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PAH Public Meeting on Patient-Focused Drug Development 05-13-2014

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PULMONARY ARTERIAL HYPERTENSION  
PUBLIC MEETING  
ON  
PATIENT-FOCUSED DRUG DEVELOPMENT  
Tuesday, May 13, 2014  
1:00 p.m.

Food and Drug Administration  
White Oak Campus  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
Phone: (301) 796-9018

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1 A P P E A R A N C E S

2 FDA PANEL

3 Ellis Unger  
Norman Stockbridge

4 Shari Targum  
Maryann Gordon

5 Anne Pariser  
James Bona

6 Theresa Mullin

7 Patrick Frey  
Pujita Vaidya

8 Soujanya Giambone  
Sara Eggers

9 Graham Thompson  
Pegah Mariani

10 Georgiann Lenzi

11

PANELISTS

12

TOPIC 1

13 Kevin Paskawych  
Cynthia "Alex" Flipse

14 Nicole Matthews  
Holly Tissue-Thompson

15 Colleen Connor

TOPIC 2

16 Lucille Monko  
Colleen Brunetti

17 Katie Tobias  
Stacey Gausling

18 Tamera Pixler

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

2 MS. GIAMBONE: All right. Well let's go  
3 ahead and get started. And we have some extra seats  
4 back there if anybody wants to take a seat, please feel  
5 free there are lots of seats up here at the round  
6 tables also. All right. Well good afternoon. My name  
7 is Soujanya Giambone. I am with the FDA Center for  
8 Drug Evaluation and Research, Office of Strategic  
9 Programs. And on behalf of all my FDA colleagues I  
10 would like to welcome you and thank you for coming to  
11 the seventh Patient-Focused Drug Development Meeting.

12 Today's meeting is on Pulmonary Arterial  
13 Hypertension, PAH, and we are looking forward to a  
14 great day of discussion and hearing from you and  
15 learning from you. And I am very happy that the D.C.  
16 Metro area is giving you a great day. So thank you for  
17 being here.

18 So I am going to spend just a few quick  
19 minutes going over the agenda. You should all have a  
20 copy of that. We had them out at the registration  
21 desk. But if you don't have one, feel free to ask one  
22 of my FDA colleagues and we will be happy to give you

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1 one. And then just a few more housekeeping items and  
2 we will get our meeting underway.

3           Okay. So we are going to start off with some  
4 presentations from the FDA Panel. We have three  
5 presentations. They'll review some opening remarks,  
6 overview of the Patient-Focused Drug Development  
7 initiative and a background on PAH and treatment  
8 options.

9           And then I will come back and review the  
10 discussion format with you. We have two discussions  
11 today; two topics. We will have a panel discussion  
12 followed by a group discussion for each of these  
13 topics. Topic 1 is on the symptoms, the most  
14 significant symptoms of PAH and how it impacts your  
15 daily activities. And Topic 2 is on your perspectives,  
16 patient perspectives to current treatment options.

17           After that we have reserved a half an hour  
18 towards the end of the day for open public comment. And  
19 what that is is if there is anybody, not just patients  
20 or patient representatives, if anybody wants to share  
21 some thoughts on PAH that are outside of the scope of  
22 Topic 1 or Topic 2 you can feel free to sign up for

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1 open public comment. We will be taking signup at the  
2 registration desk up until break time. And then we  
3 will see how many people signed up and how much time  
4 each speaker will have during open public comment.

5           And then we will have some closing remarks  
6 and that will wrap up the day. So it is a full day.  
7 But we are really looking forward to hearing from you.

8           Just a few housekeeping items: Restrooms are  
9 back out into the lobby area and make a right and go  
10 all the way down to the end of the hall and that is  
11 where the restrooms are. And you will pass a kiosk  
12 that serves basic sandwiches, snacks and drinks for  
13 purchase. And I just want to make sure that you know  
14 this might be a bit of a different kind of public  
15 meeting than others that you may have attended. It is  
16 a bit informal. It is more talk show style. I want  
17 you to feel comfortable to stretch, take a break if you  
18 need to use the restroom, grab a snack, please feel  
19 free to do so. Okay.

20           So before we get started can I have my FDA  
21 colleagues please introduce yourself.

22           MR. UNGER: Good afternoon everyone. I'm

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1 Ellis Unger. I'm the Director of Office of Drug  
2 Evaluation 1 in Office of New Drugs.

3 MS. MULLIN: Hi I'm Theresa Mullin. I direct  
4 the Office of Strategic Programs in the Center for  
5 Drugs.

6 MS. TARGUM: Good afternoon everyone. I'm  
7 Shari Targum. I'm a cardiologist and I'm a Medical  
8 Officer in the Division of Cardio Renal Drugs.

9 MR. STOCKBRIDGE: Good afternoon. I'm Norman  
10 Stockbridge. I'm the Director of the Division of  
11 Cardiovascular and Renal Products.

12 MS. PARISER: Good afternoon. I'm Anne  
13 Pariser. I'm the Associate Director for Rare Diseases  
14 in the Office of the New Drugs at Cedar.

15 MR. BONA: Hi I'm Jim Bona from the Office of  
16 Orphan Products Development here in the Office of the  
17 Commissioner.

18 MS. GIAMBONE: Graham and Pujita?

19 MR. THOMPSON: Graham Thompson, Office of  
20 Strategic Programs.

21 PUJITA VAIDYA: Pujita Vaidya, Office of  
22 Strategic Programs.

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1 MS. GIAMBONE: Great. Thank you. So I am  
2 going to be turning this over to Ellis for your  
3 comments. And just a very quick note this meeting is  
4 being recorded and transcribed; so after the meeting is  
5 over the recording will be available on our website.  
6 Okay.

7 With that I'll turn it over to you.

8 MR. UNGER: All right, everyone, again good  
9 afternoon and welcome to our seventh meeting on  
10 Patient-Focused Drug Development; this one on pulmonary  
11 hypertension. And as I mentioned I am Ellis Unger, I  
12 am the Director of the Office of Drug Evaluation 1; and  
13 our office oversees the Division of Cardiovascular and  
14 Renal Products. And they are the Division that  
15 regulates the drugs for pulmonary hypertension. So you  
16 have the key people here this afternoon and you have  
17 our ear. We are very excited to have all of you here.  
18 I believe we have a number of patients; we have  
19 caregivers and patient advocates in the audience.  
20 There are also many people who have joined us online, I  
21 guess we will have a count later but there are  
22 generally a lot. I know we have representatives from

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1 industry and academia joining us here. And I would  
2 like to thank all of you for participating in this  
3 meeting and it is a meeting that involves  
4 participation.

5           So this is one of a series of meetings that  
6 we've had. And the goal is to try to better understand  
7 how patients feel about their disease; how they  
8 experience, how you experience your disease or your  
9 loved one's disease. And help us understand your  
10 perspectives, your viewpoints and hopefully help us  
11 better help the drug companies to develop drugs that  
12 are what you need for your disease.

13           Our job as you know is to protect and promote  
14 the public health. And we evaluate the safety and the  
15 efficacy of new drugs. And of course part of what we  
16 do is to oversee the drug companies as they develop new  
17 agents. Some of you may be surprised to know that we  
18 don't actually do what most people think of a drug  
19 testing. We don't do clinical trials at the FDA  
20 generally. So the drug companies that do those trials.  
21 But we work very closely with the drug companies to  
22 help them design those studies so that when we receive



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1 those studies, the results of those studies we can  
2 actually get the information we need to make very  
3 rational decisions about whether the drug works or not,  
4 how well it works and whether the drug is safe or not,  
5 how safe it is. And so that is what we do and we want  
6 to insure that every single patient who enrolls in a  
7 trial for a drug provides information that is useful  
8 and that the benefits and risks of participating in a  
9 study are explained. Those are all things that we do  
10 here at FDA.

11 We pay a lot of attention to what we call the  
12 end-point of a study which is what is actually measured  
13 to convey whether the drug works or not. And generally  
14 for most of the drugs we have, how a drug works is  
15 conveyed in terms of how a patient feels or how well a  
16 patient functions. Occasionally it is whether they  
17 live or die or how long they live or die. And we want  
18 to hear some of your views on the end- points we've  
19 been using for these studies which generally for  
20 pulmonary hypertension is how far can you walk in six  
21 minutes, how many meters can you cover in six minutes.  
22 And that may or may not be important to you but it may,

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1 in fact, capture what it is that bothers you the most  
2 whether it's being short of breath when you exercise or  
3 hitting a wall or something. But that is part of what  
4 we would like to get out of this today.

5           So what we would like to do is hear from you  
6 in terms of what you feel and how you function and we  
7 have, I don't know, 12 pages single spaced of material  
8 from pages that was very -- I found it very  
9 enlightening going through that explained maybe seven  
10 or eight different patients and their viewpoints. I  
11 believe we are going to hear from some of you this  
12 afternoon.

13           So we are also very fortunate to have with us  
14 the key members of the review team who generally review  
15 drugs for pulmonary hypertension, Dr. Targum and Dr.  
16 Stockbridge. These are senior people in the Division  
17 of Cardiovascular and Renal Products who help design  
18 the studies, who help interpret the results, who help  
19 protect your safety. And they are the key people so  
20 they are here to listen to you.

21           We want to hear how you view your disease,  
22 what really matters to you, what symptoms bother you

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1 the most. You know what activities would you like to  
2 be able to do that you can't do? Even the hassles of  
3 dealing with therapies whether it is bandages or broken  
4 IV lines or the fear of your IV line kinking in the  
5 middle of the night and your alarm going off. Those  
6 things are important to you and we want to know about  
7 them.

8           And we would also like to know how you view  
9 the various risks of treatment for pulmonary  
10 hypertension. In general we try not to be too  
11 paternalistic here. We get criticized for having drugs  
12 out there that aren't safe enough and we get criticized  
13 for not allowing drugs on the market because they are  
14 viewed to be not safe enough when people think they  
15 are. And generally if people shout about the same  
16 volume of loudness on both sides we're probably doing  
17 things right. But in general we try not to be too  
18 paternalistic and we try to approve drugs that work.  
19 And if we think there are risks we put them in the  
20 label so that you understand what they are.

21           And I think that is pretty much what I wanted  
22 to say. We know pulmonary hypertension affects people

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1 in different way. So we want to hear your perspective  
2 on how you experience the disease and what you would  
3 like to see in treatments for pulmonary hypertension.  
4 And so I will just with that thank you again for being  
5 here and welcome you. And turn it over to Theresa  
6 Mullen who will talk about our broader efforts in  
7 patient-focused drug development.

8 Thank you very much.

9 MS. MULLEN: Thanks Ellis. And again thank  
10 you for coming out today to White Oak and joining us in  
11 this meeting and thanks very much also for the people  
12 who are participating on our webcast. These meetings  
13 are you know the more we can engage and make it  
14 possible for patients to participate the better they  
15 are, the more benefit we get out of the meeting. As  
16 Ellis was saying the whole point of these meetings is  
17 to hear from patients and get the patient's  
18 perspective.

19 And so this -- I am going to tell you just  
20 for a few minutes a little bit about this effort of  
21 Patient-Focused Drug Development and this meeting is  
22 one of a set that we committed to do over the next

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1 several years and so we are doing this to develop a  
2 more systematic way to gathering up the patient's  
3 perspective on their condition and the available  
4 treatment options as Ellis was saying. And this is  
5 recognizing the obvious but that patients are in a  
6 unique position to inform FDA about the drugs that are  
7 available and what those drugs are providing and not.  
8 They are the ones that derive whatever benefit there is  
9 to get and the ones who experience the risks that may  
10 be associated with those products.

11           And so we realized that we really didn't have  
12 a mechanism for getting a more systematic kind of  
13 comprehensive hearing from as many patients as  
14 possible. We have some mechanisms that exist that  
15 really focus more on asking an individual patient or  
16 maybe a few patients about a particular issue for a  
17 particular drug product or an application that may be  
18 under review. And that is very valuable to us. But we  
19 realize that that is very limited. That one person can  
20 really speak best for their own experience and may not  
21 be able to reflect the diversity of experience of  
22 people who have that disease. And so how can we go

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1 about getting more input from a broader cross section  
2 of patients experiencing a disease and not have to go  
3 through the kind of conflict of interest screening that  
4 we have to do in fact when you are talking about a  
5 particular product and a particular case.

6           And so this initiative came out of our  
7 thinking about how we could try to do this, the  
8 information that we get we thought would help inform us  
9 both in terms of as Ellis was saying telling or  
10 advising companies if they ask us for advice on  
11 developing a drug or even in giving us insight in  
12 reviewing an application that comes in for a drug to  
13 treat that disease. So this initiative is part of a  
14 commitment that we made under the reauthorization of  
15 the Prescription Drug User Fee Act. FDA has a number  
16 of user fee sources of funds that supplement the money  
17 we get from tax payer funding that helps us to run our  
18 operations. And when that was reauthorized we  
19 committed to do at least 20 of these meeting each in a  
20 different disease area. And the idea was this was like  
21 a big pilot to see how could we do this and how can we  
22 get good at getting this kind of information. We don't

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1 just need it for 20 diseases; we really ideally would  
2 have it for every disease. And we are learning a lot  
3 about how to do this through this process.

4           So this began in September that is the  
5 beginning of our fiscal year, actually October 1 is the  
6 beginning of our fiscal year so in September we  
7 announced a preliminary set of diseases that we would  
8 look at. Our candidate list of about 40, we got a lot  
9 of good public input about their comments on those  
10 diseases, which ones that the public thought that we  
11 should choose. We selected a set of 16 diseases that  
12 we are covering in the first three years of this five  
13 year period; so 2013 to 15. And we will go through a  
14 process again in 2015 to identify additional disease  
15 areas that we'll focus on in these kinds of meetings in  
16 2016 and 2017.

17           And here is the set of diseases that we have  
18 identified so far so you can see last year we had a  
19 meeting on Chronic Fatigue Syndrome, HIV, on Lung  
20 Cancer, and Narcolepsy. So far in this fiscal year we  
21 have a meeting on Sickle Cell Disease and Fibromyalgia  
22 and today's meeting is focusing of course on Pulmonary

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1 Arterial Hypertension. And you can see on this slide  
2 the other diseases that we will be aiming to have  
3 meetings on over the next year and a half. And there  
4 is quite a diversity as you can see; a really wide  
5 range of diseases. But they generally have in common  
6 as Ellis was saying how patients feel and how they  
7 function are areas where we would really benefit from  
8 hearing more than what we know today.

9           So we are really excited to have you here  
10 today to tell us about what your experience has been.

11           Each of these meetings because of that  
12 diversity of the range of diseases is somewhat tailored  
13 to the areas that the review division would  
14 particularly like to have asked patients about having  
15 this rather unique opportunity to ask for your  
16 perspective, they take advantage of that. And we also  
17 want to cover some common questions. And each of these  
18 meetings we do want to hear explicitly about your  
19 experience with living with your disease, the things  
20 that impact your life the most, maybe how that has  
21 changed over the course of your disease and then how  
22 the treatments that you are using today are working for



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1 you or not working for you; and so we understand just  
2 how well or not well those treatments meet your needs.  
3 And these questions of living with the disease and the  
4 impact on your life, the severity of that and how well  
5 current treatments work fit right into this framework  
6 that we use to make decisions about new drugs, so our  
7 benefit risk framework. And those two elements tell us  
8 the context of the disease really help us to sort of  
9 weigh the evidence that we get in an application about  
10 a drug and how well it works and what we know about its  
11 safety profile.

12           So we find that each of these meetings really  
13 the patient involvement in the meeting, your engagement  
14 in this discussion this afternoon is going to be  
15 critical to how much we can learn and how well this  
16 goes for all of us.

17           We'll produce a report after the meeting; we  
18 call it the Voice of the Patient Report. You can find  
19 this on our website. We try to capture what we hear  
20 through the panels, through all the audience  
21 participation, what input we get on the webcast and  
22 also any information we might receive in our docket,

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1 our electronic docket; pull these components together,  
2 we try to capture what you tell us faithfully to the  
3 way you tell us, the words you use to describe what it  
4 is like to live with the disease are the ones we try to  
5 put in the report to make sure the review divisions and  
6 people who weren't here get to hear it as close as we  
7 did to what you told us about how it is to live with  
8 the disease. That report provides a really important  
9 purpose for us to capture that for reference for the  
10 future if the division receives an application for PAH  
11 in the future they can look at this report and say this  
12 is what patients were telling us it is like to live  
13 with this disease and what they thought of the  
14 treatments that are there. That is a very important  
15 piece of information for them.

16           We think it may also in some cases trigger  
17 the development of new tools to collect better  
18 information more systematically in clinical trials  
19 about what it is like to live with the disease and  
20 whether a new treatment that is being tested has an  
21 impact on those things that you tell us about. That is  
22 called a patient reported outcome tool. Those may also

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1 follow -- ideas for those may follow these meetings.

2 So with that I am going to turn it over to  
3 Doctor Targum and she is going to give you a bit of a  
4 background on PAH.

5 Thank you.

6 MS. TARGUM: Good afternoon. Welcome. My  
7 name is Shari Targum. And as I said I am a Medical  
8 Officer in the Division of Cardiovascular and Renal  
9 Products. And this afternoon I am going to be  
10 providing you with some background on pulmonary artery  
11 hypertension and therapeutic options. So as you have  
12 heard pulmonary artery -- arterial hypertension is the  
13 third rare disease being featured in our series. And I  
14 have included a definition of what is a rare disease  
15 and at FDA what constitutes an orphan drug. So even  
16 though a rare disease is a condition or disease  
17 affecting less than 200,000 people in the United States  
18 if you take rare diseases in the aggregate it is  
19 actually much more common than that. So almost one in  
20 ten Americans suffer from rare diseases.

21 This is to show you that there are three  
22 different offices at FDA that deal with rare diseases.

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1 From a patient perspective the first office, the FDA  
2 office of Health and Constituent Affairs is probably  
3 the office that you would interface with. But there  
4 are two other places at FDA that look at rare diseases  
5 and orphan products. And we have representatives from  
6 both offices here today.

7           So pulmonary artery hypertension is a rare  
8 under diagnosed progressive condition and it is defined  
9 by an elevated pulmonary arterial pressure. The  
10 pulmonary artery circuit is generally a low pressure  
11 system. And it is the system that delivers blood from  
12 the right ventricle to the lungs. So the definition  
13 that I put here is that the average pulmonary arterial  
14 pressure is higher than 25 millimeters of mercury at  
15 rest compared with patients without pulmonary  
16 hypertension. This is one way to think about pulmonary  
17 artery hypertension. There are other classification  
18 systems as well. But I have listed three general  
19 types. There is idiopathic which means of unknown  
20 cause. There are types that are familial. And there  
21 are types of pulmonary artery hypertension that are  
22 associated with underlying diseases.

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1           In terms of symptoms there are a variety of  
2 symptoms that patients may experience such as chest  
3 pain, dizziness, shortness of breath. One of the  
4 issues with pulmonary artery hypertension is that the  
5 symptoms also occur with other conditions that are more  
6 common. So it might be that you go see a doctor with  
7 some of these symptoms and you get diagnosed with  
8 something else first because there are other conditions  
9 that occur more commonly. And so PAH or Pulmonary  
10 Artery Hypertension can be difficult to diagnose  
11 because the symptoms are similar to other conditions  
12 like asthma, pneumonia, coronary disease. And the other  
13 piece of this is that the physical examination in the  
14 early stages can be almost normal. So that leads  
15 doctors to conduct a number of tests. And I have listed  
16 a series of tests that doctors might conduct to try to  
17 get down to the bottom line of why you might be having  
18 a symptom. The most definitive tests would probably be  
19 the echo-cardiogram which gives a picture of the right  
20 heart and also might give an estimate of pulmonary  
21 artery pressures and the right heart catheterization  
22 which is a special device that doctors put into the

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1 heart and arteries to measure the actual pressures.

2           In terms of treatment options generally the  
3 goals of treatment are to make people feel better;  
4 improve their quality of life or to make them live  
5 longer. In the case of pulmonary hypertension the  
6 goals that we've had are to improve quality of life,  
7 reduce symptoms, slow down how quickly the disease  
8 progresses and improve your function as measured by the  
9 six minute walk test. The treatment options include  
10 medications which is what we deal with. In certain  
11 patients that are eligible surgery might be an option.  
12 And a third option would be lifestyle changes.

13           This is a list of some of the drugs, some of  
14 the classifications of drugs that have been approved,  
15 mostly been approved to improve symptoms. In  
16 conditions like pulmonary artery hypertension input  
17 from you and patients is very important. There are  
18 tools called patient reported outcomes that can be  
19 questionnaires that might capture how people feel. And  
20 this is a great way that patients can contribute to  
21 drug development and developing new drugs that can  
22 really help.

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1 I am going to now turn it over to the  
2 overview of the discussion format.

3 Thank you very much.

4 MS. HAMILTON: What you just went over is  
5 that available to us because you went over it pretty  
6 quickly.

7 MR. TARGUM: I am sorry for that.

8 MS. HAMILTON: The slides that you used are  
9 they available to us?

10 MR. THOMPSON: We post the slides along with  
11 the recording of the meeting maybe a week or so after  
12 the meetings are.

13 MS. TARGUM: But I apologize if I talk too  
14 quickly.

15 MS. HAMILTON: The slides were only up --

16 MS. GIAMBONE: Okay. Well thank you to my  
17 FDA colleagues for your presentations.

18 I am going to spend just a few minutes going  
19 over the discussion format. As I mentioned earlier on  
20 we have two topics to cover today. Topic 1 is on the  
21 most significant symptoms of PAH and how it impacts  
22 your daily activities. So here what we are really

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1 looking to listen for is what are your most significant  
2 symptoms and what is it that you can or can't do  
3 because of those symptoms. Or maybe activities that  
4 you are not able to do as fully as you would like  
5 because of your symptoms. And if you can even compare  
6 what an average day of symptoms looks like versus a  
7 more severe day of symptoms and give us some specific  
8 examples of what that means for you.

9           Topic 2 is on current approaches to treating  
10 PAH. So here what we are listening for is what is your  
11 current treatment regimen and is it working for you.  
12 How do you know that it is working for you? Can you  
13 give us specific examples on maybe what you are able to  
14 do now to show that your specific treatment regimen is  
15 working for you?

16           Also what are the side effects? And what are  
17 the biggest downsides that you are experiencing with  
18 this treatment. And also what would you look for in an  
19 ideal treatment for PAH.

20           Next slide.

21           So we are going to first hear from a panel of  
22 patients and I've been working closely with these



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1 panelists for the last week and a half and they've been  
2 really really wonderful in preparing some great  
3 summaries to share with you all today. They reflect a  
4 range of experiences with PAH. And they have each put  
5 together about four minutes of comments. And the  
6 purpose of the panel discussion is to really set a good  
7 foundation for our discussion for the rest of the day.

8           What we will do is after the panel is  
9 finished with their comments we are going to broaden  
10 the dialogue and invited those of you other patients  
11 and patient representatives in the audience to also  
12 share your experiences. And by that what we would like  
13 to hear from you is not just what resonates with you,  
14 what experiences did you share with what the panelists  
15 shared with us but also what is different for you.  
16 Build on what you heard from the panel and share as  
17 many specific examples as you can.

18           We are going to have some microphone runners  
19 around the room and if you are comfortable to do so  
20 raise your hand and they'll come to you. And if you  
21 could please state your name before you answer, that  
22 would be great.

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1           And periodically I am going to be checking in  
2 with the FCA panel to see if you have any clarifying  
3 questions.

4           All right. Next slide. So there are a few  
5 other ways we are going to also be learning from you  
6 and that is that we are going to have some polling  
7 questions along the way. And Chad would you mind  
8 passing out the clickers. Thank you. We are going to  
9 test these out in just a few moments. But the purpose  
10 of the polling questions is for us to get some more  
11 understanding of what are the perspectives in the room  
12 and also on the web for those of you joining us on the  
13 web. And for the web participants you can answer your  
14 polling questions via the webcast. The polling  
15 questions are not a scientific survey and it is  
16 entirely voluntary. And we ask that patients and  
17 patient representatives answer these questions please.

18           And on that note as I just mentioned we have  
19 quite a few people joining us on the web. I would like  
20 to extend a very very special welcome to all of you  
21 joining us on the web. We can't see you but your voice  
22 is being heard. And we are looking forward to checking

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1 in with you periodically throughout the meeting today.  
2 We will be reading comments that are coming in via the  
3 webcast but also we will check in via telephone with  
4 some of the people on the web. So thank you all of you  
5 for joining.

6           Next slide. And last but not least another  
7 way that we are really looking forward to hearing from  
8 you is through the public docket. So this is really a  
9 website, a space that we have that it is going to be  
10 open for two months through July 13 and we invite you  
11 and encourage you to continue to share more comments,  
12 more experiences and thoughts as they come up. If you  
13 weren't able to share that with us today you will have  
14 two months to be able to go there and enter your  
15 comments there. All of those comments will be  
16 incorporated into the summary report and anybody is  
17 welcome to comment.

18           And just a few ground rules for today we are  
19 so happy to see so many patients and care givers and  
20 patient representatives here. We are looking forward  
21 to hearing from you. And we encourage you to  
22 contribute to the dialogue. We know that there are a

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1 lot of you from the industry and academia and other  
2 government agencies. We are very happy that you are  
3 here. We think this meeting will be extremely useful  
4 for you too. We just ask that you stay in listening  
5 mode. The FDA also is here to listen. We are as I  
6 mentioned before looking forward to hearing what you  
7 have to say. And once in a while I will be checking in  
8 to see if they have any questions. But we are here to  
9 listen to you today.

10           The discussion is going to focus on symptoms  
11 and treatments. So as I mentioned we have two topic  
12 questions and we are going to try to stay in scope with  
13 those topic questions. Those are the questions that  
14 are most beneficial for the FDA to hear from you to  
15 hear your responses on. We know that there is a lot of  
16 different aspects of PAH. And we invite you to  
17 continue to share those comments with us via the public  
18 docket and again for those of you that may want to  
19 contribute to the dialogue today but if it is outside  
20 the scope of Topic 1 or Topic 2 you can sign up for  
21 open public comment.

22           The views expressed today are personal

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1 opinions. And on that note respect for one another is  
2 paramount. And last but not least let us know how the  
3 meeting went for you today. We are going to have some  
4 evaluation forms out on the registration desk. And we  
5 will also be passing them out closer to the end of the  
6 meeting. So let us know how it all went for you today  
7 and that will help us to make our next meeting better.  
8 Great.

9           So we are going to start with a polling  
10 question. And does everybody have clickers. Okay.  
11 Excellent. So we are going to start with an easy one  
12 first. Where do you live? Press A for in the  
13 Washington, D.C. metro area or B for outside of the  
14 D.C. metro area.

15           Oh, that is the result. Wow, look at that.  
16 Talk about an even split, huh. Well welcome to all of  
17 the locals but also to everyone coming outside of the  
18 D.C. metro area. I know that we have had quite a few  
19 long travels here. I know there is someone from  
20 California, Ohio, we really appreciate it. And also I  
21 know many of you took the bus to get here; right. So  
22 thank you for coming.

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1           Next question. Have you ever been diagnosed  
2 as having Pulmonary Arterial Hypertension; A yes, B no.  
3 So 59%, the majority of you have been diagnosed as  
4 having PAH.

5           And we have 41% as not having been diagnosed  
6 as having PAH. We are thankful to all of you for being  
7 here and hearing the experiences that you have to share  
8 since your diagnosis.

9           Next question. What is your age? A younger  
10 than 30, B 31-40, C 41-50, D 51-60, E 61-70 or F 71 or  
11 greater.

12           So it looks like the majority of you are in D  
13 51-60. We also have 61 70. It looks like we have a  
14 great spread of everyone. And that is going to be  
15 really helpful for us as we hear more perspectives from  
16 each of you.

17           And let's check in with the web real quick  
18 and see what the polling results look like.

19           MS. VAIDYA: Well I just wanted to chime in  
20 and say that we have a pretty similar spread on the  
21 web, were about 60% have said that they have been  
22 diagnosed as having Pulmonary Arterial Hypertension. So

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1 we are thinking we do have a good representation of  
2 patients on the web as well. And for the age group it  
3 is quite similar about 26% 51 - 60, 41 - 50 and 31 -40  
4 actually.

5 MS. GIAMBONE: Great. Thank you.

6 So now let's move on to the next polling  
7 questions. Are you A male or B female?

8 So we have mostly female in the audience but  
9 we are also very thankful to have some male  
10 representation here also.

11 Next question and I believe this is the last  
12 one. What is the length of time since your diagnosis?  
13 A less than five years, B five to ten years, C ten to  
14 20 years, or D more than 20 years.

15 So we have it looks like the majority of you  
16 in the room have had the diagnosis from five to ten  
17 years. We also have some more newly diagnosed members  
18 in the audience so less than five years. And then we  
19 also have some representation from longer periods of  
20 diagnosis, so ten to 20 years and more than 20 years.  
21 Great.

22 And can I check in with the web quickly to

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1 see what the web is looking like?

2 MR. THOMPSON: It is about the same, it looks  
3 like with a few more people who have been diagnosed for  
4 a long time.

5 MS. GIAMBONE: Great. Thank you.

6 So now let's move on to our Topic 1 panelists  
7 and on that note can I have my Topic 1 panelists come  
8 on up and take a seat and bring your name cards with  
9 you.

10 So once again just to remind everyone and we  
11 are going to have the slide up in just a moment but  
12 Topic 1 is on the most significant symptoms of PAH and  
13 their impact on daily activities. And I know our panel  
14 members have been working very hard to prepare these  
15 comments. So thank you so much.

16 So what I'll have you guys do is introduce  
17 yourself as it is your turn to speak. And make sure  
18 that you press the little red button to make sure that  
19 the microphone is turned on. We will make sure we get  
20 one for you, no problem. So shall we start with you  
21 Colleen?

22 MS. CONNOR: Sure.



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1 MS. GIAMBONE: Okay.

2 MS. CONNOR: Hello. Hi. I am Colleen  
3 Connor. Thank you for having us today to the FDA. So  
4 I am just going to quick start because I prepared some  
5 comments. My most significant symptom is shortness of  
6 breath. I was misdiagnosed for asthma for two and a  
7 half years prior to the PAH diagnosis. At work early  
8 on I couldn't catch my breath to give a presentation or  
9 even to keep up with my peers walking down the hallway.  
10 It was very embarrassing and I would tell people that I  
11 was having a bad asthma day. Once diagnosed, people  
12 were much more forgiving because it was evident from  
13 the oxygen that I needed to wear that I had a breathing  
14 problem.

15 Early on I would wake up breathless just from  
16 rolling over in my bed. I was out of breath getting  
17 into my car. The medications have helped but I am  
18 still much more short of breath than my peers and I am  
19 quite limited in what I can physically do. When I am  
20 active my oxygen requirement goes up dramatically and  
21 my heart rate increases.

22 Over the last six years I have experienced a

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1 very wide spectrum of health due to PAH. And in bad  
2 times I have had months of not being able to accomplish  
3 much, walk up the stairs, do household chores or leave  
4 the house in any weather condition other than the  
5 ideal. I needed to purchase a scooter to go almost  
6 anywhere outside my home. As an example I couldn't  
7 walk from my car to my son's baseball field.

8 I had deteriorated to a point I was  
9 encouraged to list for lung transplant. And I have  
10 since stabilized and improved and the transplant plans  
11 are on hold.

12 At one point I had a dramatic symptom of  
13 extreme dizziness which accelerated over a matter of  
14 several weeks and my cardiac output had fallen  
15 dramatically. I was not perfusing oxygen to my brain  
16 and I could no longer think or read. They put me on  
17 the IV medication and within a week and a half I had  
18 regained my ability to think, the buzzing in my head  
19 went away and I was able to read again.

20 I am very grateful to have this IV  
21 medication. But even on the best days my life is  
22 nowhere near normal. Things people take for granted

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1 like a peaceful night sleep are not in the cards for  
2 us. I sleep with my oxygen and my IV and I sleep much  
3 lighter as I am concerned I will kink my line and the  
4 alarm will sound. This has happened many times and I  
5 try frantically try to fix the kink as my husband looks  
6 on helplessly. And my biggest fear is that I worry  
7 that someday the blockage will be on the inside of me  
8 and it will be an emergency situation because my  
9 medicine has a half life of four minutes and if  
10 interrupted it can result in extreme rebound pulmonary  
11 hypertension affects and even death. In addition I  
12 worry that I will pull the IV line out accidentally if  
13 I flip around in my sleep. I also worry that I will  
14 catch a life threatening infection. I also have the  
15 oxygen on, so it is just best not to turn over for fear  
16 some point my tubing will become a noose around my  
17 neck. And yes, this happens.

18           Showers are difficult. Is the water bandage  
19 on securely? Is the IV bag pump securely hung  
20 somewhere where I can get under the water but it  
21 remains dry? Should I take off my oxygen so I don't  
22 have water shooting up my nose and I have more mobility

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1 and less tubing in the shower or do I take it off and  
2 let my heart race?

3           Daily activities such as cooking, washing  
4 dishes, family errands are often exhausting. Some days  
5 I just can't manage the work load and we order food in  
6 several days a week. I can't bring laundry up or down  
7 the stairs. Just walking up the stairs by myself  
8 causes my oxygen to drop significantly and my heart to  
9 race.

10           If I have a good day and I am on my feet a  
11 lot I start to have flint (ph) leg pain which is a  
12 common side effect of this IV medicine. On those days  
13 even when I feel great I am forced often to sit down so  
14 that my feet are up and the pressure is taken off of  
15 them.

16           Weather plays a significant role in my life.  
17 It was and still always is difficult to breathe in the  
18 cold and humid air. On windy days I can't catch my  
19 breath. This past winter for weeks at a time I was  
20 stuck inside due to the snow and temperatures of below  
21 32 in the Philadelphia region. And it is difficult to  
22 breathe.

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1           On bad days I take a shower and I feel like I  
2 need to rest following that. I don't accomplish much  
3 at all. I'll wake up, eat, and go back to sleep until  
4 my children come home from school.

5           Other bad days are caused by my heart giving  
6 off sharp pangs which scare me. And so I lay down no  
7 matter how I am feeling.

8           My condition has changed over time. I talked  
9 about some of this and other than pre-pulmonary  
10 hypertension I was very healthy. I had tremendous  
11 stamina. I could fly to the west coast for a work  
12 engagement, have lunch, dinner, fly home on a red eye  
13 and be in the office the next morning at 8:00 a.m.  
14 Since pulmonary hypertension I become very sick each  
15 winter for a matter of weeks or months with bronchitis  
16 and pneumonia. The fevers last for weeks or months on  
17 end.

18           Initially after diagnosis I still was able to  
19 work. I worked through some of my progression onto IV  
20 therapy. But as time passed I became too tired to get  
21 dressed in a business suit and to go into the office.  
22 My company modified my position to give me flexibility.

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1 But at 41 my fatigue had increased to the point where I  
2 had to stop working altogether to rest in the  
3 afternoons or I have a difficult time making it through  
4 the rest of the day.

5 The things that didn't even register as tasks  
6 pre-pulmonary hypertension serve as accomplishments for  
7 me now like going to the grocery store or shopping for  
8 my children. I am very thankful to rely on the  
9 internet for a lot of non-perishable shopping.

10 And they were the remarks that I prepared.

11 MS. GIAMBONE: Thank you so much Colleen.

12 Alex?

13 MR. FLIPSE: Hi. My name is Alex. I was  
14 diagnosed with Pulmonary Arterial Hypertension on  
15 September 6, 1998. I suffered with symptoms more than  
16 two years prior my diagnosis. My daughter recently  
17 told me how much it impacted her life for me not to be  
18 able to pick her up. I would tell her she was too  
19 heavy for me and she took it as she was fat. And if  
20 she lost weight I would be able to pick her up more  
21 often. She also told me not being able to pick her up  
22 impacted her because she felt like I didn't love her or

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1 her sisters enough. I did cuddle with them as often as  
2 I could but picking them up was so important to them I  
3 really don't understand it but that is how they felt.

4           Now with my granddaughter weighing nearly 40  
5 pounds I'm having such a hard time picking her up. I  
6 could barely pick her up when she was just a few months  
7 old and ten pounds and walk around with her in my arms.  
8 I can't carry her to bed if she falls asleep watching  
9 TV or playing. I can't lift her to wash her hands in  
10 the bathroom or to reach something that she wants to  
11 get. She is at a stage now where everything is don't  
12 help me nana, I can do it. But if she wants to reach  
13 something that she can't; picking her up is out of the  
14 question. But if I do for whatever reason I get very  
15 short of breath and I even get chest pains.

16           A couple of nights ago we took a walk to the  
17 park, she wanted to play on the swings and of course  
18 that meant picking her up and putting her in the  
19 toddler swing. That was very difficult. We couldn't  
20 stay very long after that. Before that we played on  
21 the seesaw and I got short of breath on that as well.  
22 It was almost like running a marathon I was so short of

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1 breath.

2 Walking up hills causes me to get short of  
3 breath. I don't normally stop what I am doing when I  
4 am SOB because as soon as I start again I am once again  
5 short of breath. So I usually just keep going. If it  
6 is really bad I'll stop and if I get palpitations I  
7 will stop.

8 I was on Flolan for the first four years of  
9 my diagnosis. And because of that I developed  
10 photosensitivity. I cannot walk outside without sun  
11 glasses on even on a cloudy day.

12 Exhaustion is another symptom that  
13 drastically impacts my life. Before I was diagnosed 15  
14 years ago I slept 18 to 20 hours a day. I would wake  
15 up in the morning, make breakfast for my kids, put them  
16 in front of the television and fall asleep on the  
17 couch. At noon I would get up and make lunch, send my  
18 little ones out to play with their friends and fall  
19 asleep on the couch. I would wake up with just enough  
20 time to make a quick dinner, wait for their father, my  
21 ex-husband to come from work. I'd meet him at the door  
22 with all three girls and say I am exhausted and go off



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1 and sleep for the rest of the night.

2           Even still 15 years later exhaustion plagues  
3 me. I can sleep sometimes until 11:00 in the morning  
4 after having a full night sleep and still take a two  
5 hour nap from 2:00 to 4:00. Nowadays napping is not a  
6 luxury; it is a necessity. And if I don't get a nap  
7 for whatever reason, even if I am sitting watching my  
8 granddaughter as she watches television I have zero  
9 energy for anything other than sitting.

10           Another symptom that affects my life  
11 negatively is raising my arms in the air above my head,  
12 washing my hair, reaching for a cup in the cupboard,  
13 brushing my hair; these things make me very tired. I  
14 only wash my hair once or twice a week depending on how  
15 I feel. Emptying out the dishwasher is very difficult.  
16 Putting cups and plates away makes me tired. I have to  
17 do these things in sections. For example doing the  
18 dishes; I empty the dishwasher and sit and rest. Rinse  
19 the dishes, sit and rest. Load the dishwasher, sit and  
20 rest. The same goes with vacuuming, pick up stuff off  
21 the floor, vacuum the dining room, vacuum the living  
22 room, vacuum the hallway, vacuum my bedroom. On good

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1 days I can put a couple of these steps together and not  
2 have to rest as often. And on bad days I have to break  
3 it up even further.

4 Things I cannot fully do as I'd like to  
5 because of Pulmonary Arterial Hypertension are things  
6 that include bending and standing. Picking things up  
7 off the floor makes me dizzy and most often I get short  
8 of breath. Before I was diagnosed I passed out when I  
9 would bend over. When my children were babies, my  
10 youngest daughter was two years old when I was  
11 diagnosed it was even worse. Picking them up, cooking  
12 for them, cleaning after them, these things would make  
13 me so short of breath I'd get palpitations and I would  
14 pass out. I passed out more than 30 times in a three  
15 month period and was told it was just in my head.

16 I am very afraid of taking my granddaughter  
17 out in public because I won't be able to run after her  
18 if she takes off. Watching her nearly full time is  
19 very difficult. I get exhausted after just a few short  
20 hours. She is so full of energy.

21 I would love to become a productive member of  
22 society again. Going back to work, not having to rely

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1 on family and friends to support me; being able to work  
2 a 40 hour work week; not having to rely on food stamps,  
3 Medicare and Medicaid would be wonderful.

4 My new normal is a lot slower than before, a  
5 lot calmer than before; and a lot quieter than before.  
6 But thank God I have a new normal to live.

7 Thank you.

8 MS. GIAMBONE: Alex, thank you for that.

9 Kevin?

10 MR. PASKAWYCH: Yes. I am Kevin Paskawych.

11 And at first glance I may look like a mostly healthy 32  
12 year old man. Unfortunately that is not the case. The  
13 symptoms I deal with most frequently are the greatly  
14 reduced energy levels that I have to schedule my life  
15 around. Pardon? Oh. I have to deal with the greatly  
16 reduced energy levels that I have to schedule my life  
17 around and the shortness of breath that can bring my  
18 daily activities to a screeching halt.

19 In short my daily life is rationed. I have  
20 to make decision based on how I feel every morning,  
21 look at my schedule and decide what I can or cannot do.  
22 A busy day today might mean a day of recovery tomorrow

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1 to recover my energy level. My energy is less than  
2 half of what it was five years ago. After I look at my  
3 day I have to account for what activities could be  
4 potentially taxing; what could lead me to a bout of  
5 shortness of breath.

6 Watching my children can become an issue as  
7 well as helping my wife with simple tasks around the  
8 house.

9 Finally I must add time to my daily tasks, as  
10 lapses in concentration make it much harder to complete  
11 certain jobs than I once was able to.

12 Fortunately PAH has not just cost me the joys  
13 of a schedule free day. It has cost me many of my  
14 favorite activities as well. Being able to take my  
15 kids to mini-golf, being able to go on walks and hikes  
16 with my wife. Those are all very limited now and have  
17 to be scheduled accordingly.

18 From my early teens to my late 20s I was an  
19 active hockey player, competitive rower, a kayaker, a  
20 biker and a hiker. Any excuse to get out on the water  
21 or into the woods I would take. The loss of these  
22 activities has been perhaps one of the hardest parts.

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1 Where once I could strap on the pads and play a game  
2 now I can only watch. Where once I could kayak several  
3 miles with friends or canoe with my wife now getting in  
4 the water is hard enough. Taking my kids to a game,  
5 being able to play with my step son or my daughter in  
6 the back yard, now I have to watch. Where once I  
7 enjoyed long hiking excursions in the mountains of  
8 Appalachia; now a walk downtown with my wife if I  
9 schedule my day properly is the best I can do.

10 But for me things have improved. When I was  
11 diagnosed with Pulmonary Arterial Hypertension in  
12 August 2012 my condition was such that getting up and  
13 moving from one room of my house to another as an  
14 example moving from my living room to my kitchen, a  
15 distance of 20 feet, could be taxing. Even the simple  
16 act of leaving my home and walking to my car, a 50 yard  
17 journey that required me to traverse one flight of  
18 steps had to be planned out.

19 But in September 2012 I started medication  
20 and my symptoms and condition slowly started to  
21 improve. On a three-drug cocktail Adcirca, Tracleer  
22 and Tyvaso I have been able to take back small parts of

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1 my life. My walk distances have improved and where  
2 once walking up the front steps to my home would result  
3 in shortness of breath or light headedness now I can  
4 manage a very light workout, a walk around town with my  
5 wife.

6           Where once I had enough energy to make it to  
7 maybe one appointment a day if I was lucky; with proper  
8 scheduling I can make it to several.

9           I am fairly certain that I speak for  
10 patients, some patients, in that I hope we will be able  
11 to look back at these proceedings one day and say that  
12 this was the beginning of the end for our journey for  
13 PAH; that somehow us sharing with you today our  
14 struggles as patients will empower the FDA to work  
15 closer with our community of patients, caregivers and  
16 researchers so that we can look forward to the day that  
17 this disease is either completely in the past or that a  
18 newly diagnosed patient will have no fear of what is to  
19 come.

20           Thank you.

21           MS. GIAMONE: Thank you Kevin.

22           Holly?

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1 MR. TISSUE-THOMPSON: Hi. My name is Holly  
2 Tissue-Thompson and I was diagnosed with PAH in June of  
3 2008. I am the mother of two children. They are both  
4 boys. At the time they were three and seven. I was in  
5 the midst of potty training my youngest son and was  
6 diagnosed with this disease and was told, oh, you can't  
7 pick anything up over 15 pounds. And I was like my son  
8 is 20 pounds and I have to put him on the potty. Well,  
9 you are going to have to figure something else out.

10 So as Alex said I had to figure out a new  
11 normal and a new way of doing things. And I have done  
12 very well at doing that since being placed on  
13 medications. I am on IV Remodulin and Tracleer as well  
14 as I was placed in a study for the drug Imatinib a few  
15 years ago. That drug was not approved but I have been  
16 approved by my insurance to use it off label. After  
17 starting this drug I saw an amazing improvement in my  
18 health and decided it was worth the risks to continue  
19 on that medication.

20 The three symptoms that most significantly  
21 impact my life are the fatigue, the shortness of breath  
22 of course, and I also have as weird bloaty feeling in

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1 my belly all the time. My fluid levels are well  
2 controlled; I am not over hydrated or dehydrated. The  
3 doctor said it is just a matter of backing up blood  
4 into my liver, things like that. Sometimes there is  
5 some extra fluid there and just going out to dinner  
6 with my family is sometimes not an enjoyable experience  
7 because just eating and getting that full feeling in  
8 your belly makes it hard to breath.

9 I have continued to work as a pharmacist 24  
10 to 32 hours a week. It is very difficult to stand the  
11 eight to ten hour days. I often sleep after putting my  
12 children on the bus if it is a day off almost the  
13 entire time they are at school. And then I get up, get  
14 them off the bus, get dinner and get them to their  
15 activities. So we lead a rather busy life but it is  
16 something I prefer to continue to do due to the fact  
17 that I spent a lot of time and energy to get my degree.

18 Other things that bother me is obviously the  
19 shortness of breath. Just doing things with my  
20 children that I would like to do walking our dogs,  
21 going to the park, whatever activities they want to do,  
22 that is what I would like to be doing with them. We



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1 live in a two story house with a basement. So stairs  
2 are always an issue. I typically will leave piles at  
3 the bottom of the steps and at the top of the steps of  
4 things for my husband or my boys to bring up or down  
5 when they get home.

6 Losing this independence is a difficult thing  
7 to deal with but after six years I have wrapped my head  
8 around it.

9 Laundry is an issue, stooping down to get  
10 things out of the dryer, put things in the dryer, any  
11 of that, lifting the laundry baskets to take them to  
12 the living room to fold is also something that you deal  
13 with everyday and you wonder if that is ever going to  
14 get better.

15 As I've said the medications that I am on  
16 have helped immensely with that and with the shortness  
17 of breath I am much better today than I was six years  
18 ago. But it would be great to not have to have the IV  
19 line in your chest and be concerned about the kinking  
20 of your line, possibly your line slipping out, taking a  
21 shower with having your pump hanging outside and trying  
22 to twist around without getting tangled up.

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1           We have -- as I mentioned we have two dogs,  
2 we got them as puppies about six months before I was  
3 diagnosed. So again when I was told you need to slow  
4 down, you can't be walking as much. When I was first  
5 diagnosed, that was a very difficult thing to wrap my  
6 head around. My husband and I had bought bicycles and  
7 a cart to pull our children in right before I had  
8 gotten severe symptoms. I wish I could have logged  
9 many more hours with him and our boys.

10           When I was first diagnosed I experiences  
11 extreme pain and cramping in my legs even when I would  
12 walk my son the short distance down our driveway to the  
13 bus. The Remodulin as I said has controlled my PH  
14 symptoms as well as the Tracleer. And my six minute  
15 walk test has improved.

16           About two years after my diagnosis my disease  
17 had progressed and I was put on the lung transplant  
18 list. But at that same time was when my doctor  
19 mentioned the trial of the Imatinib drug and I decided  
20 to give that a try and amazingly enough I have improved  
21 enough that I am just waiting to put the transplant on  
22 hold.

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1           Life with PH is a roller coaster of ups and  
2   downs. Some days are good, some days are bad. There  
3   is always that week or two that you think everything is  
4   going smoothly and then suddenly you find out it is  
5   not. Your cu-site that you attach your medicine to  
6   your IV catheter might get a crack in it and you didn't  
7   realize it. Later you have a spot of blood on your  
8   shirt and you're panicked at work, what is going on?  
9   And you have to go and remix your medicine. Just  
10  remixing and reconnecting doesn't make the problem go  
11  away. You then have to deal with the flushing, the  
12  headache and all of that all over again.

13           I have occasionally had problems with my line  
14  cracking or it even slipped out once. So I had to make  
15  an emergency trip to the emergency room and stay a few  
16  days to get a line replaced. So PH although we have a  
17  new normal is a ride of up and down that we have to  
18  take our family on.

19           MS. GIAMBONE: Holly. Thank you.

20           Nicole?

21           MS. MATTHEWS: My name is Nicole Matthews. I  
22  am 35 years old and I was diagnosed with Pulmonary

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1 Arterial Hypertension in 2012. It was the end of Heart  
2 Disease Awareness month and I remember that because  
3 there had been so much discussion that month about the  
4 different symptoms. And I woke up at about one o'clock  
5 in the morning with severe chest pain and heart  
6 palpitations. And at first I tried to rationalize it  
7 thinking I am 30, I am healthy or relatively healthy, I  
8 shouldn't be a candidate for a heart attack. But I had  
9 had a classmate from high school pass away from a heart  
10 attack a month before so I thought I should go to the  
11 emergency room.

12           After a few tests and several hours the  
13 emergency room doctor came to me and said I wasn't  
14 having a heart attack but before I could breathe a sigh  
15 of relief he said you do have pulmonary hypertension  
16 and we can't let you go home but we are going to have  
17 someone come and talk to you about life going forward.

18           I remember the phrase life going forward  
19 because it just seemed so final. And after doing some  
20 research and talking to the doctor on the staff I  
21 understood why.

22           I went through a battery of more tests and

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1 finally got transferred to a specialist who performed a  
2 right heart catheterization to confirm the diagnosis.

3           During the first year after my diagnosis I  
4 often dealt with extreme fatigue, shortness of breath,  
5 heart palpitations and dizziness and the same chest  
6 pain that sent me to the emergency room in the first  
7 place.

8           The fatigue started with me just being  
9 groggier in the morning but it progressed to me falling  
10 asleep at my desk at work. I've fallen asleep at a  
11 stop light. And I have fallen asleep in the driveway  
12 waiting for the garage to lift up.

13           I do have more energy today with the  
14 medication I am on but on the weekends I still need a  
15 minimum of about 12 hours of sleep.

16           The remaining symptoms that arose for me with  
17 even small amounts of physical activity were dizziness,  
18 lightheadedness, I've fainted multiple times. And just  
19 as an example before pulmonary hypertension I was very  
20 active. I have Lupus and have had it for a while but  
21 it has been under control with the use of medication  
22 for several years. I exercise regularly. I would walk

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1 our dogs in the park. My husband and I would go hiking  
2 and that kind of thing. And we had planned you know for  
3 children. Pulmonary hypertension stopped all of that.

4 Walking around the grocery store or walking  
5 from the parking lot to my office became a major task.  
6 I don't know why I am getting so emotional. Excuse me.  
7 My heart would flutter or I would get lightheaded just  
8 walking the aisles of the grocery store. I would have  
9 to stop for frequent rests because I would pass out if  
10 I didn't.

11 Sleeping at night I would have to sit up and  
12 if I laid down I would feel pressure on my chest as if  
13 I couldn't breathe and that made sleeping difficult  
14 because you are scared that you are going to pass away  
15 in your sleep.

16 I would have trouble talking for  
17 presentations and I didn't say my career in the  
18 beginning, I am an attorney, so I have to stand up in  
19 court a lot, I have to make arguments and that kind of  
20 thing and it is really a high pressure job. So the  
21 thought of not being able to give an opening argument  
22 or to be able to present an argument on behalf of a

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1 client effectively was horrible to me after all the  
2 work I had put in for school to get my degree.

3           On more severe days any amount of walking  
4 would lead to chest pain and dizziness. There were  
5 times when walking from the parking lot to my office  
6 that I would have to stop and rest in the parking  
7 garage for fear that I would pass out and no one would  
8 be able to find me.

9           The symptoms were made worse if I tried to  
10 climb the stairs. And we actually live in a three  
11 level townhouse and so there were oftentimes where I  
12 would just sleep in the living room instead of making  
13 it up to bed.

14           I am lucky that I have a job that understands  
15 my symptoms and that has been really understanding  
16 about letting me work from home when I need to. But if  
17 I have a meeting and I need to go in I always have to  
18 have oxygen available. So I keep a tank in my office,  
19 a tank in my car and obviously multiple tanks and a  
20 concentrator at home. The ability to travel for my job  
21 is greatly diminished because I can't fly without an  
22 oxygen concentrator which adds on pretty much another

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1 person traveling with you because you have to pay for  
2 rental of the concentrator is your don't own one, you  
3 have to get all of these clearances through security at  
4 the airport which as I am sure all of you can relate is  
5 already difficult enough. And it becomes a severe  
6 process which means I elect not to fly when I don't  
7 have to taking away some of the conferences and travel  
8 opportunities I would have for my job. But at least I  
9 am lucky enough to have the energy to still be working.

10           It is clear that my life totally changed  
11 after I developed pulmonary hypertension. Exercising,  
12 playing with our dog in the park, hiking with my  
13 husband were all eliminated for a while. And the  
14 fatigue caused by my symptoms and the physical issues  
15 that I developed left me without energy or ability  
16 actually to keep up.

17           Today however I am a little over two years  
18 from my diagnosis and I've gotten the right medical  
19 cocktail down with the help of a great medical team  
20 back home in New York. I take Sildenafil, I take  
21 Tracleer and I do an inhaled prostacyclin called  
22 Ventavis. I do six to nine treatments a day. With



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1 those medications if I compare this year to the year I  
2 was diagnosed I can say that my symptoms are minimal.  
3 There are still moments where I am short of breath or  
4 have chest pain but it occurs mostly with intense  
5 exercise. I am able now to walk on the treadmill and  
6 do zumba classes whereas two years ago I wasn't able to  
7 walk the 50 feet from my car to the elevator at my  
8 building or even up the stairs from my living room to  
9 my bedroom.

10           There are still days where my oxygen levels  
11 are very low. And I feel short of breath and  
12 lightheaded just walking around the house or trying to  
13 do normal household chores. I do have an oxygen  
14 concentrator in my home for those days. And if I am  
15 mobile I will use my portable oxygen.

16           Today because of the medication and I feel  
17 keeping my faith first I can say that I feel pretty  
18 normal but like everyone else on the panel has said it  
19 is a brand new normal. There are things that we have  
20 to consider that our friends don't have to consider.  
21 You know you will have friends who will call and say  
22 oh, let's go out for cocktails or friends who say let's

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1 plan a trip and go away and those are things that I did  
2 easily before and now it is a big planning process or  
3 it is just a no because I physically can't do it.

4 That is it.

5 MS. GIAMBONE: Thank you so much Nicole.

6 It takes a lot of courage to come and share  
7 such personal stories with a large group so I want to  
8 give -- can we all give our panel a round of applause.

9 [Applause.]

10 MS. GIAMBONE: Thank you to all of you for  
11 coming and sharing those experiences with us. So  
12 before I move on if you are comfortable to do so can we  
13 have a show of hands and see how many of you heard your  
14 own experience shared by one of our panelists, at least  
15 one of our panelists?

16 It looks like many of you did. And I saw a  
17 lot of heads nodding as our panelists were speaking; so  
18 we are looking forward to hearing what you have to say.

19 So before we move on to our polling question  
20 also we do have one polling question to sort of kick  
21 off our group discussion. There are a lot of  
22 interesting points that came up and I'm curious to see

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1 how many of you also share that.

2           So we heard that weather can impact your  
3 symptoms. By a show of hands how many of you agree  
4 that weather has impacted your symptoms.

5           Okay. And we also heard photosensitivity. By  
6 a show of hands, anybody else share that experience.

7           Okay. All right. Well we will be hearing  
8 from you in just a moment. But let's do our next  
9 polling question. Okay. So everybody have your  
10 clickers. All right. So of all the symptoms you have  
11 experienced -- oh, you can stay here, do you have your  
12 clickers or no? Oh okay. We will get you some. Do  
13 you have your clicker? Okay. Good. Thank you Sara.

14           So of all of the symptoms you have  
15 experienced because of Pulmonary Arterial Hypertension  
16 which do you consider to have the most significant  
17 impact on your daily life and you can choose up to  
18 three: A pain, such as chest pain; B shortness of  
19 breath, wheezing or other breathing difficulties; C  
20 dizziness, fainting or lightheadedness; D fatigue; E  
21 swelling such as swollen ankles or legs; and F other  
22 symptoms not mentioned. If you can all enter your --

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1           So here are the results and I believe that  
2 our panel has shared many of these symptoms also. So  
3 the one that came up the most was B shortness of  
4 breath, wheezing or other breathing difficulties, so  
5 87% of you said this is the most significant symptom.  
6 We also have D fatigue followed by it looks like C and  
7 E, so dizziness, fainting or lightheadedness and  
8 swelling such as swollen ankles or legs. And we did  
9 have a little bit of pain such as chest pain and other  
10 symptoms not mentioned. So I would like to check in  
11 towards the end of this dialogue, maybe we can check in  
12 and see what are some of those other symptoms that  
13 haven't been mentioned?

14           And we will get to the fatigue in just a  
15 moment but does anybody want to share -- oh, let's  
16 check in with the web. Thank you. Let's check in with  
17 the web.

18           MS. VAIDYA: So on the web it seems like  
19 fatigue and shortness of breath are the main two top  
20 symptoms followed by dizziness, fainting or  
21 lightheadedness. We do have several who mentioned  
22 other symptoms. So there are people on the web as well

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1 who said that there are other symptoms that they  
2 experienced. So we can get to that later.

3 MS. GIAMBONE: Okay.

4 MS. VIADYA: Thanks.

5 MS. GIAMONE: Great. Thank you.

6 So let's spend just a few more moments on the  
7 shortness of breath. So does anybody want to start our  
8 conversation today and tell us how you experience  
9 shortness of breath? Do you experience it differently  
10 than what you've heard from our panel? Anybody want to  
11 share your experience. Oh yes we have a hand.

12 MS. ISA: My name is Deborah Isa. Mainly  
13 when I climb hills it really has -- not stairs just  
14 flat going up the hill it makes me have a lot of chest  
15 pain and I'll be [huffs and puffs] even with oxygen on.

16 MS. GIAMBONE: Okay. Thank you very much  
17 Deborah. Yes.

18 MS. HARRINGTON: Thank you. My name is  
19 Kathleen Harrington. It impacts me -- I am always  
20 feeling like there is a tightness in my chest and that  
21 I can't get enough air and I've definitely had to alter  
22 my activity level. But I can think you know the

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1 hardest thing right now is that I have an almost four  
2 year old son and I read to him every night and I have  
3 to pick books that don't have long sentences or it has  
4 to be a lot of pictures, a lot of one or two sentences  
5 at a time. Otherwise I tell Dad he has to read. But  
6 that is -- my son is always saying no I want mommy to  
7 read. And so that is really hard not to be able to  
8 read a book to my son.

9 MS. GIAMBONE: Thank you Katherine.

10 In the back.

11 MS. MAXWELL: Hi my name is Nancy Maxwell. If  
12 I keep to my own slow pace I can walk a good distance  
13 without really feeling a shortness of breath. But  
14 almost immediately with bending or twisting I'll feel  
15 shortness of breath. Loading and unloading the  
16 dishwasher I heard people mention that; doing laundry,  
17 anything that take lateral movement I feel shortness of  
18 breath extremely quickly. So I just wanted to say  
19 that.

20 MS. GIAMBONE: Thank you Nancy.

21 Anybody else?

22 So we've heard from the panel and also I just

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1 heard you say Nancy that you have to sort of pace your  
2 day and plan your day. Does anybody want to share  
3 their experience with how that helps the shortness of  
4 breath symptom or how does that impact what an average  
5 day with shortness of breath is like if you are able to  
6 sort of plan out your day and pace what you are doing?  
7 Or maybe you can share with us what does that average  
8 day look like experiencing shortness of breath versus a  
9 more severe day?

10 MS. BROWN: I experience shortness of breath  
11 when I exert myself. So on a daily basis I have to  
12 decide okay today I can't go to the supermarket today  
13 and do the laundry at the same time. I have to make a  
14 list of non-exerting stuff and stuff that is exerting.  
15 So I have to make a conscious decision and say okay  
16 today I will do these five things and two of the five  
17 must be things that I have to exert myself in. So I  
18 can't just get up in the morning and says okay I have  
19 the laundry to do, the dishes to do, I have to go to  
20 the supermarket. No. I have to make a conscious  
21 decision today I am going to do the laundry.  
22 Supermarket will have to stay until tomorrow even if

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1 there is no food in the house. You know stuff like  
2 that.

3 MS. GIAMBONE: Thank you.

4 MS. BROWN: Oh my name is Marcia Brown.

5 MS. GIAMBONE: Thank you.

6 Anyone else? Yes.

7 MS. PIXLER: My name is Tammy Pixler. And  
8 basically every day that I wake up I live in a three  
9 story townhouse and I live by myself. So every morning  
10 when I wake up I determine what I need to do because I  
11 need to minimize going up and down the steps. So if I  
12 have outside appointments, that means I stay in my  
13 room, I get dressed, I get showered. I do everything  
14 that I need to do upstairs before going downstairs to  
15 let the dog out, to make my coffee and to take on the  
16 rest of my day. If I am not going out that means I can  
17 just get up and go down and get my coffee right away.  
18 So it is all about chopping up your day and trying to  
19 figure out what you can do. Things take longer because  
20 cooking you really have to take into consideration how  
21 you are going to have to plan things because it does  
22 take longer because you have to chop up the vegetables



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1 and then sit back and take a break and you know do  
2 another piece. I do laundry by carrying it step by  
3 step up the stairs because I can't do it. And I just  
4 move it around from level to level. When people come  
5 over I am like hey can you get that laundry upstairs or  
6 downstairs. I take advantage of people when they come  
7 over. And then I also do grocery deliveries and stuff  
8 like that. But it really is your whole perspective of  
9 things that you used to take for granted it is just --  
10 it is amazing. And yeah bending over my goodness,  
11 bending over is not a good thing. So I understand all  
12 this stuff as well.

13 MS. GIAMBONE: Thank you Tammy. I saw a lot  
14 of heads nodding. It sounds like it is a similar  
15 experience, a shared experience.

16 Yes another comment here.

17 MS. HAMILTON: I can use -- my name is  
18 Blanche Hamilton. I can walk about one mile on a  
19 treadmill indoors without any problem. I can barely  
20 walk a block outside. It is a lot more difficult to  
21 walk in air, no matter, the outside no matter whether  
22 it is warm or cold, whatever, it is just very

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1 difficult.

2 MS. GIAMBONE: It is very interesting. Let's  
3 do a show of hand here. Does anybody share that  
4 experience that being outside versus inside - being  
5 outside is more difficult with breathing?

6 Okay. Good to know.

7 Tammy, hang on. Let's get you on microphone.

8 MS. PIXLER: No I am the same way. If I am  
9 outside and I am on oxygen but it is much harder for me  
10 to get around or get down an aisle at the grocery store  
11 because I'll put my oxygen in the cart and push it but  
12 it still takes forever. But at home I can do the same  
13 thing, I can get on the treadmill, I have to crank up  
14 the oxygen really high but I can go on the treadmill  
15 for like 20 minutes very easily and not be too terribly  
16 short of breath. So I understand what you are saying.

17 MS. GIAMBONE: Okay. And we will take one  
18 more comment and then we can check in with the web  
19 also.

20 MS. MAXWELL: Thank you. For me the weather  
21 has become a major issue. I live in the Washington,  
22 D.C. area and it is so hot and humid here in the

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1 summers. I was a school counselor for the past 15  
2 years until last week disability was approved sadly.  
3 But in the summers I have been spending as much time  
4 with friends and family in the northeast as possible  
5 because I can just breathe when I am there. If I am at  
6 home I am completely home bound all summer and as you  
7 can imagine with a small child that is not fair to  
8 either one of us. So definitely weather hot and humid  
9 makes it very hard to breathe.

10 MS. GIAMBONE: Okay. Thank you.

11 Let me check in with the FDA Panel did you  
12 have any follow up questions regarding this particular  
13 symptom.

14 Okay.

15 Can we see what is coming in on the web?

16 MR. THOMPSON: Yeah, so we have a lot of  
17 similar comments from people talking about shortness of  
18 breath, fatigue, exhaustion, mentioning that activity  
19 outside is more difficult than inside. We also had  
20 several people mention weather sensitivity and light  
21 and heat sensitivity and one person also put a lot of  
22 emphasis on irregular heartbeats usually from exertion

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1 but sometimes just spontaneously.

2 MS. GIAMBONE: Okay. Thank you Graham.

3 So I think this is a good lead in for the  
4 next symptom that came up in the polling which was  
5 fatigue one of the most significant symptoms being  
6 fatigue. So we've heard exhaustion now, we've heard  
7 from the panel also their severe days of exhaustion and  
8 so forth. So does anybody want to share their  
9 experience with the fatigue?

10 Yes.

11 MS. WILLIAMS: Hi, my name is Debbie  
12 Williams. And I just wanted to say you get tired doing  
13 anything that requires oxygen. And that is like 90,  
14 95% of everything that you do. Thinking takes oxygen,  
15 talking takes oxygen. I had a friend come over to help  
16 organize my house so it was much more convenient for me  
17 a few weeks ago and Shari did all the work. I just sat  
18 in a chair and told her save this, put this in front,  
19 put that in back, things like that. She picked  
20 everything up, she moved everything. I just went around  
21 from room to room, sat in a chair and told her what to  
22 do. But I had to think about what we were doing. I

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1 had to tell her what to do. Shari left at five o'clock.  
2 And I decided I need to rest a little bit before I  
3 started supper. I went in and laid down around 5:30, I  
4 woke up at 8:00 the next morning. Just talking, just  
5 thinking all day, that is it.

6 MS. GIAMBONE: Thank you for sharing that.  
7 Again I saw heads nodding.

8 So let me ask you a follow up question with  
9 the fatigue. Is it the type of fatigue where you --  
10 and I feel like we've heard a little bit of both, is it  
11 the type of fatigue where you need to pretty much sleep  
12 to overcome that. Or is it the type of fatigue where  
13 you need to maybe take more rest. Is there a way to  
14 tease that out? Or is it both. Does anybody want to  
15 speak to that?

16 Oh we have a hand back there.

17 MS. BROWN: My name is Burdine Brown. The  
18 fatigue for me it doesn't -- I don't do a lot of  
19 sleeping but I do need to rest for instance it can  
20 take me like four hours to just clean up my living room  
21 or something or almost all day to do one room but then  
22 when I finish if I sit down I don't really have to

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1 sleep. Matter of fact I don't do a lot of sleeping but  
2 some days you know my PH really doesn't hinder me a  
3 lot. At least I don't let it. So I am very active.  
4 And I could be gone for days, you know just go day  
5 after day after day and then I'll realize that I am  
6 really tired and then one day I will sleep all day. But  
7 as a rule I can go all day and I am good.

8 MS. GIAMBONE: Thank you Burdine.

9 Anybody else? Yes we have.

10 MS. VOLPE: Yes my name is Joann. I'm from  
11 Connecticut. And I've had it over 20 years and I found  
12 just recently I had a sleep study test and it really  
13 made a lot of difference now that I have the mask  
14 because I find I am not as tired in the morning. I get  
15 up, I am not yawning and I do still tend to have a  
16 little down time in the afternoon like between 3:00,  
17 4:00, 5:00 I have to rest, then I am okay. But like  
18 that other lady said I don't really require a lot of  
19 rest. Or maybe I fight it. I don't know. I am always  
20 on the go also and it -- the fatigue is there but I  
21 find the shortness of breath is more difficult.

22 MS. GIAMBONE: Thank you.

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1 Yes, we have somebody.

2 MS. COOPER: Hi my name is Nicole Cooper and  
3 I want to comment about fatigue. I think with some --  
4 people think that fatigue is you exert yourself when  
5 you are doing something. With PH you can sit in the  
6 chair for five hours and do nothing and get up and feel  
7 like you have ran back and forth in this room for  
8 thirty minutes. And you can absolutely just sit and do  
9 nothing.

10 MS. GIAMBONE: I see a lot of heads nodding.  
11 Nicole I think that sounds like it resonates with a lot  
12 of people.

13 Does anybody else want to talk about how they  
14 experience fatigue?

15 Yes, Holly.

16 MS. TISSUE-THOMPSON: As I stated I am a  
17 pharmacist so I work many hours on my feet which causes  
18 the chest pain and the fatigue. Luckily my work is  
19 nice enough that I can never work three days in a row.  
20 Two days I can do, three days is impossible. But after  
21 that two days I'm done for for the next day at least.  
22 Typically that next day after I am still resting and I

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1 tell the girls at work it is not -- I don't think it is  
2 the fatigue that I felt before I was sick. It is a  
3 different fatigue. I don't know how to describe it but  
4 there is a PH tired and there is a I'm tired. And it  
5 is just a totally different feeling.

6 MS. GIAMBONE: Yes, Alex. Thank you Holly.

7 MS. FLIPSE: I get both the I need to sleep  
8 as well as I need to just sit and rest. And when I  
9 need to sleep it is like an all of a sudden crash.  
10 Where it is like I am doing well, I am doing well and  
11 bam I need to go to sleep. That happens frequently to  
12 me. Also taking showers is very exhausting and on  
13 really really bad days I have a shower chair. And  
14 walking like I said before I have a wheel chair that -  
15 - a companion chair that like going to the zoo or  
16 whatever that I use as well.

17 MS. GIAMBONE: Thank you Alex.

18 Does that sound like it is a similar  
19 experience? Yes.

20 Holly brought up a point that I want to  
21 expand on just a bit. You talked about experiencing  
22 this particular symptom fatigue before PH and after,



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1 sort of a how it used to be before you were diagnosed  
2 versus what it is after PH. Can somebody talk to us  
3 about how your symptoms have changed over time? So  
4 what -- how did you experience a symptom maybe early on  
5 the diagnosis versus later on? Okay we have a few.  
6 Let's start there.

7 MS. DOYLE: Hi my name is Stacie Doyle. I  
8 have had PH for seven years now. In the beginning I  
9 used to use Ventavis and Tracleer, so I could pretty  
10 much do anything with stopping and resting. I was  
11 still very active. I still work full time. And I have  
12 a ten year old daughter. I was able to go on vacation  
13 and swim. I could even snorkel. And about a year ago  
14 I got progressively worse and I am now on Remodulin  
15 Subcu Pump and that has helped me in terms of my heart  
16 and being able to do things but the side effects of the  
17 medication has limited me more in some ways than the  
18 condition itself I feel. So I'm at a dilemma in terms  
19 of what I am able to do. I still work full time as I  
20 said. I am trying to push through this and wait for the  
21 next level of drugs to come out to help me become  
22 normal again so that I can do the things I used to be

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1 able to do if that is even possible. I do do things on  
2 the weeks when I don't have the pain. I walk. I still  
3 try to go out dancing with my family and my sisters but  
4 then I pay for it the next day and as you said with  
5 fatigue and having to sleep and recover. So it does  
6 limit what you are able to do over time. And but I  
7 have hope that some of the medications will enable us  
8 to get more of our activities back on track and we can  
9 do things that we used to be able to do if that is  
10 possible.

11 MS. GIAMBONE: Thank you for sharing that.  
12 And we had someone here.

13 MS. FRAZER: Hello. My name is Rosalind  
14 Frazer. I was diagnosed 12 years ago with PH and I  
15 started off exactly where these patients are talking  
16 about taking two hours to shower to get from the shower  
17 to the bed, from the shower to the toilet to sit and  
18 then to just get to the bed and feel like I have done  
19 it all -- my son was eight at the time. And I remember  
20 not being able to walk up a flight of stairs or to -- I  
21 was a dance instructor when I first got diagnosed and I  
22 kind of thought hey what is wrong because I was

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1 teaching dance and then next day or week I was unable  
2 to walk up stairs or anything like that. And then they  
3 diagnosed me with PH. And I remember my doctor saying  
4 to me on a scale of one to ten I was probably at a nine  
5 at needing a lung transplant. 12 years later I can do  
6 a full class of zumba and then go on the treadmill, do  
7 the elliptical, I can -- I work full time as a social  
8 worker. I am no longer in the field but I did field  
9 work just last year and I have a very busy schedule. I  
10 had stopped dancing and just directed and choreographed  
11 but now I dance again with my dance ministry. And I do  
12 also like a hand dance, not kicking and all that but I  
13 can do like hand dance for 45, 50 minutes for our  
14 routines. So my life has totally gone back to normal.  
15 The only thing that I can't do is swim because you  
16 can't get the pump wet. But otherwise to that I feel  
17 like I live a totally normal life. So I just want to  
18 encourage everybody that 12 years later you can feel  
19 100% normal outside of just having the pump. People  
20 don't even know that I have anything wrong with me  
21 because I am even more active than some people -- a lot  
22 of people that I am with who are just normal. So you

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1 can eventually become feeling just completely normal.

2 MS. GIAMBONE: Rosiland thank you for sharing  
3 that.

4 So to recap it sounds like we are hearing  
5 both sides. We are hearing that with time some of the  
6 symptoms are getting progressively -- are progressing  
7 and becoming worse and Rosiland has had the opposite  
8 experience in some aspects of the symptoms and so  
9 forth.

10 MS. FRAZER: Initially I started off on  
11 Flolan and now I am on Veletri which is still the  
12 infusion drug and I am on Adcirca. I was initially on  
13 Revatio which is Viagra but I am not on that anymore.  
14 And I am on Letairis and I know my doctors are thinking  
15 about the oral Remodulin. So right now I am on two  
16 oral meds and the infusion pump.

17 MS. GIAMBONE: Thank you Rosalind.

18 Anybody else want to share their experience  
19 with how their symptoms have changed over time?

20 Yes, Alex.

21 MS. FLIPSE: So like I said before I passed  
22 out 30 times in a three month period before I was on

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1 Flolan and I can pretty much walk as far as I you know  
2 inside like I said but and then also the different  
3 things that I can do now that I couldn't do before that  
4 would make me pass out, that would make me dizzy and  
5 that sort of thing. I can do those things now again.  
6 And I am not at 100%, definitely not. I would probably  
7 say I am at 70% from before but definitely things are  
8 getting better. But at the same time I can also feel  
9 myself declining a little bit. My six minute walk has  
10 dramatically increased. I just did one a couple --  
11 well last week I guess it was and I increased more than  
12 100 feet. So it definitely has gotten better.

13 MS. GIAMBONE: Thank you Alex.

14 Now I remember that one of the other symptoms  
15 that came up was pain, such as chest pain. And on that  
16 note we've also heard that pain can manifest itself as  
17 chest pain, we heard leg pain. Does anybody want to  
18 share their experience with how you are experiencing  
19 the pain? Is it similar? Or is there a different pain  
20 that you are experiencing?

21 Did I see a hand back there? Okay.

22 Let me ask you a follow up question. Is

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1 there a particular symptom that can make another  
2 symptom worse?

3 Yes. Okay. Do you want to share that  
4 experience with us?

5 MS. FEENEY: Hi. My name is Patricia Feeney  
6 and I am from Connecticut. I've had pulmonary artery  
7 hypertension for four years. Now the pain that I  
8 experience was the fact that I had a heart attack and  
9 triple bypass and then a year after when I was still  
10 feeling heaviness in my chest and pain my cardiologist  
11 sent me to a great, great lung specialist. They did  
12 try me on several inhalers. They at first thought I  
13 had asthma, your typical symptoms, asthma, emphysema,  
14 so I went through a lot of different type of inhalers  
15 before they actually sent me to a specialist in  
16 pulmonary artery hypertension. And he tested me. I  
17 did walk tests, I had every kind of test you can  
18 possibly think of and that is when they found out the  
19 chest pain I was experiencing was actually from the  
20 shortness of breath, the tightness in my chest, I feel  
21 it more with weather change. I can relate to  
22 everything they are saying. Many go along without

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1 having or experiencing having a heart attack and having  
2 a triple bypass. So it is very hard to distinguish  
3 between the two; the tightness, the heaviness, the  
4 shortness of breath.

5 But thankfully they resolved it and I see my  
6 doctors on a regular schedule and I am on Remodulin  
7 which is and I have an IV in my chest and it is  
8 probably the greatest thing that has happened to me. I  
9 was a hair dresser for 44 years. Unfortunately the one  
10 thing I love the most in my life I had to give up. But  
11 I thank God because they solved the problem. It wasn't  
12 -- I blamed the chemical, ladies, having my hair done  
13 and doing other people's hair but it is not the  
14 chemical and I realize it now. It took a long time for  
15 me to accept it and acceptance is part of your healing  
16 process.

17 MS. GIAMBONE: Thank you for sharing that.

18 MS. FEENEY: You're welcome.

19 MS. GIAMBONE: Thank you. So let's do a  
20 quick show of hands before I go on to the FDA Panel and  
21 we will check in with the telephone in just a moment.  
22 We talked about pain, chest pain, tightness in the

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1 chest, by a show of hands how many of you can relate to  
2 that feeling of the tightness in the chest.

3 Okay. Great.

4 Any follow up questions. Yes. Ellis.

5 MR. UNGER: Maybe we could do this with a  
6 show of hands but I'd be interested in seeing a show of  
7 hands for an answer to this question, multiple choice.  
8 If a drug could fix one of your symptoms, which would  
9 you pick and I think the answers would be shortness of  
10 breath, fatigue and chest pain. And I would like to  
11 see a show of hands.

12 MS. GAIMBONE: Okay. Great question. So  
13 let's start with the shortness of breath would you want  
14 to address that as the main symptom that a drug could  
15 fix? Okay. I see a lot of hands there and here to.

16 How about fatigue? Okay. You can raise your  
17 hand for both if you would like.

18 And the third one was chest pain. Okay. This  
19 is interesting to see.

20 MR. UNGER: Yeah, I saw about 18 hands for  
21 shortness of breath and about nine for fatigue and none  
22 for -- I didn't see any for chest pain. Does that seem



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1 right?

2 MS. GIAMBONE: Yes.

3 MR. UNGER: About half as many.

4 MS. GIAMBONE: Yes, I didn't see any for  
5 chest pain either.

6 Yes, Theresa?

7 MS. MULLIN: Soujanya can we ask that  
8 question of the people on the web cast. I don't know  
9 if you can but --

10 MS. GIAMBONE: Yes, definitely. Let's -- is  
11 there a way to sort of type that out or get their?

12 MS. VAIDYA: We have gotten some responses.  
13 So they have mentioned shortness of breath, fatigue and  
14 chest pain on the webcast. So we can't get an  
15 approximate number but about a handful have responded  
16 to each.

17 MS. GIAMBONE: Okay. All right. Good to  
18 know.

19 Okay. And I just want to take a minute. We  
20 did see some other symptoms not mentioned come up in  
21 the polling. Does anybody want to share a symptom that  
22 they are experiencing that we haven't talked about yet?

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1 Yes.

2 MS. LEVINE: Hi. My name is Lynn Levine. I  
3 was diagnosed about three years ago with PAH. I don't  
4 know if this falls into a symptom but ever since I have  
5 had the PH I tend to get a cough that turns into a cold  
6 that turns into bronchitis and I have been fortunate I  
7 haven't actually gone all the way to pneumonia though I  
8 have had at least twice when my pulmonologist did chest  
9 x-rays because they thought that I was that far along.  
10 For me it happens -- it is not a specific season. I  
11 can get a winter cold. I can get a summer cold. But  
12 normally before PAH I would get a cold, it would take a  
13 few days, it would be over. This becomes a four to six  
14 week experience sometimes with an enormous amount of  
15 coughing for many of those weeks. So I definitely  
16 associate that with PAH and it just I want to bring it  
17 up. I think somebody mentioned something about  
18 bronchitis perhaps. But for me it is a very significant  
19 event that repeats itself, three four times a year now.

20 MS. GIAMBONE: Thank you. So it sounds like  
21 from what I understand a higher frequency of colds and  
22 bronchitis and they last longer too, those episodes. Do

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1 others share that experience? Yes, Alex?

2 MS. FLIPSE: So we are a family of singers.  
3 We sing constantly. And when I was first diagnosed,  
4 before I was diagnosed and then even on Flolan I lost  
5 my voice. I could barely talk, I was hoarse like crazy  
6 but I could not sing at all. And it was during  
7 Christmas and that made me very depressed that I  
8 couldn't sign at Christmas. But changing of the voice  
9 was something that was very difficult to deal with for  
10 me.

11 MS. GIAMBONE: Okay. Thank you Alex.

12 Yes, Colleen?

13 MS. CONNOR: Yes typically I was never -- I  
14 never had a chest cold in my life until I had Pulmonary  
15 Hypertension. And then when I get them I usually get a  
16 fever, it turns into bronchitis, they treat me then and  
17 there for pneumonia because it typically turns into  
18 pneumonia, sometimes even with the medicines that they  
19 give me. Several times they have wanted to hospitalize  
20 me but they hesitate to do that because my local  
21 hospital is not authorized to deal with the  
22 prescriptions that I am currently taking, the IV

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1 medications, they don't have the facilities to mix it  
2 or administer it to me. And our greatest fear is that  
3 I'll catch another infection on top of all the  
4 infections that I currently have at that time. So we  
5 in the end always decide to treat me at home as if I am  
6 in the hospital and the doctor staff calls me daily to  
7 make sure that I am progressing in the right way. But  
8 it is very scary when you need to sleep sitting up  
9 because you can't lay down at all and you have trouble  
10 walking a couple of feet because even the shortest or  
11 most shallow breathe causes a coughing fit that you  
12 can't recover form and you know that you are blue and  
13 you start to feel anxious. And so it is scary to be in  
14 that position when it does happen. And it seems like  
15 it is unavoidable so we try very carefully to you know  
16 in my house I have soap dispensers that give me soap  
17 and separate hand towels because I have two young  
18 children in two different schools, so my thought is I  
19 am dealing with at least a thousand germs every day  
20 coming into the house. So we try to go out of our way  
21 because it is so scary to my kids to see me not be able  
22 to talk or move or to if I breathe just more the most

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1 shallow breathe going into a coughing fit that I can't  
2 recover from and they don't even want to be there.  
3 They are scared. So it is all of those things that  
4 come into it too and that is all directly related to my  
5 PH.

6 MS. GIAMBONE: Okay. Thank you.

7 So it sounds like coughing is -- let me do  
8 one thing. Let me check in with the phone. We are a  
9 little bit short on time. So let me check in and see  
10 if we can bring some callers in.

11 OPERATOR: Yes, we do have a question from  
12 Orna Levy. Your line is open.

13 MS. LEVY: Hi. It wasn't so much of a  
14 question as an additional experience. So in my case  
15 five years ago I weighed 500 pounds. I thought I was  
16 obese. I was preparing to do a gastric bypass surgery.  
17 And it turned out that I was swollen not fat once they  
18 cut me open. So I was eventually diagnosed with severe  
19 Pulmonary Arterial Hypertension. I was sent to a  
20 different hospital where they knew how to treat me and  
21 I was hooked up immediately with IV Remodulin with a  
22 little pump that I wear in my back pocket. And it

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1 turned my life around because I lost 300 pounds of  
2 fluid in one year. The first hundred pounds I peed in  
3 the first month in the cardiac ICU. So when I talk  
4 about swelling I talk about that kind of swelling it is  
5 severe swelling. So we were talking about different  
6 symptoms. That is my biggest symptom. I have to watch  
7 my sodium very closely. I stick to 1500 milligrams a  
8 day. And if I go out to dinner I am going to gain  
9 weight that day, not because of whatever fat content  
10 there might be in the food but because of the sodium  
11 content. So I don't drink coffee anymore or drink  
12 anything with caffeine in it at all. I have given up  
13 soda and I - because it is a vaso-constrictor anything  
14 that constricts my blood vessels affects me quite  
15 immediately. And like if I inadvertently get served  
16 something with caffeine I get chest pains. I feel it.  
17 So that is to me the biggest thing that affects my  
18 life. I gain and lose five pounds in a day and I gain  
19 and lose 20 pounds quite easily across the span of a  
20 week.

21 MR. GIAMBONE: Thank you for sharing that.  
22 And you didn't see but there were quite a few heads

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1 nodding when you talked about the controlling the  
2 sodium in your diet I saw a lot of heads nodding in the  
3 audience. So thank you for sharing that thought with  
4 us.

5 Operator can we have one more caller.

6 MR. THOMPSON: That is actually it for phone  
7 calls right now. If other people want to call in,  
8 please follow the instructions as we do have a few more  
9 thoughts from the webcast.

10 OPERATOR: And there are no questions in  
11 queue at this time.

12 MS. VAIDYA: So on the web we have for other  
13 symptoms, we have loss of voice that was mentioned by  
14 one of the web participants and anxiety and depression.  
15 We also have when going into talking about fatigue a  
16 participant talks about the erratic nature of fatigue.  
17 And another mentions feeling as if he or she has just  
18 pulled an all nighter, so a bit of confusion, being  
19 confused and exhausted. Another participant actually  
20 mentions dealing with not looking sick which is a  
21 problem because people don't consider them to have any  
22 issues. So that is it for the web at the moment.

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1 Thank you.

2 MS. GIAMBONE: Thank you Pujita.

3 Anymore final questions from the FDA Panel?

4 Yes, Ellis?

5 MR. UNGER: I have one more. So one of the  
6 panelists mentioned a six minute walk and going an  
7 extra hundred feet. I wonder how many people here have  
8 a six minute walk test on some kind of a repeat basis  
9 and pay attention to it, keep track of it, show of  
10 hands.

11 MS. GIAMBONE: Okay. Great. So the question  
12 was how many of you have a frequent six minute walk  
13 test. It looks like pretty much the majority of the  
14 patients and patient rep. Yes. Okay.

15 Ellis was that -- did that answer your  
16 question?

17 MR. UNGER: Yes, that is huge. Thank you.

18 MS. GAIMBONE: Okay. Great.

19 Well I want to thank you all for  
20 participating and sharing so many experiences on Topic  
21 1. We've learned so much from you on the symptoms, the  
22 shortness of breath, the chest pain, how you experience



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1 it and the activities that it limits you on. So thank  
2 you for that.

3 Let's take a break. And when we come back we  
4 will pick up with Topic 2.

5 Thanks everyone.

6 (WHEREUPON, a break was a taken.)

7 MS. GIAMBONE: So let's take our seats. We  
8 will be getting started again.

9 And Topic 2 Panelists if you could start  
10 making your way up to the panel table.

11 Tammy are you back, you are on your way.  
12 Great. Take your time. It is okay.

13 So let's go ahead and get started again. We  
14 want to thank you for a really rich discussion in Topic  
15 1. I know that we didn't get to all of the comments so  
16 if you have more to add we encourage you to go to the  
17 public docket and make sure you enter your comments  
18 there. We want to read them. We want to capture them  
19 all; so please definitely go visit that website and  
20 enter your comments.

21 And the other note I just want to mention is  
22 that we do have evaluation forms that have been passed

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1 out. They are also on the registration desk I believe.  
2 So please make sure you fill those out and that will  
3 help us a lot to hear your feedback.

4 So let's get started with Topic 2 and once  
5 again I will have the Topic 2 Panelists introduce  
6 yourselves when it is your turn to speak.

7 A really quick overview of what Topic 2 is  
8 covering, this is on current treatment approaches to  
9 PAH and patient's perspectives on these treatments. And  
10 we want to hear from you what are you currently doing?  
11 What is your treatment regimen? Is it working for you?  
12 And how do you know it has made a difference for you?  
13 How do you know that it is working for you? And if you  
14 could point to specific examples on how you know it is  
15 working for you. What are the most significant  
16 downsides to these treatments? And what specific  
17 things would you look for in your ideal treatment?

18 So let's get started with our panel. And  
19 Tammy would you like to go first

20 MS. PIXLER: Sure.

21 MS. GIAMBONE: Make sure you press the red  
22 button. There you go.

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1 MS. PIXLER: Hello. Hi my name is Tammy  
2 Pixler. And I was diagnosed in 2008. My current  
3 treatment plan is I take Revatio, Tracleer and  
4 Ventavis. I am on oxygen 24/7. I use a pulse oximeter  
5 to monitor my oxygen levels throughout the day and when  
6 I exercise. I maintain a low sodium diet. I limit my  
7 fluid intake. And I also take a hefty dose of lasix  
8 everyday, except today I did not. And I do light cardio  
9 exercises.

10 Each of these medications took a couple of  
11 months to start feeling the effects. For Revatio it's  
12 a pill three times a day. And after a little while I  
13 did feel a little bit more energized. Tracleer was  
14 then layered on and that is a pill that you take twice  
15 a day. And you have to take a monthly liver function  
16 test. And my improvements after a few months were  
17 significant. I could tell it in my oxygen levels. I  
18 could tell it in my energy and my stamina. Then  
19 Ventavis was added. And this is an inhalation  
20 nebulizer. And you are supposed to take it six to nine  
21 times a day. And it has a very tedious maintenance  
22 requirement. I noticed a big improvement in my oxygen

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1 levels my stamina after taking that therapy for a few  
2 months.

3           This combination of drugs is working really  
4 well for me and I am so grateful for the improvements  
5 that I have achieved through my whole routine. I can  
6 do multiple errands in one day. I rarely need to take  
7 a morning or afternoon nap. I have much more energy  
8 and stamina to accomplish daily tasks as well as enjoy  
9 some leisure time and low key activities.

10           The downsides to these medications are there  
11 are no automatic refills for the drugs. They are  
12 provided through a specialty pharmacy that calls you  
13 every month for each medication; wants to know how many  
14 pills you have; and they schedule deliveries for each  
15 one of those.

16           Travel is also to be considered. You either  
17 have to get early delivery or you have to have it  
18 rerouted to an alternate location. And that is the  
19 same for my oxygen as well.

20           And Ventavis is a nebulizer and you are  
21 supposed to take it at least two hours apart and each  
22 treatment takes about 10 to 15 minutes by the time you

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1 put it together, take it apart and actually do the  
2 treatment. And the parts have to be stored in  
3 distilled water. The nebulizer has to be wiped down  
4 with alcohol after each use. And all of the parts are  
5 washed daily in a distilled water and dawn detergent  
6 and then rinsed in the distilled water. And then once  
7 a week they have to be boiled to be sterilized. The  
8 prescribed dosage is six to nine treatments a day. When  
9 I first started these treatments I can tell you I was  
10 not awake for 12 hours a day to be able to accomplish  
11 that. The most I was ever able to do consistently was  
12 seven. I was never able to do eight or nine in one  
13 day. My current dose is five which is manageable. And  
14 I use about two gallons of distilled water a week. And  
15 again gallons of water, bringing them into the house,  
16 very heavy, not an easy task to do all the time.

17 I need to make sure that my medication bag  
18 for my Ventavis is ready to go. I need to make sure  
19 the nebulizer is charged; my oxygen tanks are full. I  
20 have a stash of AA batteries for my oxygen tanks. And  
21 this insures that I am prepared for any kind of power  
22 outages or the need to leave the house unexpectedly.

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1           Leaving the house is a process. I have to  
2 determine if I need to take my Ventavis with me or if I  
3 can get my five doses in throughout the day. I also  
4 need to determine how much oxygen I need to take with  
5 me. Usually I take minimally two tanks which are about  
6 five pounds a piece. No longer can I grab my keys, my  
7 purse and run out the door.

8           What would help? A medication that is as  
9 effective as Ventavis but last longer so that the  
10 treatments only need to be done three or four times a  
11 day. A medication that is as effective as Ventavis but  
12 is in an inhaler form instead of a nebulizer. A less  
13 cumbersome cleaning and maintenance process would be  
14 beneficial. And also medications that do not  
15 contribute to fluid retention.

16           For oxygen and I know this is more supposed  
17 to be medication driven but if we could have lighter  
18 portable tanks and a truly portable oxygen concentrator  
19 with continuous flow greater than three liters a minute  
20 and a longer battery life; that would be very great for  
21 me as well.

22           Thank you very much.

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1 MS. GIAMBONE: Thank you Tammy.

2 We have Colleen.

3 MS. BRUNETTI: Hello before we begin I'd just  
4 like to take a moment to thank the FDA for having us  
5 here today. As you all know in a rare disease state  
6 like pulmonary hypertension it can be a challenge to  
7 feel heard and we really appreciate you taking the time  
8 to listen.

9 I was diagnosed on January 2, 2008. What I  
10 thought was shortness of breath due to being de-  
11 conditioned from having a baby and high stress job was  
12 in fact pulmonary hypertension. From the night I went  
13 to the ER for an unrelated illness to the point of  
14 diagnosis was actually just two weeks. And we know if  
15 often takes well over two years to get a diagnosis if  
16 not more so I was very lucky.

17 I currently take three medications: Adcirca,  
18 Lotaris, and Tyvaso. I am also on nocturnal oxygen.  
19 For the first couple of years after diagnosis I needed  
20 digoxin but do not any longer.

21 To begin I wanted to try one treatment at a  
22 time so that I could gauge which might be helping me

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1 and how I might be impacted by side effects. We  
2 started in the beginning with Revatio which was later  
3 switched to Adcirca for convenience. We added Lotaris  
4 about eight months after the Revatio. And I felt okay  
5 on those two medications but there were definitely  
6 moments my PH stopped me short particularly when it  
7 came up to keeping up with my son who was a toddler.

8 I caught swine flu when it came through in  
9 2009 and I was unable to fully recover. So it was at  
10 that point that we added Tyvaso which had worked quite  
11 well and it was soon after I started taking it that my  
12 activity levels started to come back up. And today I  
13 feel like I function just about as well as I did prior  
14 to diagnosis which is a huge improvement for me.

15 In addition to all these treatments I have  
16 practices integrative medicines almost from the  
17 beginning. I believe that the PH medications alone are  
18 not enough. I could see how they helped a great deal  
19 and I could also see how they would never work as well  
20 as I wanted them to if I used them as a standalone  
21 approach.

22 I take supplements which are carefully



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1 selected with the help of my naturopathic doctor and  
2 the go ahead from my PH specialist. I exercise several  
3 times a week and I try to have a spiritual practice  
4 that keeps me in balance.

5 I also overhauled my diet a few years after  
6 diagnosis and now I'm vegetarian. After studying  
7 nutrition for some time I felt that a vegetarian diet  
8 was the most heart healthy and conscientious decision  
9 that I could make. I do think I fare better eating and  
10 living this way because fighting disease is a mind,  
11 body, and soul approach.

12 My current treatments in conjunction with  
13 life style practice control the shortness of breath and  
14 heart function quite well. But as we heard earlier  
15 nothing has been able to touch the fatigue that comes  
16 and goes.

17 The medications have definitely improved  
18 quality of life, however, they also kind of run my life  
19 because every four hours I am taking something. I was  
20 due for a Tyvaso treatment at the break and I opted to  
21 push it back because I was afraid I would cough through  
22 this presentation. So you do have to plan sometimes.

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1           My quality of life is also impacted by the  
2 specialty pharmacy system. I personally experience  
3 quite a few barriers to getting my medications in a  
4 timely fashion primarily due to issues with the order  
5 and delivery process. And I know many other patients  
6 have experienced the same; some even being forced to go  
7 without treatment or getting dangerously low on vital  
8 medication because the system does not always work as  
9 smoothly as it should.

10           I have taken an active role in addressing  
11 those issues with the help of the Pulmonary  
12 Hypertension Association. In fact we now have an  
13 entire system in place where many of our key players in  
14 the pharmacy industry are taking their own direct role  
15 in gathering and analyzing patient feedback and working  
16 with PAH on working to build best practices as well as  
17 improve in areas where there is need.

18           The downsides to the treatments themselves  
19 include the nagging cough from the nebulizer and acute  
20 nasal dilation which makes it a little uncomfortable to  
21 breathe through my nose on a good day and impossible if  
22 I get a minor cold. The equipment can be somewhat

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1 cumbersome.

2           One key area of impact for me is actually  
3 psychologically related. I understand that it is a  
4 mandate that I must use two forms of birth control, get  
5 monthly pregnancy testing and monthly pregnancy  
6 counseling because of one of my medications. And I  
7 can't stress enough the emotional toll that monthly  
8 counseling can take on women like me. We do not want  
9 to have to relive every month the way this disease has  
10 taken one of life's most precious gifts of being able  
11 to have our own children. And yet we are forced to as  
12 if we could ever forget for a minute what this disease  
13 has done not only to our lungs and hearts but to our  
14 families and our lives as well.

15           Assuming that there is no complete cure  
16 directly on the horizon my dream is to have treatments  
17 where the side effects don't impact us just as badly as  
18 the disease. I want equipment that doesn't get us  
19 treated like potential criminals at the airport because  
20 we carry high caliber medication. Or better yet no  
21 need to carry equipment at all. If there are more way  
22 to titrate up and down on oral medications more

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1 carefully that would be wonderful. I am five foot two.  
2 I don't know how the same Lotaris dose works for me as  
3 it does for someone much larger or smaller.

4           Finally I would like FDA approved medications  
5 for children with Pulmonary Hypertension. This is a  
6 pretty tough disease to handle as an adult but we have  
7 a lot of options. I would love to see so much more  
8 research and opportunity for the kids. Right now we  
9 know the outcome of PH for children is likely worse  
10 than it is for adults in any treatment that might be  
11 selected or prescribed off label. Additional research  
12 and trials that will get our kids appropriate treatment  
13 options would be priceless.

14           Again thank you for taking the time to hear  
15 us today and to weigh our thoughts and ideas moving  
16 forward. I feel confident speaking for the PH  
17 community in saying we very much appreciate it.

18           MS. GAIMBONE: Thank you Colleen.  
19           Lucille?

20           MS. MONKO: Hi. Hello my name is Lucille  
21 Monko. I am 53 years old. And I have idiopathic PH. I  
22 was diagnosed in August of 2010. Unlike many of the

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1 others I was fortunate enough to have a primary care  
2 physician who listened and sent me to a knowledgeable  
3 cardiologist who made the difference. He took  
4 immediate action once the diagnosis was complete. My  
5 pulmonary systolic pressure was between 80 to 100. By  
6 the end of September I was hospitalized and began a  
7 combination therapy of Remodulin IV and Tadalafil  
8 Adcirca. My only choice was subcu or IV and it was  
9 determined that the IV would cause immediate relief and  
10 assistance to me.

11 In addition I take a diuretic, a beta  
12 blocker, several vitamins and an allergy suppressor  
13 which is actually for another medicine that I take.

14 I try to maintain a healthy lifestyle by  
15 limiting coffee, caffeine, eating healthy, minimizing  
16 salt intake and getting plenty of rest. This is very  
17 difficult because I have to limit the water intake. I  
18 cannot perform vigorous exercise. I do not sleep well  
19 because of the meds and waking to readjust my IV line  
20 so that it is not being pulled or tangled; hence the  
21 need for extra coffee and/or protein to maintain  
22 energy.

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1           After two years Lotaris was added to my  
2 treatment because my second cath showed slight  
3 improvement. My Remodulin dose was at a 108 nanograms.  
4 Most recently this increased to 120.5 nanograms as my  
5 latest cath in November showed a lowered pressure of  
6 60. It was about a 25% improvement but my doctor still  
7 thought the number should be better. They  
8 recommendation titration to 130 nanograms. I wasn't  
9 ready for this. Mentally I wonder if I -- if I have  
10 any other options if the treatments do not work or if  
11 any of the other meds would make more of a difference.  
12 I do believe, however, that without this treatment I  
13 would not be alive today.

14           Days when I miss my morning scheduled  
15 Tadalafil I feel sluggish by noon and notice breathing  
16 is different, slightly harder. Similarly if I do not  
17 replace the Remodulin within that 24 hour shelf life I  
18 feel like a wall is against my chest, a slight  
19 tightening begins. It is a little difficult to explain  
20 but it is a different feeling that I have when my  
21 medicines are not taken as scheduled.

22           The meds do allow me to have a new norm. I

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1 can do almost anything I used to before diagnosis. But  
2 if I do over exert myself I pay for it the next day by  
3 resting the entire day. I still work full time but I  
4 am granted tele-work every other day. This allows me  
5 for the needed recuperation time. Having the meds  
6 allow me to continue with life even though I have to  
7 stop and take a rest or take deep breathes to keep on  
8 going.

9           The meds are very strong and I feel the  
10 general side effects but I also feel the lack of oxygen  
11 throughout my body; I note that oxygen doesn't go to  
12 the brain anymore. I often feel dehydrated. I hate  
13 the tube in my chest. I hate cleaning the site and  
14 changing the dressing and carrying an emergency kit  
15 which I have used a few times. My line is always  
16 getting caught on something. I smell like the  
17 medicines I take. My skin coloring is always flushed.  
18 This is not a tan. And I hate that there are many  
19 medical persons not versed in PH, the respective meds,  
20 and how they should be administered.

21           For me the ideal treatment should include  
22 information, statistics and/or examples that would

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1 explain to me why certain meds are used and others are  
2 not; why doctors choose the treatments they do; perhaps  
3 a protocol that is proven effective. I would like to  
4 see more natural and/or alternative treatments, studied  
5 and approved for PH; treatments that are age  
6 appropriate for pediatrics, for geriatric if they  
7 should live that long; FDA approval of the internal  
8 pump that administers the protast -- Remodulin, I can't  
9 say that word. But mostly I would like to see full  
10 coordination and communication between all government  
11 agencies and medical participants to work together on a  
12 best treatment and possible cure.

13 Thank you.

14 MS. GIAMBONE: Thank you so much Lucille.

15 And next we have Stacey.

16 MS. GAUSLING: Hi I am Stacey Gausling. I  
17 was diagnosed with Pulmonary Arterial Hypertension in  
18 2006, secondary to Lupus and Mixed Connective Tissue  
19 Disorder. Prior to diagnosis I had finished two  
20 marathons, the Chicago and the D.C. marathon and at the  
21 time of diagnosis I was working full time as a medical  
22 sales rep. I also have a background as a licensed



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1 occupational therapist of 24 years.

2           At the time of diagnosis my pulmonary  
3 pressures were between 80 and 100 and I was short of  
4 breath with all activity even just sitting and resting.  
5 I was immediately started on two oral medications  
6 Revatio and Tracleer. Within six months my doctor  
7 wanted me to start Remodulin. At first the  
8 subcutaneous route was presented to me, however, the  
9 pain that I experienced was unbearable and the only way  
10 that I can explain to those of you that don't have a  
11 subcu treatment is it feels like a hot burning iron is  
12 on your skin continuously. So I opted to go the IV  
13 route and I've never looked back since.

14           There were a variety of other prescription  
15 medications added to address fluid retention and meds  
16 to counteract the side effects of my medications such  
17 as potassium.

18           The way that it impacted my daily life I  
19 chose to take my Lasix at night so that I could  
20 continue to work full time. I was also on oxygen  
21 therapy for two years 24/7. So I left my house with my  
22 medications on board, all my oxygen tanks for the

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1 entire day and made sure that I was going to be near a  
2 toilet at all times or ready to stop because of the  
3 side effects of the medications.

4 I also stated following a low sodium and low  
5 fat diet which was recommended by my doctor which was  
6 at the time of initial diagnosis was hard for me to  
7 grasp at first because I had never been on a true diet  
8 before. And you know I had a little bit of a pity  
9 party for myself saying well if I am going to have this  
10 diagnosis you know I want to be able to eat what I  
11 would like to eat. But then I soon realized that  
12 embracing eating a low sodium diet made me feel better  
13 and counteracted the fluid retention that I was  
14 experiencing.

15 I slowly started to improve and after about  
16 two to three years, that was my turning point where I  
17 was able to come off of the oxygen during the day. I  
18 was able to start integrating some exercise in addition  
19 to working full time and I went ahead and made the  
20 decision to switch from Revatio to Adcirca because to  
21 be quite honest with you the mid day dosing was getting  
22 missed. When you are trying to maintain an active

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1 daily schedule stopping to take an additional  
2 medication during the middle of the day just got  
3 forgotten.

4           So a couple of years ago we decided that we  
5 wanted to make a drastic change. We decided to move  
6 back to California from Texas at the end of December.  
7 We sold all of our belongings including our house,  
8 wanted to simplify life and enjoy the weather that  
9 would allow me to improve my health; so just the act of  
10 moving and being around a community of excessively  
11 healthy people kick started a new adventure in  
12 alternative health. I cut out all artificial  
13 sweeteners, sodas, and made a strict conscious effort  
14 to stay under the 1500 milligrams of sodium per day.  
15 Shopping at the local farmers' market and eating  
16 organic as well as going for walks and exercising has  
17 become a new normal as I am not only short of breath  
18 with attempts at jogging or climbing more than three  
19 flights of stairs at a time.

20           Now I have added personalized supplementation  
21 with vitamins and minerals and striving to follow an  
22 anti-inflammatory diet.

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1           So in summary, yes my drug regimen has been  
2 effective but it hasn't changed after year one. Yet my  
3 function and feeling of well-being has steadily  
4 improved with each year now. I am not eight years  
5 post. And my six minute walk test I can surpass 640  
6 meters. So is it the medication after a certain point  
7 or is it lifestyle with the medication?

8           I know it is going to take a new medication  
9 that has proven benefits over my current regime in  
10 order for any changes to be made since I am doing so  
11 well. I would love to not be on IV but I will not  
12 trade my function for it. My ideal treatment would be  
13 one that allows me to receive my medications in the  
14 least invasive way possible with the least harmful side  
15 effects. I would consider the implanted pump over my  
16 current IV strictly for the additional freedom it would  
17 allow me to swim or shower without fear of an  
18 infection. A treatment option that would allow for the  
19 greatest amount of freedom and flexibility such as a  
20 monthly infusion or longer or a patch would help  
21 normalize our lives. I would like to see some new  
22 options other than reinvention of the same drugs to

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1 different forms or versions. I would live to see the  
2 concept of personalized medicine carry over into the PH  
3 community. DNA testing that would show which  
4 medication within a category would work best for our  
5 individual genetics using the simple swab test that  
6 they are currently using for other drugs. I would also  
7 like to see how the new advances in stem cell such as  
8 growing new lung tissue and genomic technologies such  
9 as genetically coding the manipulation may benefit us.  
10 I am very grateful for all the new treatment options  
11 available to us with PAH but with the advances in  
12 technology I would like to see alternatives other than  
13 IV, subcu and oral options. If those were the only  
14 options then I would like to see some developments in  
15 smaller pumps, pain free delivery systems and  
16 alternative oxygen delivery systems that are less  
17 cumbersome.

18 MS. GIAMBONE: Thank you Stacey.

19 And Katie?

20 MS. TOBIAS: My name is Katie Tobias. I am  
21 27 years old. When I couldn't breathe they said I had  
22 asthma. I was passing out and they called it epilepsy.

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1 Three years and several specialists later I was finally  
2 diagnosed with PH in September 2006.

3 IV Remodulin was started immediately and  
4 Revatio was added a year later. Breathing and heart  
5 function had greatly improved. I went from knocking on  
6 death's door to living a relatively normal life.

7 The palpitations started in July 2010.  
8 Lotaris and digoxin were added. By November I was  
9 using four liters of continuous oxygen and could barely  
10 walk without gasping for air. With every exhale there  
11 was an intense squeezing pain in my back. The Remodulin  
12 dose was raised several times but my condition only  
13 worsened. I transitioned to Flolan in November 2010.  
14 Flolan is considered the gold standard in PH treatment.  
15 I was on the drug for a little over two years and it  
16 was the worst experience I have ever had. The pain  
17 started halfway through the transition. It felt like  
18 every last piece of skin was constantly being pinched.  
19 The sharp pain never went away. The slightest touch  
20 made me want to scream. Sitting on the couch sometimes  
21 took up to eight ice packs; one to sit on, one under  
22 each thigh, one under each foot and one under each arm

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1 and one to hold on to.

2 Over time the pain just went deeper and  
3 deeper. I remember saying it is like my blood hurts. I  
4 went through several different narcotics in a little  
5 over two years. Each one only helped for a few months.  
6 Despite around the clock use the pain never fully went  
7 away. On a one to ten scale with ten being the worst  
8 pain you ever felt my good days were maybe a six but  
9 the bad days could easily be a ten or above.

10 I tried Veletri but couldn't finish the  
11 transition; the pain was ten times worse. I am still  
12 on Revatio and Lotaris. In February 2013 I  
13 successfully transitioned from Flolan to Tyvaso. Within  
14 a week I was completely pain free. Tyvaso liberated me  
15 from the tube in my chest and the machine at my waist.  
16 I no longer feared the next site infection, the next  
17 line break, the next life and death crises. Breathing  
18 is better than ever and so are the test results.

19 However, there is now extreme pressure and  
20 bloating every time I eat. Nosebleeds can start  
21 suddenly and can last 45 minutes or more often causing  
22 me to vomit blood and blood clots. Mood swings have

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1 changed drastically. It is as if someone flips a  
2 switch and I am suddenly ecstatic, a few hours later  
3 flip the switch again and I am absolutely terrified  
4 then content, then depressed, then livid, around and  
5 around several times a day. Steps have been taken to  
6 help relieve these issues but I never had them before  
7 Tyvaso. But I would gladly take a bad day on Tyvaso  
8 over a typical day on Flolan.

9           Every drug has side effects. But every drug  
10 also has the potential to improve lives, to save them.  
11 I hope that one day the pills we take will be just as  
12 effective and strong as the IV medications we have now.  
13 Until then I hope we can find a safer and more reliable  
14 alternative to the central lines currently used for IV  
15 treatments. Site infections mean extended hospital  
16 stays. And line breaks mean life threatening  
17 emergencies. I was on IV medications for about seven  
18 years. The central line had to be replaced six times.  
19 Five of those times were because the line broke. When  
20 IV medications have a half-life measured in minutes  
21 like Flolan every single time that piece of plastic  
22 breaks your life is in jeopardy. I had one site



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1 infection and a few infections under the skin when new  
2 line was placed. I even had a piece of an old line  
3 left inside of me.

4 In spite of all the negative effects these  
5 drugs have I would have died without them.

6 Life with PH is not easy and the current  
7 treatments are not perfect. But these treatments  
8 enable us to defy the odds with every breath we take.  
9 We are alive; we will live to see tomorrow; and  
10 tomorrow may hold the cure.

11 Thank you.

12 MS. GIAMBONE: Thank you so much, Katie.

13 Let's give this panel a round of applause.

14 [Applause]

15 I know it is difficult to talk about such a personal  
16 story but we truly are grateful that you are here  
17 sharing this with us.

18 Now one thing I do want to do is we are very  
19 grateful today to have the pediatric perspective in the  
20 room. We have Martha Gonzalez here and Martha would  
21 you like to share just a few comments before we open up  
22 to the greater group.

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1 MS. GONZALEZ: Yes. Hi. Like she said my  
2 name is Martha Gonzalez. My son, Daniel, could not  
3 make it today. But I brought a picture of him. It is  
4 not a recent one. I am the mother of Daniel, an eight  
5 year old patient. Daniel was diagnosed with PH when he  
6 was one year old. He started his PH treatment with low  
7 doses of Revatio. Every month the dose was increased  
8 until he reached 20 milligrams three times a day. As  
9 we all know proper dosage in child patients is  
10 impossible for many PH pediatric specialists which is  
11 why it has to be well monitored. Reaching the proper  
12 dosage of 20 milligrams took months to achieve.

13 However, the hard work paid off. As Daniel's PH is  
14 stable and has shown no sign of progression since then.

15 His specialist decided to be proactive as  
16 Daniel was growing and added a second medication to his  
17 treatment, inhaled Treprostinil. With this other  
18 medication Daniel has completed and gradually improved  
19 his six minute walk test. Now he walks an average of  
20 600 meters with a saturation of 94 at exercise and back  
21 to 98 after he completes the test.

22 While the downsides to his medication are

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1 minimal Daniel does sometimes have random nosebleeds  
2 which are attributed to Sildenafil. That is what we  
3 think. He has borderline low platelet counts which is  
4 known to be possible effect to Tyvaso.

5           The only major downside to his medication is  
6 if he contracts a respiratory virus due to the Tyvaso  
7 if he has a cough he cannot take his medication. His  
8 specialist advised us to use Ventalin and Flolan 30  
9 minutes prior to treatment to prevent him from coughing  
10 out of the medication if he is sick. However, if the  
11 cough is unmanageable we must take him to emergency for  
12 alternative treatment.

13           Using these medications also interrupts his  
14 school day as he must take it during class.

15           Yet in the face of those obstacles we are  
16 grateful that Daniel is doing well due to his  
17 treatment. He is growing to be an active elementary  
18 school student. Like many children his age he has  
19 expressed an interest in sports as well. He loves to  
20 play and lives his life uninhibited by his disease.

21           Lastly I would like to say that although  
22 there are no PH drugs approved for children, children

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1 benefit from drugs approved for adults. On behalf of  
2 my son and many children affected by this terrible  
3 illness I ask the FDA to consider more studies to  
4 target the approval of treatment for children.

5 Thank you.

6 [Applause.]

7 MS. GIAMBONE: Okay. Now it is working. We  
8 really -- you know when we learned that Martha was  
9 going to be able to attend today's meeting we really  
10 thought it would be very, very helpful and important to  
11 hear the pediatric perspective. So Martha thank you  
12 for joining us today.

13 And thank you again to our panel members for  
14 your comments.

15 So before we move on to the polling question  
16 let me ask as I did with Topic 1 how many of you felt  
17 that you heard your experiences being shared by at  
18 least one of the panelists here?

19 Okay. It looks like the majority of you  
20 share similar experiences.

21 And just to sort of recap what I heard it  
22 sounds like the treatment regimen has changed over

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1 time, you've had to sort of determine which drug  
2 therapy works best for you, you seem to also have  
3 incorporated lifestyle changes and so we are looking  
4 forward to hearing what the rest of you also have to  
5 say and experiences that you have.

6 So let's go on to our polling question. And  
7 I am going to apologize in advance if I mispronounce  
8 some things. So jump in and tell me if I am saying  
9 something wrong, okay.

10 So have you ever used any of the following  
11 drug therapies to help reduce the symptoms of Pulmonary  
12 Arterial Hypertension, check all that apply. And really  
13 quick do you all have your clickers? Okay. Good.  
14 Okay. A Endothelin Receptor Antagonist such as  
15 Tracleer, Letairis, and Thelin; B PDE5 Inhibitors such  
16 as Revatio, Adcirca and Levitra; C Prostanoids such as  
17 Flolan, IV Remodulin, and Beraprost; D Calcium Channel  
18 Blockers; E other or F I am not sure.

19 And also to those of you on the Web please  
20 make sure you enter your responses.

21 Okay. So here is what we see here. It looks  
22 like 88% of you are taking the ERA, Endothelin Receptor

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1 Antagonist followed by almost the same 79% of you are  
2 taking PDE5 Inhibitors, 58% take the Prostanoids, am I  
3 saying that correctly. Okay. Good and we also have  
4 other so we look forward to hearing some of the other  
5 drug therapies that you are using. And finally Calcium  
6 Channel Blockers. Okay.

7 Let's check in with the web. Do we have  
8 something similar?

9 MR. THOMPSON: So the biggest difference on  
10 the web is that about 50% of people said they took  
11 something other than these categories listed above.

12 MS. GIAMBONE: Okay. Great. Thank you.

13 So let me ask a question to sort of you know  
14 begin this discussion. How many of you take these  
15 therapies, it sounds like most of you take these  
16 therapies on a daily basis; is that correct. Okay. And  
17 it sounds like it is multiple times a day too; right?  
18 Okay. Lots of heads nodding. So would anybody like to  
19 start our discussion with what you are taking and if  
20 you could point us specifically if it works for you how  
21 do you know that it is working for you?

22 Would anybody like to share?

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1 Yes. Alex?

2 MS. FLIPSE: Thank you. So right now I am  
3 taking Sildenafil, I am about to take it. And I know  
4 that it is working because my six minute walk increased  
5 by over 100 feet. Prior to that I was on Flolan for  
6 four years. My pulmonary arterial pressures were at  
7 115. After I think about four months they went down to  
8 25. Four years later I was transitioned off of Flolan  
9 on to Tracleer, they shot back up to 55. And now that  
10 I am on Sildenafil they are still at about 50. So I  
11 know that it is working because they could go way back  
12 up to 115 again. And I can do the six minute walk a  
13 lot further plus walk a mile and not have to stop.

14 MS. GIAMBONE: Okay. Thank you for giving us  
15 specifically those examples on how it is working for  
16 you.

17 Yes we have another comment here.

18 MS. VOLPE: Okay. I started on Flolan  
19 because obviously it was many years ago. There was  
20 nothing else. It was that or I had to have a lung  
21 transplant. At the time it was going to be a lung and  
22 heart. I started on Flolan before it even became FDA

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1 approved. And I feel it saved my life. I can't  
2 believe what Katie went through because I didn't have  
3 anything like that. I did go on a couple of oral  
4 medications but I just -- they made me so flushed and I  
5 just felt terrible with them. Tracleer did a job on my  
6 liver. So I couldn't take that. And now I am on  
7 Remodulin with the Crono pump and I kind of liked  
8 better like Velettri on my other pump, this seems more  
9 sensitive and even though it is longer lasting and  
10 everything but I wished I could -- I even tried it one  
11 time coming off all IV medication and going with oral.  
12 And I went like for four months and I just couldn't  
13 breathe. So they had to put me back on IV treatment.  
14 But that is what I am stuck with for now until  
15 something better comes along.

16 MS. GIAMBONE: Thank you. And sorry, your  
17 name?

18 MS. VOLPE: I am Joann.

19 MS. GIAMBONE: Joann, Thank you Joann.

20 Yes and right next to Joann we have another  
21 comment.

22 MS. LEWIS: I am Ann Lewis. And I have had



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1 PAH for about five years. I think I started with  
2 Revatio and then it was changed to Adcirca and then we  
3 tried Tracleer because my pressures were not what the  
4 physician felt they should be and that did not work for  
5 me because of the liver situation. I am so grateful  
6 that there were other drugs we could turn to, we didn't  
7 have just one choice. So I am on Letairis now and that  
8 seems to be working fine for my body.

9           But I think I would want to go just a little  
10 further with this to say that I think the other  
11 medications of course oxygen but exercise and diet  
12 change have made a tremendous difference for me. So I  
13 think it has been a holistic change in how I view my  
14 body and how I view PAH. I think it is hard to  
15 separate out you know which is more effective. I have  
16 done some studies at NIH so I know that my pressures  
17 are better, I know that I am walking farther, the  
18 stress test with checking the oxygen and all of that  
19 showed significant improvement even over a six month  
20 period. But I can't tease out is it the medicine; is  
21 it the exercise; is it the diet change.

22           MS. GIAMBONE: Great point. And to your

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1 point we will have a second polling question in just a  
2 moment that is going to address some of the other non-  
3 drug therapies such as lifestyle changes that you've  
4 made. I know we've heard some on the panel too.

5           Anybody else that wants to share more about  
6 their current treatment regimen and if it is working  
7 for you and how you know?

8           MS. HAMILTON: I am not sure how I know. I  
9 am taking as of December the 17th I started on Opsumit  
10 and that was just approved by FDA. And the pharmacist  
11 told me that he thought I would see a difference in  
12 four months. And I can't say that I have found that I  
13 have any significant improvement. And none of the  
14 other medications that I am on which is Adcirca and  
15 Tadalafil. I don't see any significant changes. So I  
16 honestly with the exception of the six minute walk that  
17 seems to be the only real measurement that we have and  
18 that has not been up. So we'll see and probably a  
19 change in diet and exercise; I've been exercising but  
20 maybe a change in diet would be helpful as well. I  
21 just don't know.

22           MS. GIAMBONE: Blanche, thank you very much.

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1 I think we had one more comment here.

2 MS. HARRINGTON: I just wanted to say I've  
3 been on the medications for nine years and I went from  
4 hiking and running and biking to not being able to walk  
5 up a flight of stairs within six months. Once I was  
6 started on the medication, starting with Revatio, it  
7 took about a year for me to get back to a comfortable  
8 level. I can you know now walk on the treadmill  
9 whereas I couldn't before. And one way I know for sure  
10 that the medicines are helping is I tried a quick 24  
11 trip to New York City to visit my niece and put all of  
12 my meds that I would need in that 24 hours in one  
13 bottle and was so nervous about what if I need them and  
14 they are in my backpack. Well okay then I will put them  
15 in my purse and it turned out that I didn't put them in  
16 either place. So within 12 hours of getting to New  
17 York I couldn't even walk a block. And I can walk on a  
18 treadmill with oxygen right now. So you know I could  
19 not wait to get home and but a day or two later after  
20 getting back on my regular medicine regime I was okay.  
21 But that was very scary and it tells me that it is  
22 working.

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1 MS. GIAMBONE: Thank you for sharing that.

2 And I am sorry your name.

3 MS. HARRINGTON: Kathleen.

4 MS. GIAMBONE: Kathleen.

5 And I believe we had one more comment?

6 MS. DOYLE: Okay. Hi I am Stacey Doyle. I'm  
7 currently on Remodulin. When I started I was on  
8 Ventavis and Tracleer. And I noticed the biggest  
9 difference when I went on Tracleer because I came to  
10 Baltimore and was able to walk around two weeks --  
11 pretty much two or three weeks after I went on Tracleer  
12 when before I couldn't even walk a up a flight of steps  
13 when I came out of the hospital. And I was pretty  
14 stable on both of those medications for almost six  
15 years. And then I started to get worse, I started to  
16 get more fluid in my legs. And I started to have  
17 trouble walking up a slight incline, having trouble  
18 with stairs again. And I went on the Remodulin pump  
19 and stopped the Ventavis. And part of that was because  
20 I was having trouble getting all the treatments in. I  
21 was supposed to have six treatments a day, every three  
22 hours, I had a full time job, I had a two hour commute

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1 every day, ten year old daughter, I wasn't getting my  
2 six treatments in a day. So that did affect me. I  
3 felt like that made me get a little worse. And then  
4 when I went on Remodulin I got better. I mean the  
5 symptoms, the fluid, what I am able to do so I know it  
6 is working but I have to deal with the downside. I  
7 have to deal with the site pain. I have to deal with  
8 the site changes. And that is impacting my life, my  
9 work, my relationships. But I know I need it. So I am  
10 thankful to have the medications that I've had over the  
11 past seven years or I don't think I would be here. But  
12 it is just learning to deal with the side effects in  
13 order to continue to live your life.

14 MS. GIAMBONE: Thank you Stacey.

15 I am going to make a quick comment to those  
16 of you joining us on the Web. I will be checking in  
17 with the phone in a few minutes. So if you would like  
18 to dial in, please make sure you do that.

19 Okay. And I do want to follow up with a  
20 question that somebody had -- Blanche I think it was  
21 you could you share your experience -- all of you,  
22 would anybody like to share your experience on how long

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1 you give a particular treatment a try or you try it  
2 before you know that it is not working and it is time  
3 to make a change. Blanche I believe you mentioned  
4 about four months you had tried. So does anybody else  
5 want to share their experience with that?

6 Yes, Lucille.

7 MS. MONKO: I actually can't share that  
8 experience but in my situation the combination therapy  
9 that I am on, I am actually too afraid to try something  
10 else for fear of it not working as good and not taking  
11 that chance for something else because I understand  
12 that if the disease does progress it is then either  
13 much more difficult to regress again and/or does not at  
14 all. So contrary to that I am too afraid to change and  
15 try out another therapy.

16 MS. GIAMBONE: Let's do a show -- oh, yes.

17 Thank you Lucille.

18 MS. FEENEY: My name is Patricia Feeney. And  
19 I have been on Remodulin since day one which my doctor  
20 included Letairis and Adcirca. I've been on it for  
21 four years now and because my condition and my walking  
22 test was doing so well I said to my doctor if I am

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1 doing so well why can't I get off of one of the drugs.  
2 Well, believe me if we were all doctors we would not be  
3 here. I said to my doctor I'd like to get off the  
4 Adcirca and try it. I've been off for two months and I  
5 have been starting to experience a change in my  
6 breathing. I realized that my decision to go off it  
7 was not a good one; that he was 90% right; and I was  
8 10% wrong.

9 [Laughter.]

10 MS. FEENEY: So we all realize that they put  
11 us on these drugs for a reason. And it is to help us.  
12 And I've never felt better. I went from being 20% to  
13 97%. Since I have been off of the Adcirca for two  
14 months I bet you I am down to about 50% and having a  
15 hard time with walking distance. My walking test was  
16 up to 1400. I don't know how they measure it out but  
17 now if they were to test me today I bet you it is  
18 probably way down. So next week I see him and I am  
19 going to go back on it.

20 Thank you.

21 MS. GIAMBONE: Thank you for sharing that.

22 Yes. We have one comment here from Alex.

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1 MS. FLIPSE: I can't really say how long I  
2 let a medication work because I think I am from the old  
3 school generation where if a doctor tells you take this  
4 you take it and you don't question it. That was my  
5 only thing.

6 MS. GIAMBONE: Thank you.

7 Yes and let's take one more comment there.

8 MS. CONNOR: Hi it is Colleen Connor. I was  
9 just going to say when I was first diagnosed back in  
10 late 2007 my doctor wanted to start me on the least  
11 intrusive therapy so we started with Calcium Channel  
12 Blockers. We gave it three to four months at a time.  
13 They just made me swell. My legs were probably 20  
14 pounds heavier each side. I couldn't put any socks and  
15 shoes on and I didn't feel any benefit other than like  
16 a swollen mess. So we moved on to Tracleer and I still  
17 didn't feel a benefit to that. So after three months  
18 he added Revatio. I still was like doc I can't do  
19 anything more than I have ever been able to do since we  
20 came to you. So then I went to Ventavis which was the  
21 breathing treatment and most people -- you know at the  
22 time it was supposed to take eight to ten minutes, for



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1 me for whatever reason it would take me like 20 minutes  
2 until this nebulizer would finish. They had the nursing  
3 staff out to watch me do it. Of course they would say  
4 don't wear your oxygen so the oxygen is off, so I am  
5 blue doing the nebulizer for Ventavis several times a  
6 day when I am trying to work, stopping in the middle of  
7 meetings to say excuse me while I break my vials and I  
8 need to be quiet for the next 20 minutes during a  
9 conference call. It was when I was on Ventavis that I  
10 had the experience where I felt dizzy and within four  
11 to five weeks I could no longer think or read. And we  
12 were in an emergency situation I clearly was in  
13 distress not getting enough oxygen to my brain. So  
14 they put me on the Flolan at that time and like I said  
15 within a week and half of being on Flolan my brain  
16 unwound as my cardiac output improved and that was a  
17 huge, huge life changer for me. So since then I have  
18 been able to switch to what is the name of -- the other  
19 version of Flolan where I don't need to worry about ice  
20 packs which is -- Veletri which is a giant quality of  
21 life improvement to not have those ice packs on your  
22 hip and a frozen hip for years. So yeah, so my -- we

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1 started at the beginning at the smallest therapies and  
2 then quickly kind of ramped up with I would say three  
3 to four months in between each one.

4 MS. GIAMBONE: Let's do a quick show of hands  
5 here. Thank you Colleen. So Colleen mentioned and now  
6 we have heard multiple times now about three to four  
7 months of trying a drug therapy you are able to tell  
8 whether it is working for you or not. By a show of  
9 hands does that sound similar to what you think?

10 Okay. So we have about five or six hands  
11 being raised. Thank you for that.

12 Let me check in with the FDA Panel.

13 Ellis I believe you had a question and  
14 anybody else?

15 MR. UNGER: Well I had a question, kind of a  
16 follow up to the earlier panel but this question will  
17 work. We had a question about the six minute walk and  
18 what it was people thought kept them from walking  
19 faster than they were able to walk. Was it -- could  
20 they walk faster if they had less shortness of breath?  
21 Or was the problem energy? In other words was their  
22 legs just couldn't do it or was it the breathing

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1 problem? I wondered if we could get a show of hands on  
2 that.

3 MS. GIAMBONE: Okay. Great question. So did  
4 everybody hear that? The question is what specific  
5 symptom is it that maybe you are not able to complete  
6 the six minute walk test or --

7 MR. UNGER: Well what -- why everyone walks  
8 at a certain maximum speed.

9 MS. GIAMBONE: Uh-huh.

10 MR. UNGER: The question is finish the  
11 sentence you could walk faster if not for and is it  
12 shortness of breath or energy.

13 MS. GIAMBONE: Got it. So let's do a show of  
14 hands. How many of you think it is the shortness of  
15 breath that was stopping you from walking faster on the  
16 six minute walk test?

17 Okay. So we have -- I am counting about 13  
18 to 15 -- about 17 hands or so being raised. Does that  
19 sound right?

20 And the other chest pain --

21 MR. UNGER: Energy.

22 MS. GIAMBONE: Energy.

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1 MR. UNDER: Tiredness.

2 MS. GIAMBONE: Okay. Tiredness. Let's see  
3 we have one, two, three, four, five. Okay. We have  
4 five hands being raised for that. So it sounds like it  
5 is more of a shortness of breath issue.

6 Thank you Ellis.

7 All right. So let me do this, let me check  
8 in with the web to see what comments are coming in  
9 there.

10 MS. VAIDYA: Just to get back to Ellis's  
11 question on the web they are also saying shortness of  
12 breath.

13 MS. GIAMBONE: Okay.

14 MR. THOMPSON: We have a lot of similar  
15 comments on the web as to things we've heard before.  
16 People mentioning IV Remodulin, Revatio, oxygen therapy  
17 in general, Tracleer, Adcirca and some people noted  
18 some bad experiences with IV regimes and a few people  
19 have noted that they've seen significant improvements  
20 on some of the drugs you mentioned. I think overall I  
21 have a balance that reflects what we've heard in the  
22 room so far.

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1 MS. GIAMBONE: Great. Thank you.

2 And I am going to check in with the phones  
3 now. For those of you who are going to be providing us  
4 some comments on the phone we would be curious to see  
5 what your thoughts are on what specific things you'd  
6 look for in an ideal treatment.

7 So operator can we have the first caller.

8 OPERATOR: Yes we do have a comment from Toni  
9 Minerva. Your line is open

10 MS. MINERVA: Hi. I am Toni. I was  
11 diagnosed with Pulmonary Hypertension. I was diagnosed  
12 when I was two months old. It is due to a congenital  
13 heart defect. I was first put on Tracleer in 2002 for  
14 that and I was on no treatment just seeing my  
15 cardiologist every few months. And then in 2011 I was  
16 placed on Adcirca for nine months which I had to come  
17 off of due to intense joint pain. About a month or so  
18 later I was placed onto Revatio which I am still on.  
19 The combination of these two drugs have been  
20 indispensable really. I am quite sure that I wouldn't  
21 still be here were it not for the medication.

22 I don't know my walk test numbers. I don't

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1 keep track of them. I find doing that can just sort of  
2 provoke anxiety. And I really don't need that.

3 But I can tell you that I do know my walk  
4 test has been better as have my echo cardiogram  
5 results. So that for me is fantastic.

6 I do wish that going forward and finding  
7 medication that, of course, there would be less side  
8 effects from a drug and more convenience in both taking  
9 them and obtaining them.

10 MS. GIAMBONE: Thank you. Thank you for  
11 that.

12 MS. MINERVA: Thank you.

13 MS. GIAMBONE: Can we take one more caller?  
14 Okay.

15 OPERATOR: Yes we do have a comment from Orna  
16 Levy. Your line is open.

17 MS. LEVY: Hi I spoke earlier about the  
18 swelling that I deal with as a result of the Pulmonary  
19 Hypertension. I wanted to talk a little bit about my  
20 experience with Remodulin which is my IV medication. I  
21 have it through a PICC line in my arm. When I was  
22 first put on Remodulin I was in the hospital. I could

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1 barely move due to my 500 pound weight and as they  
2 started me on medication, of course, they are dilating  
3 my heart and lung blood vessels so my heart was finally  
4 able to pump which it hadn't been able to do for a very  
5 long time because I had constricted blood vessels. As  
6 a result I became very, very, very flush, very, very  
7 hot. They had to put ice packs on me Because I was so  
8 heavy I couldn't move my own legs so I had to ask the  
9 nurse to reposition my legs periodically because I  
10 would get so hot. And I had severe nausea and  
11 diarrhea. So I remember one particular day I could  
12 only take one -- eat one of two saltine crackers that  
13 day which is impressive.

14           Slowly as my body began to adjust to it,  
15 those things calmed down a little bit although I am  
16 still on a daily anti-diarrhea dose that I take along  
17 with my 30 other oral medications but all of those side  
18 effects were definitely worth enduring. I have jaw  
19 pain occasionally when I bite into something. I have  
20 occasional leg achiness. But all of that is worth  
21 enduring for the amazing benefits that I've achieved or  
22 received because of this medication. I can now walk a

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1 mile and a half where when we reached the hospital at  
2 500 pounds I was only able to walk about four feet. So  
3 it is a huge tangible difference for me besides the 300  
4 pound weight loss; just mobility.

5           Also a couple of times you guys have  
6 mentioned sort of is it tiredness or is it shortness of  
7 breath that causes you to have problems walking. And my  
8 answer is it is both combined because a lack of oxygen  
9 causes both of those things. When you don't have  
10 enough oxygen in your body your body becomes fatigued,  
11 your muscles don't have enough oxygen to function  
12 properly so your muscles themselves get tired, there is  
13 not a quick enough exchange of oxygen in and out of  
14 your muscles to refresh them. It also means that your  
15 brain becomes fatigued. You make mistakes; we call it  
16 PH brain because you are unable to think as clearly.  
17 Being an attorney that is for me the greatest downside  
18 to PH my inability to focus for long periods of time  
19 like I used to. I can't function as well as an  
20 attorney because I don't have that clear thinking. I  
21 am not as bright as I used to be because there simply  
22 isn't as much oxygen in my brain consistently.



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1 MS. GIAMBONE: Thank you so much Orna, thank  
2 you for sharing those comments. And I saw heads  
3 nodding especially when I heard the PH brain I saw some  
4 heads nodding there, so it sounds like it is a shared  
5 experience with the concentration or memory.

6 Great. Thank you so much. Now let's move on  
7 to our next polling question. So everybody get your  
8 clickers out again.

9 Let's see here. So the question is and again  
10 those of you on the web if you could also let us know  
11 what your responses are.

12 The question is what else are you doing to  
13 help reduce your symptoms of PAH? Check all that  
14 apply. A other drugs such as blood thinners; B  
15 supplemental oxygen; C surgery such as lung or heart  
16 transplantation or atrial septostomy; D lifestyle  
17 changes such as limited activity or changes in your  
18 home; E other therapies not mentioned; or F I am not  
19 doing or taking any therapies to treat symptoms.

20 So this is very interesting. We see that the  
21 majority of you have identified that there are other  
22 therapies not mentioned that you are doing to help

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1 reduce the symptoms of PAH. So we will definitely want  
2 to hear more about that followed by D lifestyle changes  
3 such as limit activity and changes in your home.

4 Let's check in with the web. Are the polling  
5 responses similar?

6 MS. VAIDYA: On the web we have a majority  
7 that say that are doing some type of lifestyle change  
8 and then an equal distribution in taking blood thinners  
9 and supplemental oxygen. So it is pretty high. And  
10 then some have mentioned other therapies.

11 MS. GIAMBONE: So slightly different.

12 Great. So let's cover the -- does anybody  
13 have anything more to add with the lifestyle changes  
14 because I'd like to spend some more time on some of the  
15 other therapies that haven't been mentioned. So are  
16 there any comments?

17 Yes. Sorry?

18 MS. COOPER: I pressed C but I see it says  
19 zero, but I pressed C.

20 MS. GIAMBONE: Oh, okay. I wonder why it did  
21 that. Thank you for telling us that you put that as an  
22 option. Thank you.

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1           So to the lifestyle changes we heard  
2 everything from diet changes to you know planning your  
3 day, making some changes around your home. Are there  
4 any comments that anybody wants to share on some of the  
5 lifestyle changes you've made before we move to some of  
6 the other therapies?

7           Yes, Holly? We have Sara coming to you.

8           MS. TISSUE-THOMPSON: I am Holly. I talked  
9 earlier on the first panel. I think that the lifestyle  
10 changes I would probably do more diet and exercise if I  
11 had more energy to do them. I have a treadmill at  
12 home; however, I have passed out on it a few times. So  
13 I am afraid to do it when my husband is not home. So  
14 with his schedule with work and my schedule with work  
15 it is just not a feasible thing to do and probably if I  
16 had more time to make maybe healthier meals then I  
17 would probably do that as well as some of the other  
18 people have spoken about.

19           MS. GIAMBONE: Thank you Holly.

20           Anybody else?

21           Yes, Colleen.

22           MS. BRUNETTI: I had some pretty good luck

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1 with alternative therapies. I used a lot of  
2 acupuncture at the beginning. It helped relieve the  
3 chest pressure and some of the feelings of  
4 breathlessness and also for stress reduction around  
5 being pretty upset about such a diagnosis. And more  
6 recently Reiki therapy which is a form of energy  
7 healing has been very helpful.

8 MS. GIAMBONE: So alternative therapy.

9 Let's go here.

10 MS. COOPER: Hi, I'm Nicole Cooper and I had  
11 an open heart and lung surgery and because my PH was  
12 caused from a blood clot. So after I had the surgery  
13 going into my lifestyle because the bottom of my lungs  
14 wasn't getting any blood for like three years so after  
15 I had the surgery me and my doctor came up with things  
16 that I could do as far as exercises. So I decided to  
17 learn how to swim because she told me the swimming  
18 would help open my lungs. So I swim everyday all year  
19 except today I am here. But I swim so that -- and it  
20 really is -- the breathing part I have trouble with  
21 under the water. But as far as if I don't keep my  
22 lungs active then they have a chance to collapse.

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1 MS. GIAMBONE: Thank you for sharing that.

2 And let me stick to Nicole's point quickly.

3 It didn't seem like the polling question captured your  
4 response. So I am curious were there others that had  
5 also chosen the surgery as one of the treatments?

6 Thank you Nicole.

7 Yes we have a comment back here.

8 MS. MATTHEWS: Yes. I spoke earlier. I am  
9 Nicole. One of the things in terms of lifestyle that I  
10 changed was my diet from a regular carnivorous diet to  
11 a vegetarian diet that is largely vegan. I have eggs  
12 every now and then. And that helped me tremendously.  
13 And I am not sure if it -- I have Lupus as I said  
14 earlier and I am not sure if it helps by decreasing the  
15 inflammation in my system which when my Lupus is very  
16 inactive I find I feel better in terms of my PAH  
17 symptoms. But in addition to the medication the diet  
18 change really helped a lot.

19 MS. GIAMBONE: Okay. So we've heard quite a  
20 bit about diet changes, reducing sodium. Let's take  
21 one more comment.

22 MS. BROWN: I just wanted to say that

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1 exercise has been a big factor that helps me. And I  
2 didn't realize it was helping until I -- I was doing  
3 the treadmill and I stopped for several months. And  
4 when I went to get my six minute walk it was not good.  
5 And my doctor knew right away; he said are you still  
6 doing the treadmill? And I was like no. So he said I  
7 can tell, so he said I needed to step it up. Now I am  
8 a PH patient, I was doing 30 minutes. I was like so  
9 step it up to what? But I am glad to say that I now  
10 can do one hour on the treadmill but I have my liter  
11 flow is only ten. But that is helping me a lot.

12 MS. GIAMBONE: Thank you.

13 How many of you by a show of hands if you are  
14 comfortable to do so also think that exercise is an  
15 important part of your treatment regime.

16 It looks like the majority of you. I see a  
17 lot of hands raised here.

18 Let's focus a moment on some of the other  
19 therapies we've heard acupuncture; we've heard  
20 alternative therapies, some energy healing therapy that  
21 you are doing. Anybody else want to share some  
22 experiences with other therapies?

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1 Yes, Maratha?

2 MS. GONZALEZ: Hi. We do know that PH  
3 patients do not do well with congestion and my son in  
4 particular he has seasonal allergies and I know that  
5 living in the Garden State, I live in New Jersey, maybe  
6 there are some people here that live also in New  
7 Jersey, do suffer a lot of allergies. So we try to  
8 prevent that congestion on my son. So he is taking  
9 continuous medicine for allergies such as he started  
10 with Zyrtec and now he is in Claritin. It is something  
11 that he is on all the time, everyday. So it is  
12 something added to his treatment just to help to  
13 prevent the congestion.

14 MS. GIAMBONE: Thank you for sharing that,  
15 Martha.

16 Let's do another show of hands here because I  
17 do recall hearing some other panel members I believe  
18 share that they were also taking some allergy  
19 medications.

20 So who else takes allergy medications on some  
21 sort of daily basis or very frequent basis?

22 So we have one, two, three, four, five, six.

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1 So I am seeing about six hands raised. Great.

2 FDA Panel do you have any questions, any  
3 follow up questions regarding some of these other  
4 therapies?

5 Great.

6 So let me ask now to get some input from you  
7 on what would you look for in an ideal treatment. We've  
8 heard everything from you know I wish the equipment or  
9 the management of all the equipment wasn't so  
10 cumbersome to perhaps rather than IV medications  
11 something oral. Any other thoughts that you want to  
12 share?

13 Yes, Holly?

14 MS. TISSUE-THOMPSON: If we could find  
15 something that is more specific to just the lung  
16 vessels instead of all vessels because the prostanoids  
17 they dilate all the vessels which in my case brings my  
18 regular blood pressure down very low. It runs about 90  
19 over 58 on a routine basis which I think contributes to  
20 my fatigue as well because if you don't have the blood  
21 pressure behind you you are not able to keep up with  
22 your activities. So if there was some way to find a



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1 drug that is more specific just to the lung blood  
2 vessels instead or throughout the body that would be  
3 great.

4 MS. GIAMBONE: Thank you Holly.

5 Yes. We have a few more hands raised over  
6 there.

7 MS. MAXWELL: My name is Nancy Maxwell. I  
8 think ease of use and that is a relative term with PH  
9 but I am on Veletri and it takes a lot of planning just  
10 from when am I going to do the dose and where am I  
11 going to do it if I am away from home. You know do I  
12 have the proper sterile condition or close to sterile  
13 condition. You know if the weather is going to be bad,  
14 if we are going to get a snowstorm, if we think there  
15 is going to be electricity going out, what is going to  
16 be the plan for that. So any of the IV medications are  
17 hard to use. And we already do so much planning in our  
18 daily life just trying to live our daily life the  
19 medications just add to that planning and that high  
20 degree of difficulty. So it would be really great if  
21 we could have something that was easier to use. My  
22 dream is a pill. So just something that would be

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1 easier to use and that is it.

2 MS. GIAMBONE: Thank you Nancy.

3 Yes.

4 MS. FLIPSE: Hi, Alex again. I would say  
5 something with not so many side effects. Obviously  
6 medications are going to have side effects but when I  
7 was on Flolan I had everything, the jaw pain, the  
8 flushing, the leg pain, the nausea and the vomiting. I  
9 got the Flolan diet; I went from 180 pounds down to 92  
10 pounds within a matter of months. I could not eat and  
11 breathe at the same time. It became a choice and I  
12 believe that might have been a side effect of the  
13 Flolan you know.

14 MS. GIAMBONE: Thank you Alex.

15 Anybody else? Yes, Lucille?

16 MS. MONKO: And of course this may not be the  
17 right forum but the cost of any of these medicines are  
18 just so astronomical and I do know that a few in the  
19 support groups I go to people were taken off the brand  
20 names and whether they have generic or something  
21 similar to but needless to say they do not provide the  
22 performance that the brand names. So I mean the cost

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1 is a great deal in sometimes the doctor selecting you  
2 know what treatment they can be given in relation.

3 MS. GIAMBONE: Thank you Lucille.

4 So that is probably a good lead in to some of  
5 the questions that I know some of the FDA panel  
6 received during the break earlier when we had the  
7 break. Ellis, would you mind rephrasing the question  
8 and answer the question that you received during the  
9 break.

10 MR. UNGER: Okay. We received a couple of  
11 questions about whether we could comment on any drugs  
12 that might be being developed to treat pulmonary  
13 hypertension. And the answer is that there are drugs  
14 being studied to treat pulmonary hypertension. And  
15 hopefully will bear fruit for people in this room at  
16 some point. But we are barred from discussing any kind  
17 of information about drugs that are under development  
18 because that is trade secret information. So we promise  
19 to keep that information confidential because it  
20 involves trade secrets and a lot of proprietary  
21 information. So we can't talk about it.

22 A point I would like to make though about

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1 generics. Generics are very strictly regulated by FDA.  
2 And they have to be -- they have to perform similarly  
3 to the name drugs. And there are many people who  
4 believe that generics don't work as well as the brand  
5 name because heck if you pay less for it, it can't be  
6 as good; right? But that is not true and we would love  
7 to dispel that way of thinking because it really isn't  
8 true because the standards are quite strict. They are  
9 tested. They have to meet certain performance  
10 standards. And I can guarantee you that any of us at  
11 the FDA who take drugs will always take a generic if it  
12 is available rather than a trade name because it is  
13 cheaper and it's just as good. So I would like to add  
14 that.

15 MS. GIAMBONE: Thank you very much Ellis.

16 So on that note let me recap everything we  
17 discussed in Topic 2; again a very, very rich  
18 conversation. We've learned so much from you and we  
19 are very thankful for that.

20 So we learned from you that most of you your  
21 current treatment regimen involves multiple  
22 medications, drug therapies. It sounds like many of

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1 you have had to change that treatment regime over time  
2 based on what is working for you and what is not  
3 working for you. It sounded like many of you have  
4 incorporated lifestyle changes, everything from  
5 modifying how you go about your day, planning your day  
6 to diet changes such as limiting your sugar or sodium.  
7 It sounds like you are also incorporating some  
8 alternative therapies that are helping you. And you  
9 have given us some really great feedback on what you  
10 are looking for in an ideal treatment.

11           Additionally I want to mention that you also  
12 brought up the downsides of the treatment that you are  
13 currently taking. We've heard nose bleeds, we've heard  
14 a nagging cough. Let's see we heard dehydration. So  
15 we've captured all of that and if there is something  
16 that we didn't capture today or that we couldn't get to  
17 today, I just want to remind everybody to again go to  
18 the public docket, visit the public docket and provide  
19 your comments there. They are very, very valuable to  
20 us. And they will all be part of the public record.

21           So yes, let's check in very quickly with the  
22 web.

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1 MR. THOMPSON: Just to wrap up the discussion  
2 we had a lot of comments on the web about ideal  
3 therapies, people just wanting fewer side effects in  
4 general but specifically avoiding the external IV  
5 lines, drugs that target the lungs or heart  
6 specifically instead of all blood vessels. And for  
7 personal oxygen carriers things that what we said  
8 earlier, just making them more convenient. And just in  
9 general therapies that don't interfere with daily life  
10 as significantly.

11 MS. GAIMBONE: Thank you Graham.

12 And thank you to all of you on the web for  
13 continuing to provide your comments. We really, really  
14 appreciate that even though you weren't able to join us  
15 in person that you have been so actively participating  
16 via the web.

17 So on that note I am going to turn it over to  
18 Sara, my colleague Sara for the open public comment  
19 period.

20 MS. EGGERS: Good afternoon. My name is Sara  
21 Eggers. And I am going to do the open public comment.  
22 We had two comments come in today so we will let you

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1 each speak for three minutes because we let the  
2 facilitated discussion go longer today. The purpose of  
3 this open public comment period as Soujanya mentioned  
4 is to give people a chance to make a comment that might  
5 be outside the scope of the discussion today. Or make  
6 a comment by someone who is not a patient or a patient  
7 representative.

8 FDA won't be able to address the comments  
9 that are made. We are in listening mode but they are  
10 part of the transcript, they're part of the public  
11 record. And as a transparent process if you are  
12 supported or funded or associated with an organization  
13 and you want to make that public as well we encourage  
14 you to do so although you don't have to.

15 So we have Sally and then Rino I think. So  
16 we are going to let Sally go first. Yes. I am not  
17 going to use the timers but I will give you a gentle  
18 nudge if we need to move on. Thanks Sally.

19 MS. OKUN: My name is Sally Okun. I'm from  
20 Patients Like Me. I am representing about 350 to 400  
21 patients on Patients Like Me who are suffering and  
22 living with the condition of pulmonary hypertension. I

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1 wanted to bring it to the attention of the group today  
2 because we actually have a relatively small number of  
3 patients on the site with this and I wanted to come  
4 today to learn from all of you and I've learned a lot.  
5 And I want to bring that information back to our  
6 patient population.

7           We are a patient powered research network  
8 that really is set up with the idea of being able to  
9 systematically collect information about your treatment  
10 experiences as well as you symptom experiences. And  
11 some of the things I heard today were consistent with  
12 some of the things our patients are already telling us.

13           However I think this teasing this issue out  
14 of energy and fatigue is important because many of the  
15 patients on our site are telling us that their fatigue  
16 is actually more severe and that their shortness of  
17 breath actually while severe it is moderate to severe  
18 and their fatigue seems to have a greater level of  
19 severity. So helping to understand that might be  
20 helpful.

21           But the other thing, there are a couple of  
22 other symptoms our patients are telling us about more



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1 frequently. Depression and anxiety and I heard today a  
2 few things that actually could be teased out too. Some  
3 was just the anxiety of sleeping at night. And so the  
4 insomnia associated with that might be significant.  
5 And so these are the sort of things real world and  
6 quality of life issues that I think we could begin to  
7 learn more about.

8 I finally wanted to say just a couple of  
9 things. One of the things we didn't hit on today much  
10 about are clinical end points and patient reported  
11 outcome measures. I would encourage us to really start  
12 thinking about the experiences that the people were  
13 telling us about today from the perspective beyond the  
14 six minute walk. What can we learn more from the  
15 patient reported outcome measures that would actually  
16 tell you a bit more about what their real world  
17 experiences are? In fact I would even challenge that  
18 the six minute walk is actually maybe not an accurate  
19 reflection of their real world walking because we know  
20 that the influence of weather, whether it is warm or  
21 cold or whatever, is actually influencing their ability  
22 to walk yet on a treadmill they are doing better. So

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1 we may not be getting a real accurate measure.

2           And then finally I just really wanted to  
3 mention just the significant burden on patients with  
4 the treatments that they have and encourage the FDA to  
5 find ways of really moving beyond the burdensome types  
6 of treatments with all of the equipment really the  
7 heavy load that people are carrying because frankly I  
8 think we also heard that it influences their ability to  
9 adhere appropriately to their regimes of their  
10 medications. So I think if we can really begin to look  
11 at some of these kinds of things and I encourage people  
12 to think about joining Patients Like Me in the patient  
13 powered research network to really start having a  
14 systematic way of collecting your data, to aggregate  
15 that and then share that appropriately not only with  
16 drug development but also with the FDA and we'd be  
17 happy to help you with that.

18           Thank you so much for the opportunity to  
19 comment. And I really want to thank all the patients.  
20 I will be bringing your voice back to our community.

21           Thank you.

22           MS. EGGERS: Thank you Sally.

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1 And then we have Rino? Turn the mike on.

2 MR. ALDRIGHETTI: Hello. Yes. My name is  
3 Rino Aldrighetti. I am the president of the Pulmonary  
4 --

5 MS. EGGERS: Can you speak in a little bit  
6 more. Just take it off. You can take it off.

7 MR. ALDRIGHETTI: Okay. Thank you. My name  
8 is Rino Aldrighetti and I am the President of the  
9 Pulmonary Hypertension Association. First of all we  
10 really want to thank you for this program and the  
11 opportunity for you to hear from patients. It is as  
12 you know something that is unique, it's valuable and  
13 it's appreciated.

14 What I would like to do is speak a little  
15 more broadly about some of the issues that really may  
16 go beyond the scope of what the FDA does but are  
17 important in looking at comprehensive treatment of this  
18 disease.

19 First of all looking at data from the Reveal  
20 Registry which is the largest registry of pulmonary  
21 hypertension patients ever produced several physician  
22 began to produce papers about three years ago that

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1 demonstrated that during the past 20 years there has  
2 been little if any reduction in the onset of symptoms  
3 for the point of diagnosis to onset of symptoms for  
4 this disease. So basically 20 years ago it didn't  
5 matter. There were no treatments as you know.

6 Today it matters a great deal if patients  
7 don't get diagnosed. And so what we are doing is we  
8 have created about a year and a half ago an early  
9 diagnosis campaign. And that is based on doctors  
10 working together through three committees and an  
11 advanced public relations program to get information  
12 out to the general public.

13 But ultimately what is going to be very  
14 important is simplifying diagnosis for this disease.  
15 Many patients are still not seen in time to take  
16 advantage of the 12 treatments that are now available.

17 Another issue that is really important to  
18 understand is this field has grown from about 100  
19 treating physicians in 2001 to over 10,000 today. And  
20 not all of those physicians and I would say most of  
21 those physicians are not connected to the rapidly  
22 developing research in this field. Consequently with

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1 most of those doctors seeing two or three patients it  
2 becomes very important to create some order in this  
3 field. You know if you are in France there is a clear  
4 system of treatment and French doctors will tell you  
5 that they don't have misdiagnosis issues. Here any  
6 doctor who wants to treat pulmonary hypertension can.  
7 So what working over the last two years with leading  
8 physicians in the field through four committees we have  
9 now created a system for the accreditation of PH  
10 centers. We are in the pilot stage of that project and  
11 completing that and following the evaluations. We will  
12 be launching that program within the next two months.

13           And third and finally it is important not  
14 only to get drugs approved but it is important to get  
15 drugs in the hands of patients. We all know that our  
16 health care system is changing. What we are seeing in  
17 terms of specialty pharmacies is mergers and what we  
18 are seeing is payers coming into the field with a  
19 control over how patients are getting their drugs often  
20 causing delays in patients getting their drugs. And  
21 consequently we working with Patients Family Members  
22 Medical Professionals, the specialty pharmacies

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1 themselves and the pharmaceutical companies have  
2 created a cooperative structure to begin to create  
3 feedback on how these systems are working. And that  
4 program is now entering phase 2 where we will be  
5 gathering a great deal of feedback on how these systems  
6 are working.

7 So those are a few of the things that --

8 MS EGGERS: Rino, we are going to have to ask  
9 you to wrap it up.

10 MR. ALDRIGHETTI: I will wrap it up right  
11 now.

12 MS. EGGERS: Great.

13 MR. ALDRIGHETTI: Simply to say thank you and  
14 just a word about what you did in terms of adjusting  
15 your position in terms of Sildenafil. We know that the  
16 pediatric PH physicians greatly appreciate what you did  
17 in listening to them.

18 Thank you.

19 MS. EGGERS: Thank you very much.

20 [Applause.]

21 MS. EGGERS: And with that I believe that  
22 Norman Stockbridge will be giving some closing remarks

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1 to end the meeting.

2 MR. STOCKBRIDGE: Yeah. I want to say that  
3 the division that I work in and Dr. Targum to my left  
4 works in manages a portfolio of drugs that try to  
5 prevent need for dialysis, prevent heart attacks,  
6 prevent strokes. But when we got polled maybe 18  
7 months ago to name a patient group that we'd like to  
8 interface with and have some dialogue it took no time  
9 at all to decide it was you that we wanted to talk  
10 with. So I very much appreciate the effort that it  
11 took whether you came from inside the Capital Beltway  
12 or Connecticut or Texas the effort that you made coming  
13 and sharing your experiences with us is very much  
14 appreciated.

15 We I think got some useful interesting  
16 insights from you today; something we can carry into  
17 what remains a lively development area. And I am  
18 hopeful that in years to come you will get some better  
19 therapies and work some different mechanisms.

20 But mostly I want to say thank you very much  
21 for your efforts in coming today.

22 [Applause.]

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1 MS. GIAMBONE: Thank you very much. So on  
2 behalf of all my FDA colleagues I just want to say  
3 again thank you. Thank you for making the trip to come  
4 here. I know that it is not easy. But we appreciate  
5 it. We've learned so much. And we thank you for that.

6 And just a reminder that if you haven't  
7 already completed your evaluation forms to please do so  
8 and you can leave them right on the table.

9 And last but not least if you could leave  
10 your clickers. They are not going to do much good once  
11 you leave campus. So thank you.

12 (WHEREUPON, the meeting ended.)

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2

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