comments. Let's take
22 another caller.

1 OPERATOR: Yeah. The next question
2 comes from -- or comment comes from Pete Kaiser.
3 You may ask your question.

4 MR. KAISER: This really isn't a
5 question -- well, it's a -- one of things that
6 really helped me is the humidity control
7 (inaudible) which makes a tremendous difference
8 (inaudible). So that's (inaudible).

9 MS. GIAMBONE: Okay. Thank you. You
10 kept going in and out, but I think what we heard
11 is that humidity control was a beneficial therapy,
12 that it helped to have humidity control. Okay.
13 And do we have one more caller? That's it? Okay.

14 Okay. So what I'd like to do is just
15 take another minute. I want to make sure that we
16 discuss two things here. One, were there other
17 therapies that you take that weren't mentioned?
18 Is there anything different that you'd like to
19 share in terms of the therapies that you're doing
20 or taking? Yes, Teresa?

21 MS. BARNES: You know, one of the things
22 that I hear a lot from patients is a lot of the --

1 I'll call them alternative therapies, some of the
2 Eastern medicines that they are trying. There are
3 a number of -- I'll call them products on the
4 market that promise to reverse fibrosis, that
5 promise to dissolve it, that promise to improve
6 conditions, and a lot of patients are believing
7 that, and maybe it helps them in some way. So --
8 but, anyway, those are very commonly brought up.

9 Also, in -- on a regular -- I would say
10 in intervals, I hear about stem cell therapies.
11 And I'm not talking about clinical trials looking
12 at stem cells in IPF. I'm talking about stem cell
13 therapy that is some sort of infusion of your own
14 blood or something. I hear that a lot, and it's
15 like a \$50,000 treatment. You know, patients are
16 using this. I don't know that it's a large
17 number, but it is happening, and there are
18 evidently a few centers that are doing that. I
19 don't know much about it except to tell you that
20 that is a commonly brought up issue.

21 MS. GIAMBONE: Thank you, Teresa. Okay.
22 And then anybody else want to share any other

1 therapy that they're taking? Oh. Yes?

2 MR. VAN DEN ASSUM: There's a very well-
3 known activist, and his name is Bill Vick, and I
4 think he's smiling (inaudible), and he believes in
5 the Paleo diet, which goes back to nuts and those
6 kind of things. And he strongly believes in it.
7 And he's a -- he's the guy -- one of the people
8 that actually was in the movie Every Breath
9 Counts. I don't know if you've ever heard of it,
10 but if you haven't seen it, look it up online,
11 everybreathcountsfilm.com. It's about IPF.

12 MS. GIAMBONE: Thank you very much.
13 Okay. And then I guess the very last question I
14 have for you, and then we're going to wrap up the
15 day and begin our open public comment period, but
16 does anybody want to share any final thoughts on
17 the ideal treatment? I know that we heard many of
18 you say that stopping the progression of the
19 disease, catching it early on, you know, make sure
20 it's not misdiagnosed. Is there any other
21 thoughts that you had to share regarding the ideal
22 treatment? Yes, we have

1 FEMALE SPEAKER: Early on --

2 MS. GIAMBONE: Oh, hang on one second.

3 We'll have a microphone (inaudible).

4 FEMALE SPEAKER: Someone commented about
5 a doctor saying, "Oh" -- what was the phrase?
6 "It's no big deal." That was said to my brother,
7 who has IPF, by a primary care physician. And
8 maybe it's not the purview of this particular
9 public meeting, but that seems to be a big issue,
10 that the primary care doctors aren't picking up on
11 this.

12 And my brother eventually -- when he got
13 a cold, a bad respiratory infection and pneumonia
14 and so forth, that was -- you know, all hell broke
15 loose and so forth. And that was like seven or
16 eight months after a doctor looked at an X-ray and
17 said, "Oh, I see some, you know, webbing," or
18 whatever, "but it's no big deal."

19 MS. GIAMBONE: So more awareness,
20 understanding of the condition. Okay. Thank you.
21 Okay. Oh, we'll take one more comment, and then
22 we'll wrap up. Yes. Go ahead, Heather.

1 MS. SNYDER: I just want to mention one
2 thing about, you know, the doctors and the
3 hospitals and all the physicians don't know a lot
4 about pulmonary fibrosis, and when patients come
5 into the emergency room, they don't know how to
6 take care of them. They really don't understand
7 that, you know -- I was given an IV with a lot of
8 fluids. That's what threw me in respiratory
9 failure. I wasn't in respiratory failure until
10 that happened, and then all the liquid went around
11 my heart and lungs, and within 24 hours, I was
12 almost dead.

13 So those type of initiatives, we need to
14 speak out how to handle this. And I know -- I
15 don't think the patient's here -- or the family
16 member's here, but, you know, the story I heard
17 from a family member yesterday was a doctor had
18 told her that, and I've never heard of a doctor
19 say that, but that was, you know, my -- again, my
20 experience. And she went into the hospital with
21 her husband, and then they were going to call
22 security on her because she was adamant to not

1 allow them to put an IV in him. And (inaudible)
2 to call security and everything, but I think that
3 needs to be looked at and brought to attention.

4 MS. GIAMBONE: Thank you. Okay. Well,
5 thank you so much. We've had such a -- for us, I
6 know that we have learned so much from you on not
7 just symptoms and the impacts and living with IPF
8 on a daily basis, but the treatments that you're
9 taking. And we sincerely appreciate how much
10 you've shared with us and opened up, and you've
11 taught us so much today, so we thank you for that.

12 And with that, I'm going to get started
13 with the open public comment period. So, Pujita,
14 if you'd like to

15 MS. VAIDYA: Hello, everyone. I'd like
16 to thank you all for coming here today. And we're
17 now moving on to the open public comment session.
18 And for those of you who are not aware, the
19 purpose of this session is to allow an opportunity
20 for those who have not had a chance to speak on
21 issues that are not related to our main -- two
22 main discussion topics today.

1 So this is an opportunity for folks who
2 are not a patient or a patient representative to
3 comment. Please keep in mind that we will not be
4 responding to your comments, but they will be
5 transcribed and be part of the public record.
6 Since we would like this process to be
7 transparent, we encourage you to note any
8 financial interests, if any, that you have that
9 are related to your comment.

10 So we have collected sign-up before --
11 during the registration and during the break, and
12 so far we have 5 people signed up and about 15
13 minutes, so we'll probably give each person about
14 3 minutes to speak. Please be respectful for your
15 other colleagues here and other patients and try
16 to stick to that three-minute mark. And if you do
17 start to approach that three minutes, I will need
18 to ask you to start wrapping up.

19 So I will run through the order of
20 speakers, and I apologize if I mispronounce your
21 name. First we have Sally Okun, then Donna
22 Appell, Greg Cosgrove, David Lederer, and then

1 Dolly Kervitsky. So could I first please have
2 Sally Okun?

3 MS. OKUN: Thank you so much, and I want
4 to really thank then FDA for taking the
5 opportunity to study this very important mission.

6 I'm from PatientsLikeMe, and on March
7 8th of 2013, we opened an IPF community. Today we
8 have over 2,500 people who are participating on
9 the site who are actively engaging in not only
10 socializing with each other and supporting each
11 other, but, more importantly in many ways, really
12 gathering data on a day-to-day basis about their
13 experiences with treatments and symptoms as well
14 as other opportunities to participate in projects
15 that we're doing, either with industry or academic
16 research groups. So we have a huge amount of
17 information, I think, that could be useful.

18 And I also wanted to reinforce two
19 important pieces that actually have been brought
20 up, but maybe haven't really been reinforced
21 enough. Twenty-five percent of our patients tell
22 us that it takes them more than three clinicians

1 to get to the point of getting a diagnosis over
2 periods of years, and so this is really abysmal.
3 We have to help people get diagnosed more quickly.
4 We've heard that throughout the day today. So I
5 think there has to be an opportunity for us to be
6 speaking to clinicians.

7 Now, as a palliative care clinician, I
8 can tell you my own experience with caring for
9 these patients is it's desperate. It's a time in
10 their life when they're trying to figure out
11 what's going on, and people are just telling them
12 that it's going to be okay and we'll be all right,
13 but it's frankly not. So I think we have to get
14 beyond that.

15 The last thing I wanted to say, and,
16 again, thank you for the time, is to really focus
17 on patient- reported outcomes. We have an
18 opportunity -- we've heard so much about feeling
19 and function today and the impacts of the things
20 that are happening to patients on a day-to-day
21 basis. We really need to get to the point where
22 those endpoints are the ones that actually matter

1 in the clinical trials, along with the biomarkers,
2 because we actually learned about things that are
3 non-drug therapies and other interventions.

4 And just to let you know, on our site,
5 one of the most important things that people say
6 was -- in our survey, when we ask them about these
7 same questions, that helped them day-to-day with
8 their day- in and day-out was the social
9 connectedness aspects of their world, where they
10 made virtual or real connection with other people
11 and were able to share their experiences on a
12 regular basis. So I think those are things that
13 you can measure in a pharmacological study per se
14 without asking the patient-reported outcomes on
15 that. So thank you so much for the time.

16 MS. VAIDYA: Thank you, Sally. Next we
17 have Donna Appell.

18 MS. APPELL: Thank you for this
19 opportunity. Thank you so much to the FDA for
20 listening to all this. I think it was hard for
21 everybody, and it means a lot to us to have you --
22 to have this accessibility -- I -- means a great

1 deal, gives us some sort of hope, and that's
2 medicinal.

3 So I also want to apologize to the three
4 people that might be coming after me, but I have
5 to get a taxi to get a plane, so I'm going to be
6 leaving right after this comment. So I represent
7 the Hermansky-Pudlak Syndrome people. I have a
8 daughter with Hermansky-Pudlak Syndrome. She has
9 HPS Type 1. So we knew 27 years ago that she would
10 be dying of pulmonary fibrosis, and our people
11 look at it, staring it in the face, watching all
12 the activity, and their friends, and know that
13 it's coming, because 100 percent of the time in
14 HPS 1, 2, and 4, they will develop pulmonary
15 fibrosis, with a great knockout mouse (ph) for
16 pulmonary fibrosis studies.

17 So why am I here, because it's not
18 idiopathic? Well, I guess there are drugs that
19 are coming to you and in front of you that have
20 been tried in the idiopathic arena, and I can't
21 change that, but my request is for you to think
22 about, in future applications, to try to get rid

1 of that word, "idiopathic," for the rest of us.

2 And why? One of the reasons is because we pay our
3 medical bills as idiopathic pulmonary fibrosis, so
4 we're kind of paying -- they don't pay for
5 Hermansky-Pudlak Syndrome pulmonary fibrosis.
6 They pay for IPF.

7 And then I started the organization 22
8 years ago, and then I feel very sad, after 22
9 years I've been educating people and
10 pulmonologists about it's not an idiopathic, it's
11 Hermansky-Pudlak Syndrome, and darned if I should
12 have just kept my mouth shut so that my patients
13 could actually get medications for idiopathic
14 pulmonary fibrosis. And I go to bed feeling bad
15 about that.

16 So our misdiagnosis is great, because
17 there are a lot of people out there that actually
18 have HPS PF. And then let's think about that.
19 There are a lot of different causes. I know that
20 in the beginning, it was mentioned the diverse
21 phenotypes. Well, we're a diverse phenotype, and
22 there's exposure, and it's going to be genetics

1 and familial, and it's going to be the combination
2 of both. So why not just ditch the idiopathic
3 idea and just treat pulmonary fibrosis and open it
4 up to everyone?

5 Reason why we might personally feel like
6 we need it is because in 1999, our patients were
7 on pirfenidone, before it was even owned by
8 InterMune, when it was with Marnac, based on the
9 fact that it was an anti-fibrotic, and our people
10 were the Phase II trial people for that drug,
11 which probably possibly helped it actually go on
12 further. We have anecdotal reports that our
13 patients are still doing well on it, and it's a
14 blessing that it's finally coming to the market.
15 I worry that our people might have it off- label.
16 Our uninsured, certainly our disenfranchised might
17 have a really hard time getting the drug. So that
18 needs to be done, and that's my three minutes, I
19 think. Is that what you're waving to me about?

20 MS. VAIDYA: Yeah.

21 MS. APPELL: Thank you very much for
22 having this opportunity, and thank you for

1 listening to us all today.

2 MS. VAIDYA: Thank you, Donna. Next we
3 have Greg Cosgrove.

4 DR. COSGROVE: Hello. I'm Greg
5 Cosgrove. I'm a pulmonologist from National Jewish
6 in Denver, and I'm also the Chief Medical Officer
7 of the Pulmonary Fibrosis Foundation, so I'm
8 speaking on behalf of the 100,000 patients with
9 pulmonary fibrosis in the United States, and I
10 humbly submit the data from our survey with over
11 1,400 respondents from the past three and a half
12 weeks to the questions (inaudible) to the registry
13 -- or queried from the registry, and that's been
14 submitted and will be available for anyone to
15 review.

16 What is important is I think there's a
17 unique opportunity here -- and it's unique in that
18 everyone has the same goal. We understand
19 misdiagnosis is incredibly problematic
20 misunderstanding, and that's not just by patients,
21 but by physicians, whether they're pulmonologists
22 or primary care physicians. And that's been

1 distressing as a pulmonologist, sitting in the
2 audience today, understanding the travesty of
3 misdiagnosis and perhaps limited ability to
4 intervene when intervention could significantly
5 improve symptoms.

6 And so the challenges are who to treat.
7 We've heard of patients that are too healthy for
8 treatment. Some are too sick for treatment. And
9 it kind of harkens back to the prior discussion
10 about which patients is pulmonary fibrosis,
11 because idiopathic is one of 200 different
12 diseases, but there are many other diseases that
13 are rapidly progressive and debilitate patients
14 with almost identical symptoms.

15 And so the challenge is quite
16 apparent. The opportunities are even more readily
17 achievable to collaborate together, not just in
18 academia, but with governmental agency industry
19 partners to advance the field. How can we do
20 that? One mission we have is to set up the
21 network, a care center (ph) across the United
22 States with a registry. We can begin to quantify

1 patient-related outcomes. We can collaborate
2 together, get better care for patients, enhanced -
3 - excuse me. Excuse me. Enhanced awareness,
4 enhanced education, and in doing so, I think we
5 can rapidly advance this field to improve care,
6 not just from one disease, but for many of the
7 diseases. Importantly, IPF is one that is
8 devastating, given its mortality. If it's 1 in
9 200, we need to be thinking about that as we move
10 forward. There's a unique opportunity with many
11 medications and many trials. Unfortunately, based
12 on our data, 14 percent of patients avail
13 themselves to the opportunity of the clinical
14 trial. Why is that? Fifty-seven percent say their
15 doctors never even addressed it. And so with
16 (inaudible), hopefully we can rapidly evaluate
17 medications moving forward, rapidly implement
18 evidence-based therapies so that, you know, we're
19 just not treating symptoms, but hopefully we treat
20 the disease, and, more importantly, we treat the
21 patient. But thank you for this

22 MS. VAIDYA: Thank you, Greg. Next we

1 have David Lederer.

2 DR. LEDERER: Thank you very much. My
3 name is Dave Lederer. Just a disclosure, I'm a
4 consultant for Gilead (inaudible) matters related
5 to IPF clinical trials. I'm a pulmonologist in
6 clinical practice, taking care of patients with
7 pulmonary fibrosis and lung transplant recipients.
8 I'm also a medical advisor for the Pulmonary
9 Fibrosis Foundation on patient communications.

10 Today I want to share with you a
11 perspective -- I think summarizes quite well what
12 was discussed today, maybe add a little bit of
13 additional insight. So I often hear from
14 healthcare professionals, particularly doctors,
15 and from patients that there's nothing that we can
16 do for this disease. Of course, this is not true.
17 We can do many things for this disease, and we've
18 talked about it today. Aggressive oxygen therapy,
19 getting people off toxic (ph) therapies, getting
20 people enrolled in pulmonary rehabilitation. But
21 this statement that there's nothing to do is
22 rooted in our paltry armamentarium, which right

1 now consists of a blank prescription pad.

2 What my patients need today, right now,
3 are therapies that help them live longer,
4 healthier, more normal, and independent lives;
5 therapies that slow progression of the disease;
6 and we also need to improve healthcare delivery to
7 PF patients. Most patients don't show up to an
8 (inaudible) Center of Excellence for two or more
9 years after their symptoms have begun. And we
10 know the people who show up earlier have better
11 outcomes, regardless of the disease severity.

12 We need to educate healthcare providers
13 about how to recognize, how to diagnose and manage
14 this disease better, and we also need to
15 prioritize research and oxygen delivery methods.
16 Oxygen should be free. Oxygen should never run
17 out. Devices should be lightweight and discreet,
18 and we need to study methods with oxygen combined
19 with exercise. These are the only things that
20 make anyone with this disease feel better.

21 So that's today, but tomorrow, we need
22 something more. We need therapies that halt

1 fibrosis in its tracks; therapies that heal lung
2 tissue; therapies that eliminate shortness of
3 breath and cough; therapies that allow people to
4 return to the independent life they once had.

5 And tomorrow, we need to be able to grow
6 a biological lung (ph) (inaudible) or develop an
7 artificial lung that could be used instead of lung
8 transplantation and avoid those harmful therapies.
9 In short, it could be a cure. And I see a day, as
10 Teresa said, someday, in the not-too-distant
11 future, when no one will die from pulmonary
12 fibrosis. Thank you.

13 MS. VAIDYA: Thank you, David. And,
14 lastly, we have Dolly.

15 MS. KERVITSKY: Hi. I'm Dolly Kervitsky
16 with the Pulmonary Fibrosis Foundation. First I'd
17 like to thank the FDA and all of the patients and
18 the family members that are here, participating in
19 this meeting and sharing your very personal
20 stories. I know how difficult it is, and we
21 didn't have enough tissues in this room. Let me
22 just say that, because you all have amazingly

1 touching stories to share, and I hope the FDA
2 listened carefully to all of those stories,
3 because those are the stories that I live with
4 every day, working in the capacity that I do with
5 the follow-up. It's very touching.

6 So the one thing that I think is very
7 important for all of us to consider is that
8 finding treatments for this devastating disease
9 requires participation from all of us in this
10 room. This is a very good first step. I think it
11 needs to be followed up. We need to continue on
12 this path.

13 Right now, there are two drugs being
14 reviewed by the FDA. They are for idiopathic
15 pulmonary fibrosis. And, as Donna said -- and I'm
16 sorry she's not here to hear this -- but there are
17 many other patients with devastating fibrotic lung
18 disease that do not have therapies. So finding
19 and making sure that those patients are not
20 forgotten and that we continue on this path
21 becomes very important to all patients with
22 pulmonary fibrosis.

1 One of the ways that I think is really
2 helpful to the community is the creation of a
3 guidance for industry in developing therapies.
4 Really accelerating the development and review of
5 therapies for all fibrotic lung diseases, similar
6 to what Duchenne's Multiple Dystrophy Foundation
7 did, working on clinical trial design, outcome
8 measures, and considerations so that we can move
9 the science forward and really make an impact in
10 this disease.

11 Dr. Cosgrove talked a little bit about
12 clinical trials and designs. When we looked at
13 the survey results that we did, I have to say that
14 I was pretty surprised that 42 percent of patients
15 did not participate because they were concerned
16 that they would get a placebo and their disease
17 would continue to progress.

18 So that is something that we have to fix
19 within the system. So if we create well-
20 intentioned clinical trial designs and guidance,
21 that we can move the science forward, and
22 hopefully many of us in this room will be talking

1 about how well they're doing and thanking all of
2 the people involved for finding a treatment,
3 eventually a cure. Thank you.

4 MS. VAIDYA: Thank you, Dolly. So that
5 ends our open public comment period. And I would
6 like to call upon Dr. Banu Karimi-Shah for the
7 closing.

8 DR. KARIMI-SHAH: Thank you. I brought
9 my notes up here with me because I know that today
10 we were supposed to be in listening mode, and I
11 was, but I was also in writing mode. So I wrote
12 down a lot, and I don't want to leave anyone out,
13 but I'm going to just take a little time to be the
14 last one today to express our gratitude. Once
15 again, we're so thankful that all of you were able
16 to be here.

17 I learned so much today, and I know that
18 it wasn't just a great learning opportunity for
19 me, but for all of us here at the FDA. And
20 because I can't talk about everything that
21 everyone said -- that'll all be captured in the
22 minutes, I know -- I just want to go over some of

1 the things that really resonated with me today and
2 I'm sure resonated with a lot of us. Number one,
3 oxygen. Oxygen resonated with me today, and as
4 Taleena said, IPF patients need oxygen, but one of
5 -- and I'm a pulmonologist. I knew this. But one
6 of the things that really resonated with me today
7 was the panic, the panic around oxygen, the
8 planning that's necessary around oxygen, the fear
9 that's associated with oxygen and running out of
10 oxygen. As Bill said, the feeling like you're in
11 jail and feeling that no one is equipped to take
12 care of you where you go unless you bring it with
13 you. So that's one of the things that really
14 resonated with me today.

15 Another thing that really resonated with
16 me today are the things that the patients and the
17 caregivers have given up. Diane talked about the
18 beach. Laura talked about power-walking. Travel,
19 hobbies, jobs, long conversations, laughing,
20 sports, driving, your homes, and time. You give
21 up time, not just the time that you lose to the
22 disease in terms of your life span, but everyday

1 time, because it takes so much longer to do
2 things. The most menial of tasks takes so much
3 longer. So the time issue really resonated with
4 me today.

5 The cough. I know not everyone
6 experiences the cough, but the characteristics of
7 the cough also resonated with me today, how tiring
8 it can be, how violent it can be, how embarrassing
9 it can be, how it comes on with even small
10 exertions, that it's difficult to sometimes end
11 it, and that you're often left completely
12 exhausted after.

13 Again, I'm a pulmonologist. I know
14 about the shortness of breath. But I think what
15 Heather said resonated with me, that it feels like
16 a tightening of the noose around the neck.
17 Somebody commented on the fact that they have to
18 remember, remember to breathe, and to know what
19 it's like to drown. So those things really made
20 an impact on me today.

21 And so I just -- I'd like to close,
22 because I know that we're a little bit over, or

1 maybe almost just on time. I'm a pulmonologist.
2 I trained at a place where IPF patients were
3 treated, where lung transplants were available,
4 and today, I was reminded -- I took care of
5 patients with IPF before I came to the FDA as a
6 clinician, and today I was reminded about the
7 patient community, again, which was so valuable to
8 me, because both the patients and the caregivers
9 have so much to teach us, and I was reminded again
10 that you're scared, and -- but that fear doesn't
11 make you shy away from things, it makes you
12 stronger, and you're motivated to go to aerobics
13 classes and to the gym and -- so that you can get
14 your lung transplant. You're motivated to deal
15 with the side effects of your drugs and to change
16 your lifestyles so that you can live better and
17 feel better.

18 And you have hope, despite all the bad
19 things that happen, despite the misdiagnoses,
20 despite not knowing whether or not certain
21 treatments are working, despite uncontrolled
22 symptoms. And you have a great sense of humor,

1 because, despite the sort of weighty topic in the
2 room, there was a lot of laughter today. And that
3 you're selfless, because there were a lot of
4 comments today that said we know that maybe the
5 therapies that are coming down the line aren't
6 going to help us, but they're going to help our
7 children, and they could help others, and you want
8 it for other people.

9 And we heard what you want. Bill wants
10 an app, so we'll -- I wrote that down. But
11 everybody just wants more time and more quality
12 time to spend living their lives and with their
13 loved ones. And you want a voice early on in drug
14 development, and we hear that.

15 So we've really had the privilege of
16 listening to everyone in the room today. You've
17 thanked us, and so I'd like to close by thanking
18 you. Your stories were so important to us. Both -
19 - all the people here and on the phone and on the
20 Web, everything you've said today was very, very
21 valuable to us, and please know that at FDA, we do
22 shoulder the responsibility of developing drugs

1 for IPF and moving science forward, and this
2 weighs on us, and we don't take it lightly, so
3 thank you very much.

4 MS. GIAMBONE: So I just had two
5 additional comments. One is if you don't mind
6 filling out your evaluation form. If you didn't
7 already receive one, we have more at the
8 registration desk, and we can bring you one. And
9 second, very importantly, please make sure that
10 you submit any additional thoughts or comments or
11 experiences to the public docket, which was the
12 website that I had shown you earlier on, but
13 please make sure you go there and continue
14 providing your feedback there. So thank you
15 again. Thank you all so much for being here
16 today.

17 MR. GRAHAM THOMPSON: One last comment.
18 Please don't take those little clickers with you.
19 We need those.

20 (Whereupon, at 4:57 p.m., the meeting
21 was adjourned.)

22

1 CERTIFICATE OF NOTARY PUBLIC

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



17
18 MICHAEL FARKAS
19 Notary Public in and for the
20 STATE OF MARYLAND

21 My commission expires: 6/27/2018

22 Notary Registration No.: 256324

CERTIFICATE OF TRANSCRIPTION

1
2
3
4 I, MARY E. YOUNG, hereby certify that I am not the
5 Court Reporter who reported the following
6 proceeding and that I have typed the transcript of
7 this proceeding using the Court Reporter's notes
8 and recordings. The foregoing/attached transcript
9 is a true, correct, and complete transcription of
10 said proceeding.

11
12
13
14 

15 _____
16 Date

MARY E. YOUNG
Transcriptionist

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