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Breast Cancer Patient-Focused Drug Development 04-02-2015

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U.S. FOOD AND DRUG ADMINISTRATION

BREAST CANCER PUBLIC MEETING ON  
PATIENT-FOCUSED DRUG DEVELOPMENT

April 2, 2015

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U.S. Food and Drug Administration  
White Oak Campus  
10903 New Hampshire Avenue

Reported by: Michael Farkas  
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1 A P P E A R A N C E S

2 FDA REPRESENTATIVES:

3 SOUJANYA GIAMBONE, MBA

4 AMNA IBRAHIM, MD

5 TERESA MULLIN, PhD

6 SUPARNA WEDAM, MD

7 AMY McKEE, MD

8 GEOFFREY KIM, MD

9 ASHLEY SLAGLE

10 JONCA BULL, MD

11 GRAHAM THOMPSON

12 PUJITA VAIDYA

13 PANELISTS:

14 KAREN DURHAM

15 KATY McRAE

16 DEBBIE DRAKE DUNNE

17 SANDY FINESTONE

18 KATHERINE O'BRIEN

19 GINNY KNACKMUHS

20 ELIZABETH CAPPEL

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

2 (Continued)

3 PANELISTS (continued)

4 SUSAN FARIS

5 JOANNE BUZAGLO

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7 COLLEEN DUFFY

8 SHIRLEY MERTZ

9 CINDY GEOGHEGAN

10 KIMBERLY BEER

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

2 MS. GIAMBONE: All right. So we'll go  
3 ahead and get started. So good afternoon,  
4 everyone. My name is Soujanya Giambone. I am  
5 with the FDA Center for Drug Evaluation and  
6 Research Office of Strategic Programs and on  
7 behalf of all of my FDA colleagues, I'd like to  
8 thank you and welcome you all to the Patient-  
9 Focused Drug Development Meeting on Breast Cancer.

10 So it's really nice to meet so many of  
11 you and especially for all of you that I've been  
12 speaking to on the phone, it's nice to finally get  
13 to meet you all in person and we really appreciate  
14 that you're all here because we have so much to  
15 learn from you today.

16 So I'm the facilitator for today's  
17 meeting and I'm going to spend just a few minutes  
18 going over the agenda. You all should have a copy  
19 of that. If not, we have some copies out on the  
20 registration desk. And then I'll go over a few  
21 housekeeping items and we'll get started.

22 Okay. So we'll start off today with

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1 some presentations from my FDA colleagues. They  
2 are going to provide some opening remarks, an  
3 overview of the patient-focused drug development  
4 initiative, and a background on breast cancer and  
5 current treatment options.

6           And then I'll come back and I'll go over  
7 the discussion format for the day. So we have two  
8 discussion topics. Topic 1 is on the disease  
9 symptoms that matter most to you as the patient,  
10 and topic two is on your perspectives on current  
11 approaches to treating breast cancer. And we'll  
12 have a panel discussion followed by a group  
13 discussion for each of those topics and that'll  
14 take us to pretty much the last half an hour of  
15 the day which we reserve for open public comment.  
16 And open public comment is -- it's basically a  
17 time that anybody in the audience, not just  
18 patients or patient representatives, but if  
19 anybody wants to share additional thoughts or  
20 perspectives that are outside of the scope of  
21 Topic 1 or Topic 2, we encourage you to sign up  
22 for open public comment, and you can sign up out

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1 on the registration desk. There's a signup sheet  
2 there and we'll take signup until break time, and  
3 then we'll take a look at how many people signed  
4 up and how much time each speaker will have. And  
5 then we'll wrap up the day with some closing  
6 remarks.

7           So, as you can see, it's a pretty full  
8 day of discussion but we're really, really  
9 thankful that you're here and we're looking  
10 forward to a great day of discussion.

11           Just a few housekeeping items. The  
12 bathrooms are back out into the lobby area and if  
13 you make a right and go all the way down the  
14 hallway, you'll see the bathrooms there. And you  
15 will also see that we have a kiosk that sells  
16 basic snacks, drinks, sandwiches for you to  
17 purchase if you would like, so please feel  
18 comfortable to get up and stretch, take a break,  
19 get a snack if you need to. We want you to feel  
20 as comfortable as you can and, you know, do what  
21 you need to do to just be comfortable.

22           And also, I just want to mention this



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1 meeting is being recorded and transcribed and  
2 within a few days after the meeting, the recording  
3 and the transcript will be available on the  
4 meeting website.

5           So with that, can I just have my FDA  
6 colleagues please introduce yourselves.

7           DR. KIM: Hello and thank you, everyone,  
8 for coming. My name is Geoff Kim. I'm the  
9 Division Director for the Division of Oncology  
10 Products 1, where many or most of the drugs  
11 related to the treatment of breast cancers are  
12 regulated.

13           DR. IBRAHIM: Hi. I'm Amna Ibrahim.  
14 I'm the Deputy Division Director for DOP1.

15           DR. WEDHAM: My name is Suparna Wedam.  
16 I am a medical reviewer in the Division of  
17 Oncology Products in the breast cancer group.

18           DR. MCKEE: My name is Amy McKee. I'm  
19 the Clinical Team Leader in DOP1 of one of two  
20 teams that handles breast cancer products.

21           DR. MULLIN: Hello, I'm Theresa Mullin.  
22 I direct the Office of Strategic Programs in the

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1 Center for Drugs and I am the lead for this  
2 patient-focused drug development effort for the  
3 Center. Thanks.

4 MS. SLAGLE: Hello, I'm Ashley Slagle  
5 with the Study Endpoint staff in the Office of New  
6 Drugs.

7 DR. BULL: Good afternoon. Jonca Bull.  
8 I direct the Office of Minority Health in the  
9 Office of the Commissioner.

10 MS. GIAMBONE: And could I have  
11 colleagues over here introduce yourselves?

12 MR. THOMPSON: Graham Thompson, Office  
13 of Strategic Programs.

14 MS. VAIDYA: Pujita Vaidya, Office of  
15 Strategic Programs.

16 MS. GIAMBONE: Great. Thank you so  
17 much. And with that, I'm going to turn it over to  
18 Anna for her presentation.

19 DR. IBRAHIM: Good afternoon again and  
20 welcome to today's meeting on breast cancer  
21 patient- focused drug development. AS I introduce  
22 myself, I'm Anna Ibrahim. I am the Deputy

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1 Division Director of DOP1. Our division houses  
2 the breast cancer group where the drugs which are  
3 aimed at the treatment of breast cancer reside.

4           This is a very important meeting and we  
5 are looking forward to hearing from participants  
6 about their experiences and what they look for in  
7 treatments for this condition. We are happy to  
8 see so many patients and advocates in the audience  
9 and I understand that there are many others  
10 joining remotely from the web. Thank you for  
11 being here and being part of this meeting.

12           Today's meeting is one in a series of  
13 what is called FDA's Patient-Focused Drug  
14 Development Meetings. Theresa Mullin will be  
15 talking about this initiative in more detail in a  
16 few minutes.

17           Breast cancer has a significant public  
18 health impact on the country. It is the most  
19 common cancer among women in the U.S. We are  
20 really looking forward to hearing directly from  
21 patients about the symptoms they experience and  
22 how they view existing and potential therapies for

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1 treating breast cancer and the challenges they  
2 face in prolonging life while also maintaining  
3 quality of life.

4           When we discuss drug development, we are  
5 referring to the process of identifying and  
6 evaluating potential therapies that can help  
7 patients treat their cancer. FDA's mission is to  
8 protect and promote public health by evaluating the  
9 safety and effectiveness of new drugs. While we  
10 play a critical role in drug development, we are  
11 just one part in the process. We do not develop  
12 drugs or conduct clinical trials. Drug companies,  
13 often working with researchers or patient  
14 communities, are the ones who conduct the trials  
15 and submit applications for new drugs to FDA. We  
16 work closely with these drug companies throughout  
17 their drug development process. We are, therefore,  
18 glad to see such representation and interest in  
19 today's meeting from industry, academia, and other  
20 government partners in the room and on the web.

21           I want to spend a few minutes providing  
22 a bit of background on FDA's important role in

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1 drug evaluation. For a drug to be approved for  
2 marketing, FDA must determine that it is safe and  
3 effective for its intended use. Our regulating  
4 decisions are based on science, medicine, as well  
5 as legal and regulatory standards. First and  
6 foremost, the drug must demonstrate a minimum  
7 standard of efficacy for its intended use. The  
8 safety of a drug should be such that the benefits  
9 of the drug should outweigh the risks. The FDA  
10 makes determination for the risk- benefit  
11 assessment for the new drug based on the totality  
12 of information provided by a sponsor in the new  
13 drug or biologic application which is a request  
14 for marketing authorization in the U.S. FDA  
15 benefit- risk assessment takes into account many  
16 factors such as the disease setting, the  
17 population of patients treated, presence of  
18 alternative therapies for the indication and the  
19 improvement provided by them, the magnitude of the  
20 demonstrated benefit, and the nature of the risks  
21 associated with the product.

22 What we hear today can help us

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1 understand how patients view benefits and risks  
2 and will strengthen our understanding of what  
3 patients want to see in their treatment options.  
4 Sometimes we struggle with how to evaluate  
5 treatments that might have a small benefit to  
6 patients and a very large risk, so hearing what  
7 patients think about these issues can really help  
8 strengthen our benefit-risk thinking in those  
9 situations.

10 Thank you again for your participation  
11 and for being here today. We do appreciate it. I  
12 now turn it over to Theresa Mullin who will  
13 provide some background on FDA's overall patient-  
14 focused drug development efforts. Thank you.

15 DR. MULLIN: Thank you, Amna, and good  
16 afternoon again and thank you for joining us at  
17 this meeting today. This meeting on breast cancer  
18 is one of, for us, a series of meetings where  
19 we're launching this new effort under this  
20 reauthorization of the User Fee program, and I  
21 wanted to just spend a minute to put it in that  
22 context for you before we get into the specifics

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1 of the questions and the content of the focus of  
2 our meeting today.

3           As Amna -- as Dr. Ibrahim mentioned, she  
4 referred to the risk-benefit or the benefit-risk  
5 assessment framework that's used by -- in our  
6 review of new drugs and even continuing to look at  
7 drugs on the market over time, two of the factors  
8 in that framework are the severity of the  
9 condition, sort of the experience of the patient  
10 and the severity of the impact of the disease on  
11 their life and, in fact, including the treatment  
12 on their life and what treatments are available  
13 today, and how well do those treatments work, and  
14 what is it like to have to use those treatment for  
15 the patient. And those two components really set  
16 the stage -- and this is what reviewers have told  
17 us over -- as we've developed this framework --  
18 that sets the stage for their evaluation of the  
19 other evidence that they have, the benefit  
20 information, what they hear about the safety  
21 issues, how you might manage those risks. So  
22 those two components are really where we wanted to

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1 focus and get more information.

2           And at the start of this effort in 2012,  
3 we realized that we had very limited means for  
4 getting that kind of information from patients.  
5 We have a patient representative program and  
6 that's very valuable except that the limitation  
7 there is that we have to put the patient  
8 representative who may or may not have the disease  
9 that is of interest and to -- they have to go  
10 through conflict of interest screening. We don't  
11 -- because we're talking about a particular drug,  
12 we have to make sure there's no conflict there,  
13 and so that really limits the input we can get and  
14 we know that you can't -- one person really would  
15 have an impossible job to represent the views of  
16 all the diversity of patients who may be  
17 experiencing a condition. And so we wanted to  
18 have a meeting structured not around a product but  
19 around the disease area so we could not have to  
20 deal with that screening and really get a much  
21 broader and more diverse range of input from  
22 people who are suffering from the disease or in



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1 some cases, people or families who are living with  
2 persons and caring for people with a particular  
3 disease. So that was the motivation for this.

4           And we realize we -- you know, patients  
5 are the most critical informant, really, for these  
6 benefit-risk assessments because the patient is  
7 the one who will be using the drug and getting any  
8 benefit there is to gain and be suffering any harm  
9 there is, that they may be exposed to from the  
10 drug. And so how could we get a better richer and  
11 broader input from the patient community. And so  
12 this is a sort of experiment, if you will. We're  
13 doing these 20 meetings. Breast cancer is one of  
14 the 20 diseases that we chose and the Review  
15 Division identified breast cancer as one of the  
16 priorities for them and, you know, you'll hear  
17 more from their questions today about what they're  
18 hoping to gain and the opportunity there. And so  
19 these 20 are really giving us a test bed to figure  
20 out where do we go from here in this kind of  
21 engaging the patient more and getting more  
22 systematic input from patients to inform drug

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1 development. And so this is part of the effort.

2           We began it in 2012. We put out an  
3 announcement with a set of diseases that we got  
4 public comment. We got over 4,000 comments from  
5 the public about the list that we published, with  
6 other ideas as well. We took that list and the  
7 input that we got and identified 16 diseases for  
8 the first three years of the program. And in a  
9 few months, we'll be able to publish the set of  
10 diseases that have identified for the final two  
11 years of this five-year program. I say "final  
12 years" of this program but this is water heaters  
13 at we view as the first phase of this effort. We  
14 very much plan to continue and evolve it and  
15 actually expand it beyond this five-year period.

16           Here is the list of the diseases that  
17 we've included in the first three years and as you  
18 can see, today's meeting is focused on breast  
19 cancer. We have four more coming up later in this  
20 fiscal year so between now and the end of  
21 September, we'll have some others. And so -- and  
22 as I said, we'll be covering more later.

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1           There are some standard questions  
2 related to those two considerations that I  
3 mentioned. Severity of the condition and the  
4 impact and benefits of the treatments currently  
5 available are the focus of every one of these  
6 meetings, so there are some standard questions  
7 that we will cover related to those in the disease  
8 area. And then we'll also be asking other  
9 questions. I say "we" but I particularly mean the  
10 Review leadership is probably going to be asking  
11 other questions as well of things that they may  
12 want to probe further taking advantage of the  
13 opportunity of having you here in the room land  
14 having our participants on the webcast to get  
15 firsthand input from you about other things that  
16 they may be concerned about or aspects of  
17 treatment or development that they think you would  
18 be particularly able to help them understand  
19 better or inform.

20           We produce a report after these  
21 meetings. It's called "The Voice of the Patient  
22 Report" and those are available on our website.

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1 If you "Google" "voice of the patient" -- I mean  
2 I'm lazy, that's what I would do but I find --  
3 that's how I find stuff on our website. I go to  
4 Google.

5 (Laughter.)

6 DR. MULLIN: And don't share that with  
7 our IT people please. But it's a report that  
8 tries to capture very faithfully not just what  
9 people tell us but really what and how they tell  
10 it to us because how they describe what they're  
11 going through is just very much part of the what  
12 and so we recognize that. We try to capture that.  
13 We both get the information from the room, from  
14 the input from our webcast, and we keep an  
15 electronic docket open for any additional  
16 information that you may think of or have you want  
17 us to include in what we capture as part of this  
18 report effort, and other comments that we get are  
19 submitted to the Docket. We give a few more weeks  
20 for that to come in and then we take all that to  
21 produce these reports. And they provide a very  
22 useful way to capture that information for

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1 subsequent reference by the Review Divisions.  
2 When they maybe get another application for that  
3 disease area, they'll go back and that -- and we  
4 actually shape up those first two sections. We  
5 provided some examples of how -- what they might  
6 be thinking about and encapsulate some of it. The  
7 reports are short enough that they're readable and  
8 reviewers and others, we hope -- I've heard from  
9 friends who are patients with some of the diseases  
10 that we've had that the reports have resonated  
11 with them, too, which is very gratifying for us to  
12 hear. That's what we hope to do. But it's a first  
13 step. It does provide that context and it's also  
14 prompting a certain amount of further thinking on  
15 our part about what we want to do to sort of more  
16 systematically capture this information longer  
17 term, maybe find ways to capture it and measure it  
18 so that it can become evidence of benefit in  
19 addition to providing very critical context.

20           And so that's what we're doing with this  
21 effort and with that, I'll turn it over to  
22 Suparna Wedam who is going to give us more

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1 information about the topic of disease and current  
2 treatment. Thank you.

3 DR. WEDHAM: Great. Thank you, Theresa.  
4 Good afternoon. So as mentioned earlier, my name  
5 is Suparna Wedam and I'm a Medical Officer in the  
6 Division of Oncology Products here in the breast  
7 cancer group. I also continue to see patients  
8 regularly, breast cancer patients in the clinic  
9 each week, actually on Thursday so today is my  
10 clinic day but I thought it was very important to  
11 come to this meeting here. So I am well-aware of  
12 the direct impact of our treatment decisions as  
13 far as the benefit that they provide, which is  
14 obviously the intended goal of our therapy, but  
15 also the unfortunate side effects and toxicity  
16 that we have to deal with, and this can be wide-  
17 ranging from very mild such as some dry skin or  
18 mild constipation to much more serious or severe  
19 such as blood clots or debilitating neuropathy.  
20 And as patients are living longer and the  
21 treatments are becoming more chronic, this is more  
22 important than ever that we really take these all

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1 into consideration in our treatment decisions.

2           So again, I'm going to echo the  
3 sentiments of my previous speakers that I'm very  
4 happy you're here. I think this is a very  
5 important forum and it's fantastic that we have  
6 this opportunity to hear from you today.

7           So my task today is to give a brief  
8 background on breast cancer and the therapeutic  
9 options. So as mentioned earlier, breast cancer  
10 remains a major public health concern. We've made  
11 major strides over the last few decades but we  
12 still have a lot of work to do. It is the second  
13 leading cause of cancer-related death among women  
14 in the United States, second only to lung cancer.  
15 And this year, it's estimated that a little over  
16 230,000 will be diagnosed with breast cancer and a  
17 little over 40,000 will die of the disease in this  
18 country.

19           So as with all cancers, breast cancer is  
20 very complicated and we don't really know what  
21 exactly causes it, but there are many risk factors  
22 that have been associated with breast cancer and

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1 implicated in its etiology and these are often  
2 divided into unmodifiable and modifiable risks  
3 which I have listed in two columns here.

4           So on the left-hand column are some of  
5 the unmodifiable risks which, as the word implies,  
6 are things that we cannot change, we do not have  
7 control over yet, they put us at a higher risk  
8 such as being of female gender, increasing age,  
9 certain genetic risk factors. This actually only  
10 makes up about 5 to 10 percent of breast cancers  
11 and what we most commonly hear about out in the  
12 public and the media is BRCA1 and BRCA2, but there  
13 are many other genes that increase a patient's  
14 increased risk of breast cancer such as ATM, p53,  
15 PALB2. They're just much rarer and we don't  
16 understand them that well. These are important  
17 not only for screening and for monitoring but they  
18 may have therapeutic implications as we understand  
19 them better. Also important are personal and  
20 family history, dense breast tissue, certain  
21 breast conditions such as atypia or hyperplasia  
22 and the age of menarche and menopause.



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1           In the right-hand column are some  
2 modifiable risk factors. So these are things that  
3 we have control over and could potentially change:

4           nulliparity which is not having  
5 children, certain hormonal birth control methods,  
6 hormone replacement in menopause, breast feeding,  
7 alcohol use, obesity, and physical activity.

8 There are many other factors that have been  
9 mentioned and discussed and it's not really clear,  
10 again, what their association is.

11           So when patients present to us with a  
12 suspected breast cancer, they're actually often  
13 asymptomatic. A patient may have a palpable  
14 breast mass that they have felt themselves or that  
15 has been palpated by a healthcare provider but in  
16 this country, actually, most people present after  
17 an abnormality has been seen on a screening  
18 mammogram or MRI. In the late stage, patients may  
19 have some generalized constitutional symptoms such  
20 as fatigue, weight loss or decreased appetite, or  
21 localized symptoms such as bone pain or abdominal  
22 discomfort depending on where the tumor is. But

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1 even then, a portion remain asymptomatic and I  
2 think this is important to keep in mind that  
3 actually most breast cancer patients, when they're  
4 diagnosed, are asymptomatic and feel well but we  
5 can make them feel unwell with our treatments. So  
6 we want to make sure that that toxicity is really  
7 balanced with a clear benefit.

8           So once breast cancer is suspected, we  
9 need tissue confirmation as a diagnosis cannot be  
10 made on physical exam or imaging alone. The  
11 tissue is important not only to confirm breast  
12 cancer but to gain other important information in  
13 formulating a treatment plan. And then once the  
14 diagnosis is confirmed, we stage the patient  
15 according to the TNM system. So this looks at the  
16 size of the tumor, the extent of nodal status and  
17 whether metastases -- distant metastases are  
18 present or not, and the patients are given a stage  
19 of one, two, three, or four and this is shown in  
20 the schematic here.

21           So stage one breast cancer is where the  
22 tumor is confined to the breast. Stage two is

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1 where the tumor might be slightly larger and may  
2 have lymph node involvement. Stage three is where  
3 the tumor may be yet a little larger, may have  
4 more lymph node involvement and may have some  
5 chest wall involvement. And stage four is where  
6 the tumor has moved out of the breast and local  
7 regional area and actually, only a minority of the  
8 patients are diagnosed at stage four at the onset.  
9 This is really only about 5 to 10 percent of  
10 patients.

11           So stage is not only important for  
12 prognosis but, again, to formulate a treatment  
13 plan and to really know what our goal of therapy  
14 is, whether it's for curative intent or for  
15 palliation. Along with that, we need to know if  
16 the tumor is invasive or non- invasive and  
17 actually, this we usually know before we stage the  
18 patient; tumor histology, the estrogen receptor  
19 status, progesterone receptor status and HER2  
20 status. And these are important not only for  
21 prognostic reasons but have predictive value also  
22 because we have treatments targeted toward these

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1 and we want to make sure that we're using it in  
2 our treatment plan. We also look at the  
3 histologic grade of the tumor and certain genomic  
4 testing may be warranted. And finally, we look at  
5 the age and associated comorbidities.

6           So our understanding of breast cancer  
7 has greatly evolved over the last couple decades,  
8 and this is really with the advent of molecular  
9 profiling and more genomic tests. So we're not at  
10 the point that we really understand breast cancer  
11 is not just one disease. It's quite varied and  
12 diverse and actually, it's a compilation of  
13 several different subsets that behave very  
14 differently.

15           In clinical practice, we already subset  
16 these to some extent and that's by assessing the  
17 hormone receptor status, the HER2 status, and we  
18 use certain genomic tests such as Oncotype DX to  
19 assess if further adjuvant chemotherapy is needed  
20 or not. But there are many other tools that are  
21 being used for research purposes in clinical  
22 trials. These are not quite ready for routine use

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1 yet but, really, it's only a matter of time. As  
2 our understanding of the biology in the subsets  
3 continue to mature, we are going to use more and  
4 more of these tools in the clinic to help identify  
5 the right patient for the right treatment.

6           So the way that we make a treatment plan  
7 now is really a combination of several different  
8 modalities and this includes surgery, radiation  
9 therapy, cytotoxic chemotherapy, targeted therapy,  
10 and one other box I'm missing which is actually on  
11 the next slide is hormonal therapy. Some patients  
12 may receive all of these or only a few of these.  
13 And again, it goes back to all of those factors I  
14 discussed earlier, the stage of the patient and  
15 the goal of therapy. It's great that we have a  
16 lot of options that we can kind of put together  
17 and that we can treat patients but unfortunately,  
18 none of them are benign. They all come with side  
19 effects. They can be overlapping side effects.  
20 They can be different side effects and only some  
21 of them are listed here. Obviously, it's not a  
22 complete list. And some of the side effects can

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1 be quite toxic and so it's very important that  
2 we're discussing this with patients as we're  
3 making the treatment decisions of how we proceed.

4           So some of the approved therapies that  
5 we do have available to us - -again, this is not  
6 an exhaustive list and, in fact, I'm missing one  
7 of our most recently approved drugs, palbociclib,  
8 on this list but we do have several hormonal  
9 agents and we choose to use those based on  
10 menopausal status and kind of the stage of therapy  
11 or whether it's in the adjuvant setting or  
12 metastatic setting. We have several cytotoxic  
13 chemotherapy agents that we can use in combination  
14 or as single agents and then targeted therapies.  
15 And the four that I have listed here are used  
16 solely in HER2-positive tumors. So again, we do  
17 have many therapies that are approved at this  
18 time.

19           But in approving any of these therapies,  
20 it comes back to this balancing act again. In  
21 oncology, we are always dealing with a serious  
22 disease and unfortunately, our treatments can be

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1 toxic and so in approving a drug, we really want  
2 to make sure that we are helping make a patient  
3 live better or live longer and so in other words,  
4 this means that they have some direct clinical  
5 benefit, either improving how they feel or  
6 function or prolonging their survival. So I think  
7 this is my last slide. So one of the ways that we  
8 can get direct measurement of this as far as a  
9 treatment benefit is, obviously, from the patient.  
10 So we can use these patient-reported outcomes or  
11 PROs which are direct measures of treatment  
12 benefit and allow the patients to be involved  
13 because we know that healthcare providers under-  
14 report the side effects. So we can get a more  
15 accurate assessment.

16           Here at the FDA, we definitely encourage  
17 use of these if they're used properly because then  
18 they can be very helpful and properly means that  
19 they're well-defined, reliable, validated tools  
20 that are measuring what they say that they're  
21 measuring. So that's all I have. Thank you.

22           MS. GIAMBONE: Thank you to my FDA

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1 colleagues for your remarks. So I am going to now  
2 go over the discussion format again and as I  
3 mentioned, we have two discussion topics for  
4 today. The first is on the symptoms that matter  
5 most to you. So in this topic, what we're  
6 listening for is how do you live with your breast  
7 cancer. How do you experience your breast cancer?  
8 What are the symptoms that are most important to  
9 you, and how do they impact your day-to-day life?  
10 So here you can tell us are there activities that  
11 you can't do at all or as fully as you would like  
12 because of your symptoms.

13           Also, if I can share with us how your  
14 symptoms have evolved over time and how they've  
15 changed for you since diagnosis; that would also  
16 be very helpful.

17           In Topic 2, we're going to discuss  
18 current approaches to treating breast cancer. So  
19 here what we're listening for is, what is your  
20 current treatment regimen? What are the benefits  
21 that you see of your current treatment regimen?  
22 Is it working for you? And vice versa, what are



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1 the downsides? What are the biggest side effects  
2 that you experience? Also, what do you look for  
3 in an ideal treatment?

4 We're also going to spend a portion of  
5 Topic 2 talking about the factors that go into the  
6 decisions you make regarding treatment options.

7 So first we're going to hear from a  
8 panel of patients and on that note, could I have  
9 my Topic 1 panelists come on up and have a seat?

10 So the purpose of the panel discussion  
11 is to really set the stage for the greater group  
12 discussion. Our panelists reflect a range of  
13 experiences with breast cancer, and I have had the  
14 privilege of working with them over the last two  
15 weeks and I know they've spent a lot of time and  
16 put in a lot of effort to put their thoughts down,  
17 so we really appreciate that you're here doing  
18 this.

19 Our panelists will have five minutes to  
20 present their remarks and after they finish their  
21 remarks, we will open the dialogue, broaden the  
22 dialogue to invite more patients and patient

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1 representatives in the audience.

2           So the purpose of the group discussion  
3 is to really build on what you've heard from the  
4 panel, so share with us not only what is similar  
5 for you but also how you experience differently  
6 the breast cancer. Periodically, I'll look to my  
7 FDA panel for some follow-up questions and we  
8 invite you to continue participating in the  
9 conversation. You can raise your hand and we'll  
10 have microphone runners around the room and  
11 they'll come to you. And if you're comfortable to  
12 do so, just raise your hand, they'll come to you,  
13 and just tell us your first name and you can  
14 present your comments.

15           So there are a few other ways that we're  
16 going to be learning from you today and one of  
17 those is that we're going to be doing thee polling  
18 questions and on that note, could I have the  
19 clickers passed out. Thank you. So the polling  
20 questions, they're not a scientific survey. It's  
21 entirely voluntary but what it allows us to do is  
22 to get more understanding of the perspectives in

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1 the room. And we're going to be trying those out  
2 in just a bit. So for those of you in the room,  
3 you'll use the clickers to answer the polling  
4 questions; and for those of you on the web, you  
5 can also participate via the webcast. And we do  
6 ask that only patients and patient representatives  
7 respond to the polling questions, please.

8           So as I just mentioned, we also have a  
9 very active webcast. Today we have nearly 100  
10 people joining us on the web so for all of you on  
11 the web, you're a very important part of today's  
12 meeting. You're a very critical part of today's  
13 meeting and although we can't see you, you're  
14 voice is being heard. We will periodically check  
15 in with you and we'll have you -- you'll also have  
16 the opportunity to call in by telephone and share  
17 your comments throughout the meeting. And we will  
18 make sure that we capture all of the comments that  
19 you're providing us via the webcast and they'll be  
20 incorporated into our summary report.

21           So another last way that we will be  
22 getting more information from you, more of your

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1 experiences and perspectives is this very  
2 important public docket that we'll keep open for  
3 two months after the meeting. So it will be open  
4 until June 2nd and you see the website up here.  
5 We encourage you to continue to keep visiting this  
6 website and continue to share your thoughts, share  
7 your comments as they come to mind and they're a  
8 very important part of the meeting, so it's an  
9 extension of today's meeting to continue to hear  
10 from you. All of these comments in the public  
11 docket will be -- we will read through those. We  
12 will summarize those and incorporate them into our  
13 summary report and anyone is welcome to comment.

14           We also have a few resources here at the  
15 FDA that we want to share with you. The first is  
16 the FDA's Office of Health and Constituent  
17 Affairs, OHCA, and the second is the Professional  
18 Affairs and Stakeholder Engagement Group, PASE,  
19 and both of these organizations within FDA are --  
20 they're a liaison. They're your link between the  
21 FDA and the public and patient groups so we  
22 encourage you to reach out to them if you have any

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1 questions at all.

2           So I'm going to go over, last but not  
3 least, a few discussion ground rules for the day.  
4 First, we encourage patients to contribute to the  
5 dialogue and patients and patient representatives  
6 also. So we know that there are academia,  
7 government agencies, industry -- we really  
8 appreciate that all of you are here today to join  
9 us at the meeting. This meeting will be very  
10 important to you, too. We just ask that you stay  
11 in listening mode. Today is really about  
12 listening and learning from the patients and  
13 patient representatives.

14           And on that note, the FDA also, we are  
15 in listening mode for the day. Periodically, we  
16 will have some follow-up questions from the FDA  
17 panel so I'll turn to them. And the third is that  
18 the discussion will focus on symptoms and  
19 treatments. So as I mentioned, we have two topic  
20 questions today and we will -- we're going to --  
21 you know, these are the topic questions that are  
22 most beneficial for us at the FDA to learn from

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1 you on. So we will do our best to stay on topic  
2 and if there is anything else, as I mentioned,  
3 that you'd like to share outside of the scope of  
4 Topic 1 or Topic 2, again, we encourage you to  
5 sign up for open public comment.

6 The views expressed today are personal  
7 opinions and so on that note, respect for one  
8 another is paramount.

9 And last but not least, let us know how  
10 the meeting went today. So we will have  
11 evaluation forms out on the registration desk and  
12 we'll also pass them out closer to the end of the  
13 meeting. It's really important for us that you  
14 fill these out and let us know what worked and  
15 didn't work so that we continue to improve these  
16 meetings for you.

17 And as I mentioned, I just want to  
18 reiterate again that we're just really thankful  
19 and grateful that you're here. Again, this is --  
20 we want you to feel comfortable. We want you to  
21 go ahead and get up and stretch if you need to.  
22 I'm personally very happy that there's nice

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1 weather outside so for those of you that traveled  
2 from afar, hopefully, you're experiencing DC  
3 beautiful spring weather.

4 Okay. So, first, what we will do is  
5 we're going to start with some polling questions.  
6 So everybody get your clickers out. Okay. Oh,  
7 they don't have clickers. Okay. Sorry.

8 (Laughter.)

9 MS. GIAMBONE: Okay. Everyone have your  
10 clicker ready? Great. Okay. So the first one is  
11 an easy one. Where do you live? Press "A" or  
12 within the DC Metro area, or "B" for outside of  
13 the DC Metro area. Press A -- yep. That's okay.  
14 Okay and -- oh, it looks like we might be having  
15 some difficulties with the Let's try it one more  
16 time. Can you click again either "A" or "B"? Not  
17 working?

18 UNIDENTIFIED SPEAKER: No.

19 MS. GIAMBONE: That's okay. Let's raise  
20 hands instead. Okay. So can I just by a show of  
21 hands how many of you are from the DC Metro area?  
22 Great. So we have a lot of neighbors visiting.

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1 And so I imagine the rest of you are from outside  
2 of the DC Metro area, right? So thank you for  
3 coming. I know there's been a lot of travel,  
4 California, Texas, Massachusetts. I've met so  
5 many of you from different parts of the country so  
6 thank you for being here. It means a lot to us.

7 Let's go to the next question. Have you  
8 ever been diagnosed as having breast cancer?  
9 Shall we give it a try? Okay, let's try this one.  
10 Press "A" for "yes" or "B" for "no." No, we're  
11 doing hands. We'll do hands again. Thank you all  
12 for being such a good sport about this. So can  
13 you raise your hand for "A, yes." Okay. And "B,  
14 no." Okay. Well, thank you very much for all of  
15 you that are here to share your perspectives and  
16 experiences with us. You will have -- we have so  
17 much to learn from you so we appreciate that  
18 you're here.

19 Okay. So this one, there's going to be  
20 a lot of hand raising I guess. Okay. What is  
21 your age or your loved one's age: A, younger than  
22 30; B, 31 to 40. Okay, we have a few of you. C,



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1 41 to 50. Okay. D, 51 to 60. Okay. E, 61 to 70.

2 Great. And F, 71 or greater. Great. Thank you.

3 And I'm not sure if they webcast polling is

4 working. Are we seeing similar results?

5 MR. THOMPSON: Yeah. We had, for the

6 previous question, about 64 percent diagnosed with

7 breast cancer; for this one, 30 percent of people

8 between 41 and 50; 41 percent between 51 and 60;

9 and 10 percent for the other categories.

10 MS. GIAMBONE: Okay, great. Let's go on

11 to the next one. Are you A, male or B, female? I

12 imagine most of us here are female.

13 (Laughter.)

14 MS. GIAMBONE: Okay. And I think this

15 is our last -- or actually, we may have one more.

16 Okay. So what is the length of time since your

17 diagnosis? A, less than one year ago. Okay, so no

18 responses there. B, one year ago to two years

19 ago. Okay. So it looks like we have one newly

20 diagnosed. C, two years ago to five years ago.

21 Okay. So we have about four hands. D, more than

22 five years ago. Okay. So it looks like the

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1 majority of people responding are in this category,  
2 more than five years ago. And E, I'm not sure.  
3 Okay. How about on the webcast?

4 MR. THOMPSON: On the web, we have 18  
5 percent for less than one year ago; 18 percent  
6 again for one to two years ago; 18 percent to two  
7 to five years ago, 43 percent for more than five  
8 years ago.

9 MS. GIAMBONE: Okay. So similar to what  
10 we're seeing in the room. Great. Okay. Which of  
11 the following best describes your current  
12 condition? A, my cancer is localized and has not  
13 spread outside my breast and/or local lymph nodes.  
14 Okay. So we have one. Okay. B, my cancer has  
15 spread, metastasized to the rest of my body?  
16 Okay. So I'm counting about eight or so, eight or  
17 nine. Okay. C, I have been treated for my cancer  
18 and currently have no evidence of disease. Okay.  
19 So I see about six or seven hands raised. And D,  
20 I'm not sure. Okay. How about on the web?

21 MR. THOMPSON: Thirteen percent say  
22 they're cancer is localized; six percent say it is

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1 metastasized; and 80 percent said they have been  
2 treated and currently have no evidence of disease.

3 MS. GIAMBONE: Okay. Thank you. So  
4 that will take us to our discussion topic. Thank  
5 you all again for bearing with us as our  
6 technology did not work. So let's have our Topic  
7 1 panelists please introduce yourselves.

8 MS. DURHAM: I'm Karen Durham.

9 MS. GIAMBONE: Okay. Go ahead if you  
10 want to just -- yeah, go ahead and introduce  
11 yourselves.

12 MS. McRAE: I'm Katy McRae.

13 MS. DUNNE: Hi. I'm Debbie Drake Dunne.

14 MS. FINESTONE: Sandy Finestone.

15 MS. GIAMBONE: Okay, great. So as I  
16 mentioned, our Topic 1 panelists will read off  
17 their remarks and I am going to -- I just want to  
18 say thank you so much for preparing all of your  
19 summary statements and for sharing these stories  
20 with us today. So can we start with Karen, if you  
21 don't mind?

22 MS. DURHAM: Good afternoon. As I

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1 introduced myself, I'm Karen Durham and I'm from  
2 Lindale, Texas. I was originally diagnosed with  
3 an aggressive invasive stage two breast cancer 25  
4 years ago, and you didn't have hardly any  
5 treatment options 25 years ago but I went through  
6 all of my surgeries. I completed all of my  
7 chemotherapy treatments and I did great for 19  
8 years. Then in January of 2009, I was diagnosed  
9 with stage four metastatic disease. Surgery was  
10 not an option. I went on a clinical trial. I  
11 took two drugs -- different drugs a day on the  
12 clinical trial. They were pill form. I thought I  
13 was doing really well until two months ago, in  
14 January 2015, I had disease progression with four  
15 new tumors. This was really emotionally  
16 challenging because of the length of time between  
17 each of the diagnoses was so long. I was lulled  
18 into a sense of kind of maybe a security, that  
19 that was it, it was not going to go any further.  
20 There is no sense of security when you have breast  
21 cancer.

22 Right now I'm doing fine for somebody

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1 that's being treated for metastatic disease, but I  
2 do not make any long-term plans. It's 6 to 12  
3 months or less because I never know what the  
4 future is going to bring.

5           To put this a little bit in perspective,  
6 in the six years and two months since I was  
7 diagnosed metastatic, I have had 193 visits with  
8 my oncologist. That's not scan time, treatment  
9 time, any other doctor time. That's just with my  
10 oncologist. That averages out to about 2.6 visits  
11 a month. I have a wonderful caregiver in my  
12 husband. He has made all but one of these  
13 appointments with me.

14           I have many side effects from the 25  
15 years, both from the surgery and from the  
16 different treatments that I've been on. I have  
17 cognitive impairment, hot flashes, dry skin,  
18 weight gain, headaches, joint and muscle pain,  
19 diarrhea and mouth sores just to mention a few.  
20 The list goes on. I have chronic severe  
21 lymphedema in my left arm from my surgery which  
22 was different 25 years ago. I was prone to

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1 current infections which can be life-threatening  
2 if they're not treated properly immediately. Now  
3 I'm on a daily antibiotic as a preventative for  
4 these infections.

5           It's very depressing when I go shopping  
6 for clothes. I have to try on clothes that fit my  
7 left arm, not the rest of my body. To fit my left  
8 arm, it's a woman's size 22 to 24. The rest of my  
9 body is a size 12. It's depressing.

10           Fatigue has become a part of my daily  
11 life. It's just something I have learned to live  
12 with. Some days it's better than other days.

13           For the six years I was on the two  
14 different chemotherapy treatments a day in pill  
15 form. Now I have five pills that I take. It's  
16 two drugs -- different drugs and I am on a  
17 different clinical trial. But, you know, I think  
18 back -- I cannot remember when I did not have a  
19 queasy stomach and smells made me very nauseous.  
20 It's been that long ago in six years and two  
21 months. I have peripheral neuropathy in my feet  
22 and legs. Sometimes the bottoms of my feet burn

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1 so badly that I cannot stand to have even socks on  
2 them. My legs do not feel like they have the  
3 strength to hold me up going up or down stairs.  
4 Walking on flat surfaces is just fine. So when I  
5 go up or down the stairs, it's one stair at a time  
6 and I hold onto the handrail with a death grip so  
7 I won't fall and risk breaking any bones.

8           The cognitive impairment I have is not  
9 forgetting things. It's the word is there but I  
10 can't get the word from my brain to come out my  
11 mouth. I can look out my window at home and see a  
12 red cardinal and I want to say red cardinal but  
13 the words won't come. It just -- there --  
14 something is blocking that from coming out. It's  
15 really embarrassing, especially in an environment  
16 like this.

17           The daily activities besides what I Have  
18 already mentioned, walking or any type physical  
19 exercise, because of the fatigue, working in the  
20 garden and doing things like that because of the  
21 chance of an infection in my arms is just about  
22 impossible.

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1           And then there is one other side effect  
2 that no one wants to talk about and that's sexual  
3 dysfunction or sexual activity. I, like nearly  
4 every woman that has taken an aromatase inhibitor,  
5 finds that the traditional position of sexual  
6 intercourse is extremely painful and  
7 uncomfortable.

8           And with that, I would just like to  
9 thank the FDA for the opportunity to appear here  
10 today and present my comments.

11           MS. GIAMBONE: Thank you, Karen. Katy?

12           MS. McRAE: My story really begins in  
13 2003. I'm going to read it so I don't diverge or  
14 whatever. Two years before my breast cancer  
15 diagnosis, I was living in Germany at the time. I  
16 had been having issues with my eyes and had laser  
17 and cryotherapy treatment of both retinas. A few  
18 months later, on my way to see my mom in Ireland,  
19 the retina in my left detached. I went straight  
20 from the airport with my sister and had an  
21 emergency surgery the following morning. Eight  
22 weeks, multiple setbacks and three additional



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1 surgeries later, I returned to my husband and four  
2 children in Germany. The entire situation was a  
3 nightmare. The pain, the fear of recurring  
4 blindness -- I had actually gone blind in my left  
5 eye at the third detachment -- the discomfort of  
6 lying in a certain position called "posturing" for  
7 an entire week, getting up only to use the  
8 bathroom and eat, I missed my husband's birthday,  
9 my birthday, our 20th wedding anniversary, my  
10 daughter's graduation -- she was salutatory out of  
11 300 kids -- and my son's Eagle Scout ceremony in  
12 the time I was in Ireland in the hospital. On my  
13 daughter's 18th birthday, July 3rd, the professor  
14 released me and I flew back to Germany.

15           While in the hospital, I had annoyingly  
16 developed depression. So once back in Germany, I  
17 had to see a new team of eye specialists for post  
18 op oil removal from my eyes, routine follow-ups,  
19 cataract surgery, etcetera. We moved house 50  
20 miles away and I got my children started in their  
21 new schools. On the day we drove my daughter to  
22 the airport to go to university in Ireland, we

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1 went directly after dropping her off to the  
2 psychiatric clinic where I was admitted and spent  
3 the following three months as an inpatient. There  
4 aren't words to describe the horror of depression.  
5 Suffice it to say, had it not been for my seven-  
6 year-old post vasectomy child at home who I  
7 believe still needed me, I would not be here  
8 today.

9           Happily, though, I was one of the lucky  
10 ones and eventually got back to living a normal  
11 unmedicated life. So I had a nice uneventful year  
12 in 2004 but in January of 2005, my mom died and  
13 three months later, I was diagnosed with breast  
14 cancer. So I tell these stories not because I  
15 want a pity party but they give me perspective  
16 when I'm dealing with the -- when I dealt with my  
17 breast cancer diagnosis. For me, breast cancer  
18 was bad, retinal problems were worse, and  
19 depression was the absolute pit of despair so in a  
20 way, I was luckier than most when I got my breast  
21 cancer diagnosis. I'd handled worse. I could do  
22 this.

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1           Two of my three sisters had already had  
2 breast cancer. One a late stage over 50-year-old  
3 and my younger sister who was diagnosed in her  
4 early 40's. My other sister developed breast  
5 cancer subsequent to my diagnosis. We're four  
6 sisters in my family and between us, we have a  
7 grand total of two breasts. I have been tested  
8 and I'm not positive for the BRCA1 or 2 genes,  
9 which is nice. So I was the only one of my  
10 sisters to take what I call the scenic route to  
11 recovery. I chose elective bilateral mastectomy,  
12 chemo, radiation, etcetera. I had breast  
13 reconstruction some months later and during that  
14 surgery, I had my ovaries removed.

15           So we relocated to the United States and  
16 all went well for about five years until September  
17 of 2009. My oncologist was alerted to my changing  
18 status after a routine blood test showed an  
19 increase in my cancer marker 2729. So metastatic  
20 breast cancer was confirmed after a PET scan and  
21 once again, the roller coaster was in motion. My  
22 son said that living with metastatic breast cancer

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1 was the ultimate chaos and I think he truly, truly  
2 nailed it.

3           For me, personally, the diagnosis of  
4 metastatic disease in my bones was very difficult  
5 to get my head around. I'm proactive. I face  
6 every challenge head on and I'm willing to move  
7 heaven and earth to fix my problems but this time,  
8 the dreaded word "incurable" was part of the  
9 equation. For me, personally, it was a lonely  
10 time because metastatic breast cancer is not well  
11 understood in the general community and as a non-  
12 survivor, I felt somewhat a failure in the primary  
13 breast cancer community.

14           So for months, cancer was the first  
15 thought in my head when I woke and the last before  
16 I finally slept. I had mixed results in the  
17 beginning of my treatment for what should have  
18 been a best case scenario, ER-positive metastatic  
19 breast cancer to the bone, the best of the  
20 metastatics to have, but I wasn't responding well  
21 to the usual anti-estrogen regimen.

22           So my oncologist and I decided that I

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1 should have a bone biopsy taken from a lesion in  
2 my left iliac crest and that proved to be HER2-  
3 positive which my primary cancer had not indicated  
4 and, of course, explained the lack of response to  
5 my initial treatments. So when I began to take  
6 Herceptin, I had immediate and positive results  
7 but then I developed LVEF problems in my heart as  
8 a side effect of Herceptin. It was horribly  
9 discouraging and I had to suspend my treatment on  
10 a number of occasions until my heart recovered.

11           But at this time, there was great  
12 excitement in the HER2 community about the pending  
13 improvement of TDM1. I was worried though that  
14 because of my LVEF status that I would not be a  
15 candidate for the drug when it became approved, so  
16 I called Genentech one day. They did the drug and  
17 I spoke to a specialist who reassured me, however,  
18 that I might be a candidate for the expanded  
19 access trial. So I had been on a weekly regimen  
20 of Herceptin but the trial dosage was given at  
21 three-week intervals and actually, I had no  
22 subsequent heart effects because of that regimen.

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1           So I have been on TDM1, which is now  
2 known as KADCYLA, for over two years, 2-1/4 years,  
3 an amazing virtually totally symptom 2-1/4 years.  
4 It's been phenomenal. However, since registering  
5 a few weeks ago for today's forum, I've been  
6 having some new symptoms and am now resistant to  
7 KADCYLA. I will begin radiation treatment on my  
8 sacrum tomorrow. I hope to begin a new protocol  
9 possibly taking PERJETA within a few weeks.

10           Metastatic breast cancer is a very  
11 different animal than primary cancer. My life is  
12 hugely dictated by my three-week chemo cycles.  
13 The most I could ever be away for was three weeks  
14 which, of course, for most U.S. citizens would be  
15 very acceptable but I'm an ex-pat and I have  
16 siblings all over, you know, Ireland and Europe  
17 and time is always a factor in keeping close  
18 family ties and it's something that's hugely  
19 important to me and to them.

20           MS. GIAMBONE: Katy, any closing  
21 remarks?

22           MS. McRAE: Pardon?

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1 MS. GIAMBONE: Any final remarks?

2 MS. McRAE: No, that's it.

3 MS. GIAMBONE: Thank you, Katy. Debbie?

4 MS. DUNNE: Hi. I'm Debbie Dunne and  
5 I'm from San Francisco, California, and I want to  
6 thank the FDA for convening this meeting and also  
7 for giving me the opportunity to share my story.

8 After finding a lump in my left breast  
9 in August 2009, I was diagnosed with breast  
10 cancer. While I had two tumors, the cancer had not  
11 spread to the lymph nodes or outside my breast. I  
12 have been cancer free for the last six years. As  
13 the majority of my symptoms and impacts were  
14 psychological, I would like to briefly describe my  
15 treatment approach as the process of decision-  
16 making sent me into a serious state of despair.

17 Despite doctors telling me that my  
18 cancer was caught early and that I had a high  
19 likelihood of survival, I was convinced that my  
20 diagnosis meant certain death. No one or no data  
21 could convince me otherwise. Most family and  
22 friends I knew who had cancer had succumbed to the

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1 disease. My stepfather passed away from cancer  
2 three months before my own diagnosis. When I  
3 heard the words "you have cancer," my body  
4 immediately went into flight or fight mode in an  
5 extended period of extreme fear and high stress.  
6 Normally a very thoughtful and analytical person,  
7 I became focused on short-term survival and was  
8 unable to think clearly or understand the long-  
9 term consequences of my choices. Even my doctor  
10 noted that I went from a calm and thoughtful  
11 person in my initial visit to a, quote, complete  
12 emotional wreck.

13 I wanted to do whatever I could to  
14 reduce my risk. As I began to contemplate my  
15 treatment plan, I quickly became confused and  
16 overloaded with information. Where I hoped to  
17 find black or white answers, there was only gray.  
18 I spent hours on the internet searching for the  
19 right answer. As I insisted in getting the cancer  
20 out of my body as soon as possible, I had a  
21 lumpectomy three weeks after my diagnosis.

22 Because there was a history of early



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1 onset prostate cancer on my dad's side, I met with  
2 a genetic counselor who recommended that I take  
3 the genetic test. I tested positive for a  
4 mutation of the BRCA2 gene but it was a variant of  
5 unknown significance.

6           What was I to do? They then asked that  
7 my father be tested and he also had the same  
8 variant so the doctors were pretty sure that, in  
9 fact, I had the mutation. I had two options:  
10 MRIs, constant surveillance, or remove my breasts  
11 and my ovaries. This would not necessarily  
12 prevent the cancer from returning but it was the  
13 choice that I took, to remove my breasts and my  
14 ovaries.

15           By this time, the doctors realized that  
16 psychologically, I needed to feel confident that I  
17 had everything -- I had done everything I could to  
18 reduce all of my risk or as much risk as possible.  
19 My other treatment options were to consider  
20 chemotherapy and an aromatase inhibitor. One  
21 doctor said chemotherapy was unnecessary as I was  
22 low risk while another doctor told me I have a

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1 young son so I might want to do everything I could  
2 to be around for him, so I decided to take the  
3 oncotype test. Once again, it was not definitive.  
4 Eighteen was low risk. I got a 20. So I took  
5 chemotherapy.

6           While I read and was told about all the  
7 possible side effects, nothing could prepare me  
8 for the emotional and mental upheaval I would  
9 experience. I literally felt like I was dying and  
10 I questioned my decision to do the chemotherapy.  
11 Every day I contemplated quitting.

12           As I have just described, the symptoms  
13 that had the most significance in my daily life  
14 were primarily psychological. Fearing for my  
15 life, I was paralyzed and immediately became  
16 depressed. I was convinced that I would never see  
17 my seven-year-old son grow up. I remember sitting  
18 in church on Christmas Eve in 2009 thinking this  
19 is my last Christmas. I lost interest in being  
20 with friends who were living normal happy lives  
21 compared to the nightmare I was now experiencing.  
22 The thought of work was overwhelming and despite

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1 coworkers being supportive, I couldn't bring  
2 myself to go to work so I went out on disability  
3 for nearly a year. Many days I didn't get out of  
4 bed, instead watching hours of TV to distract  
5 myself.

6 I also spent hours and hours on the  
7 internet reviewing the same statistics over and  
8 over hoping that it was possible I could survive.

9 I took anti-anxiety medication to try  
10 and stop the feeling that I was jumping out of my  
11 skin and to numb the pain that I constantly felt.  
12 My world was completely out of control and I  
13 really struggled to maintain a sense of calmness.  
14 As my mind continually raced night and day, I was  
15 unable to sleep for any length of time. I  
16 searched for answers wondering why me, how did I  
17 get cancer, I'm young, I'm healthy, I was supposed  
18 to have a full life ahead.

19 In addition to the psychological  
20 symptoms, I did experience physical symptoms as  
21 well. All the treatments and the lack of sleep  
22 contributed to an extremely high level of fatigue

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1 I had never before experienced and to this day,  
2 some of that fatigue still exists.

3           Given that my cancer was ERPR-positive,  
4 I was prescribed an aromatase inhibitor. The  
5 initial bone pain was excruciating so the doctors  
6 had me try three different aromatase inhibitors.  
7 While some of that bone pain has subsided, I still  
8 feel it in my lower back on a regular basis. I  
9 have also lost bone density and I now have  
10 osteoporosis.

11           As for specific activities that are  
12 important to me that I can no longer do as fully  
13 as I would like as a result of breast cancer, this  
14 is the biggest area of lasting impact for me. The  
15 loss of interest and difficulty with sexual  
16 activity and intimacy with my husband has been  
17 significant. When discussing the decision about a  
18 mastectomy with my doctors, I was told I would  
19 lose feeling in my breasts. At that time, I felt  
20 like I was fighting for my life and I wanted to do  
21 everything I could to reduce my risk of recurrence  
22 so I was very aggressive; as I mentioned, multiple

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1 surgeries, actually partial radiation,  
2 chemotherapy and an aromatase inhibitor. I had  
3 convinced myself I might not even be alive for  
4 that long so I wasn't really thinking about longer  
5 term impacts of my treatment decisions. Never did  
6 I realize that my decision for a double mastectomy  
7 and oophorectomy would have much deeper  
8 psychological implications than just the loss of  
9 physical feeling.

10           Six years later, I am grateful to be  
11 alive. I do not regret any of my treatment  
12 decisions but my relationship with my husband has  
13 been significantly altered as a result of my  
14 decisions.

15           In closing, given that many breast  
16 cancer patients are now going on to live long,  
17 productive lives, I think it is critical to  
18 discuss and consider treatment options in a  
19 different manner. I have had the opportunity to  
20 talked with a number of breast cancer patients  
21 over the years. Many of us are frightened and in  
22 a weakened emotional state when first receiving

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1 our diagnosis. As I mentioned, it was extremely  
2 difficult to understand clearly the implications  
3 of my decisions should I be one of the fortunate  
4 cancer survivors who could potentially be alive  
5 for a long time.

6 As someone who did a lot of research  
7 around my various treatment options, I had no way  
8 to gauge the validity of the various studies I  
9 read. As a result of my experience, I am now  
10 focused on helping to improve decision support to  
11 cancer patients. I firmly believe we need to  
12 strengthen the evidence base for decision making  
13 including participation in clinical trials, and  
14 better reporting and access to patient-reported  
15 outcomes would also provide a huge benefit.

16 Thank you again for allowing me to share  
17 my story.

18 MS. GIAMBONE: Thank you, Debbie.  
19 Sandy?

20 MS. FINESTONE: My name is Sandy  
21 Finestone. I'm from Southern California. I've  
22 been fortunate enough not to have to personally

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1 face the challenge of metastatic cancer.

2           I was diagnosed over 30 years ago when  
3 you were offered no options and only one  
4 treatment. When I went for my surgery, I signed  
5 an authorization allowing the surgeon to do  
6 whatever was necessary without any idea what that  
7 decision would be. Today women are given many  
8 options and these women are expected to make  
9 decisions without very much information, decisions  
10 that will impact the rest of their lives. This is  
11 particularly difficult for the patient who is  
12 metastatic at the time of diagnosis.

13           I woke from my surgery to find that both  
14 breasts had been removed and began my journey as  
15 an advocate to education women about their disease  
16 so when they make a decision, it will be an  
17 educated one. I currently facilitate support  
18 groups for newly diagnosed patients, those in the  
19 middle of treatment, those whose treatment has  
20 ended, and those whose treatment will never end.  
21 Many concerns are the same for each of these  
22 groups but some are very different, very different

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1 when facing the challenge that never to be able to  
2 put cancer behind you.

3           As a therapist, patients share many of  
4 their concerns with me during individual therapy  
5 sessions dealing with the stress and anxiety of  
6 the diagnosis. The symptoms that women mention  
7 most are pain, fatigue, hot flashes, neuropathy,  
8 lymphedema, memory loss, weight gain, vaginal  
9 dryness, loss of libido, and bone loss. Patients  
10 are frustrated because many of these symptoms are  
11 brought on by the medications that they are taking  
12 to treat their cancers or to attempt to prevent  
13 them from coming back.

14           Pain comes in many levels. Some pain is  
15 minor and annoying while other is severe and  
16 debilitating. Some pain can be managed with over-  
17 the- counter medications; some pain requires very  
18 heavy medications that can cause other symptoms  
19 such as constipation, sleeplessness or confusion.  
20 Bone pain can limit movement which leads to many  
21 other issues such as increased fatigue or  
22 depression.



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1           Fatigue prevents patients from doing  
2 many things, both big and small, from going  
3 shopping with friends to limiting the type of  
4 vacation they can plan due to the inability to be  
5 as active as they would like. Sometimes even  
6 going to a support group or a doctor's appointment  
7 take every ounce of energy they have. One  
8 metastatic patient told me that she had to be  
9 honest with her family and tell them that she had  
10 a limited amount of energy and had to choose,  
11 often painfully, which things she had the energy  
12 to do and which things she could not do. It's  
13 difficult when you've been a member of the family  
14 who always plans and prepares the holiday dinners  
15 and you can no longer fulfill that role and you  
16 begin to see yourself as someone less important in  
17 the family.

18           Hot flashes are the butt of many jokes  
19 but when you're life is impacted by them, it's no  
20 longer a laughing matter. I had a patient who was  
21 an attorney. Her hot flashes were so severe that  
22 she had to change her clothing several times a

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1 day. It was so bad that she seriously considered  
2 no longer doing court work because her concern was  
3 that the juror would see her begin to perspire and  
4 think she was lying and that her client was  
5 actually guilty. Some women have fleshing with  
6 their hot flashes which also embarrassing and as  
7 is the constant taking off and putting on of  
8 clothing or the issue it presents in an office  
9 when other coworkers are not experiencing the same  
10 weather that you are.

11           Neuropathy can be both painful and  
12 dangerous. When you cannot feel where you're  
13 stepping when you're going down stairs, there's a  
14 possibility of a fall. When you cannot feel what  
15 you're stepping on, the chances of your injuring  
16 yourself become higher. When you are unable to  
17 button your blouse or undo a zipper, you become  
18 dependent on others. This becomes a bigger issue  
19 when you live alone.

20           Many think that the issue of sexuality  
21 and intimacy are issues of only for the young but  
22 that's not the case. Many couples continue to be

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1 sexual into their 70's and 80's and treatment  
2 often interferes due to fatigue, pain, or vaginal  
3 dryness. Many medications effects one libido  
4 which can create relationship problems. It's  
5 difficult to want to be intimate when you have  
6 pain, fatigue, or nausea.

7           Lymphedema, as we've heard, can both be  
8 painful and bothersome. For some women, the pain  
9 is constant. Lymphedema intrudes into your life  
10 as you must massage your hand and arm several  
11 times a day in order to keep the swelling down.  
12 It also restricts the type of clothing you can  
13 wear as the sleeve opening must be large enough to  
14 facilitate the bandaged arm, as we heard from  
15 Karen. One of my patients was very distressed as  
16 she was unable to wear many of her favorite items  
17 of clothing due to the size of her arm. She felt  
18 she could no longer wear anything sleeveless so as  
19 not to draw attention to the bandaging.

20           The list I gave you was long and I hope  
21 you can appreciate what many women suffer when  
22 dealing with this disease. Thank you.

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1 MS. GIAMBONE: Thank you very much,  
2 Sandy. So I'd like to ask everyone to give a  
3 panelists a round of applause.

4 (Applause.)

5 MS. GIAMBONE: What you shared with us,  
6 the very personal stories -- and I think I can  
7 speak on behalf of all of my colleagues when I say  
8 that you are very brave and very courageous to  
9 come here and share those personal stories with  
10 us, so thank you very much.

11 So I just want to recap some of the  
12 points that we heard from our panelists and then  
13 I'd like to see from those of you in the audience  
14 how it resonates with you. So Karen mentioned  
15 that her life is impacted by just so many doctor  
16 appointments. She mentioned that she has  
17 cognitive impairment. She said that she can't do  
18 some of the things that she enjoyed doing such as  
19 gardening or walking and she also mentioned that  
20 she has sexual intimacy -- you know, she has  
21 experienced the impact on sexual intimacy. So how  
22 many people did that resonate with? Okay. So we

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1 have about nine people in the audience that said  
2 that.

3           Katy, you talked about -- I think you  
4 described depression. You described that it's a  
5 roller coaster ride. How many of you did that  
6 resonate with? Okay.

7           And Debbie, you talked about -- also,  
8 you talked about the psychological issues, the  
9 fear and the anxiety and the depression. Again,  
10 how many of you in the audience did that resonate  
11 with? Okay. So five or six people.

12           And then finally, Sandy, you talked a  
13 lot about, again, the stress, the anxiety, pain,  
14 fatigue, from all the different patients that  
15 you've talked with. Okay, great. Okay. So it  
16 sounds like a lot of you in the audience, that you  
17 share similar perspectives or experiences from  
18 what our panelists shared.

19           So in just a moment, we're going to hear  
20 more from you on how you experience it but first,  
21 I'd like to do a polling question. So do we know  
22 -- we're going to do hands? Okay. So I'm going

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1 to read this out loud and then we'll just do --  
2 I'm sorry that we're having these technical  
3 problems with the clickers but we'll do another  
4 hand raising exercise.

5           So of all the symptoms you have  
6 experienced because of breast cancer, which do you  
7 consider to have the most significant impact on  
8 your daily life? So we'll just go down the list  
9 and then you can just raise your hand and then  
10 we'll talk more about these in just a moment. So  
11 a), pain such as breast pain or bone pain I see  
12 about seven hands raised for pain; b) swelling,  
13 four hands raised; c) fatigue or lack of energy, I  
14 see about 11 to 12 hands raised there; d)  
15 depression or anxiety, I see about eight hands  
16 raised for that one; e) cognitive dysfunction such  
17 as memory loss, about four or so; f) numbness,  
18 tingling in the hands or feet, about four hands --  
19 four or five hands; G, fertility issues, I see  
20 about two hands for that one; H, menopausal  
21 symptoms, about five-six hands raised for that;  
22 and I, other symptoms or side effects of cancer

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1 treatments not mentioned, I see about 10 to 11  
2 hands raised for that one.

3           And can we see on the web; did we hear  
4 something similar?

5           DR. THOMPSON: Actually, pretty much  
6 evenly mentioned, every single thing listed on  
7 here.

8           MS. GIAMBONE: Okay. So I believe the  
9 one that received the most responses was fatigue;  
10 is that correct? Okay. And then followed by, I  
11 think we saw, pain? Graham or Pujita, did we see  
12 --

13           (No audible response.)

14           MS. GIAMBONE: Okay. And then can you  
15 remind me of what the third -- was it --

16           MR. THOMPSON: Depression or anxiety.

17           MS. GIAMBONE: Okay, depression or  
18 anxiety. Okay, thank you. And I'm sorry I'm  
19 having to check back. Normally, we see polling  
20 results so I see exactly what came up, what the  
21 top three answers were.

22           Okay. So let's talk about -- let's

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1 spend some time talking about some of these  
2 symptoms and we'll definitely also spend some time  
3 talking about option I, which was other symptoms  
4 not mentioned.

5           So I know this might be a difficult  
6 question to ask but, you know, we're going to be  
7 spending Topic 2, you know, talking about the  
8 treatment but if there is a way you can tease out  
9 whether the symptom is due to the underlying  
10 disease or if it's a side effect of treatment,  
11 that would also be really helpful for us to hear  
12 when you're describing. So let's talk about --  
13 can we go back to the previous slide -- so let's  
14 start with the fatigue or lack of energy. Would  
15 somebody share with us how they experience the  
16 fatigue? Would anybody like to start us off?  
17 Yes.

18           MS. O'BRIEN: Hi. So to clarify, I was  
19 diagnosed with metastatic breast cancer. I was a  
20 de novo presentation at age 43 so I was thrown --  
21 I was -- as a course of my treatments, I was  
22 thrown into premature menopause and the first



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1 treatment that I had was tamoxifen and then after  
2 that failed, two years later, Femara and now  
3 FASLODEX. And I think it would be hard -- I would  
4 say that my fatigue has grown progressive as I  
5 have been on these drugs. It is true -- one of  
6 our panelists mentioned almost a compromise. You  
7 decide -- there might be three things I want to do  
8 but I know I can only do one of them so this is  
9 what I'll do.

10           The other week, I was babysitting. I  
11 have triplet -- two nephews and a niece and I was  
12 watching these three children and I felt  
13 frustrated because I enjoy being with the kids but  
14 even only after spending like four-five hours with  
15 them, you know, I was just exhausted. And in  
16 terms of my professional life, one of my  
17 responsibilities was attending trade shows and it  
18 was so frustrating. I would be at Chicago's  
19 McCormack Place and wanting to make my rounds and  
20 having to sit down and, you know, just -- you  
21 know, the spirit is willing but the flesh is not  
22 and it's just -- the lack of control and the, you

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1 know, feeling much older than your years is quite  
2 frustrating.

3 MS. GIAMBONE: Thank you, Katherine.

4 And I think, Katherine, you bring up a point that  
5 we also heard from the panelists which was the  
6 impact of these symptoms on your ability to work.  
7 I remember -- I think it was Karen, you mentioned  
8 that -- or Debbie, you mentioned that you had to  
9 make the decision to stop working because of  
10 living with the disease, so thank you for sharing  
11 that.

12 Anybody else, would you like to comment?  
13 Yes. And if you could state your name?

14 MS. KNACKMUHS: Hi. My name is Ginny  
15 Knackmuhs and I've had metastatic breast cancer  
16 for six years. I thought I'd make my comment now  
17 because we're coming up on my nap time.

18 (Laughter.)

19 MS. KNACKMUHS: I've had a particular  
20 problem with fatigue in the last couple of months.  
21 I'm a bit of an outlier and I've been somewhat  
22 fortunate in that I was on the same treatment for

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1 5- 1/2 years. I was on Xeloda and I have triple  
2 negative breast cancer, androgen receptor, bone  
3 only mets. But 5-1/2 years on one treatment,  
4 anybody that's got metastatic disease knows that's  
5 a pretty good record.

6 But I had progression in November and  
7 one of my problems -- sometimes people get fatigue  
8 and it's not really related necessarily to blood  
9 counts but in my case, I am chronically anemic  
10 now. Once I went off of the chemo, they thought,  
11 well, maybe your red blood cells will come back.  
12 I'm actually on a hormonal drug now that's used in  
13 prostate cancer but it's been four months and it  
14 hasn't really -- my numbers haven't come back.

15 And the thing that's so frustrating to  
16 me, not only that it effects how much I'm able to  
17 do, I kind of go back to when my mother was in her  
18 80's, her rule was one thing a day and that's what  
19 I kind of feel like. You can only plan on one big  
20 thing a day, you know. But what's particularly  
21 frustrating for me is there doesn't seem to be any  
22 treatment. I've been on PROCRIT injections to try

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1 to bring up the red blood cells and, you know,  
2 that, I don't think really does work. It seems to  
3 have had mixed results and now I'm -- the  
4 insurance doesn't cover it anyways. And so, you  
5 know, I'm left with doing blood transfusions  
6 which, you know, my oncologist is really not happy  
7 about because I guess they view it more now as  
8 almost a transplant so problems with that.

9           So it's very frustrating to me because,  
10 you know, you don't seem to have an option and  
11 this is just something that you're going to have  
12 to live with and, you know, it is difficult  
13 because I'm -- you know, I'm not young, I'm 65 but  
14 I don't think I should go by the "one thing a day"  
15 rule that the 89-year-olds used.

16           MS. GIAMBONE: Thank you, Ginny. So can  
17 I ask a follow-up question? Does it -- it sounds  
18 like the fatigue is coming as a side effect of the  
19 treatment that you're taking? Is that accurate?

20           MS. KNACKMUHS: Well, in my case,  
21 initially they thought it might be the treatment  
22 but now it's been too long, so now it's a question

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1 of well, is the cancer actually attacking the bone  
2 marrow --

3 MS. GIAMBONE: Okay.

4 MS. KNACKMUHS: -- you know, so they  
5 don't really know. But a lot of times, fatigue,  
6 you just get fatigued for no -- that's why I say  
7 mine's a little different. I mean I do actually  
8 have low blood counts. A lot of times people have  
9 fatigue with breast cancer and you really can't  
10 point to anything so it's sort of the same  
11 situation. There's -- you know, that's why  
12 fatigue is so difficult because there really is  
13 nothing to treat it.

14 MS. GIAMBONE: Okay. How many of you --  
15 yes, Sandy.

16 MS. FINESTONE: I'd just like to make a  
17 comment. Words are very powerful to me and I  
18 think fatigue is not the right word. When we as a  
19 general audience think about fatigue, it means we  
20 stayed out too late or we gardened too much and  
21 we're tired and we rest and the fatigue resolves.  
22 I think it's important to note that the type of

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1 fatigue that patients experience is not like that  
2 at all. They can rest and rest and rest and the  
3 fatigue doesn't go away. So when I talk to my  
4 patients, I use the word "weakness" and that  
5 resonates with them a lot more and they seem to  
6 say yes, that's what it is. It's not that I'm  
7 tired. It's that I'm weak. I just can't do these  
8 kinds of things. So I sort of make it my  
9 challenge not to use the fatigue word and I'd like  
10 to hear comments from some of the other patients,  
11 because I think it's misunderstood.

12 MS. GIAMBONE: Thank you very much for  
13 presenting that perspective. I actually saw  
14 several heads nodding as you were speaking so  
15 maybe we can do a show of hands here. Does that  
16 sound -- does that resonate with you that it's the  
17 weakness, this persistent weakness versus a more,  
18 I guess, temporary type fatigue? So could you  
19 raise your hands and does that resonate with you?  
20 Okay, great. Thank you, Sandy. Thank you for  
21 clarifying that.

22 Okay. Any other -- yes. Oh, no, she'll

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1 bring over the microphone to you.

2 MS. CAPPEL: My voice can be big. Hi.  
3 My name is Elizabeth Cappel. I also have  
4 metastatic disease. I think the weakness is more  
5 when you're going through treatment and when  
6 you're not in treatment, the leftover side effects  
7 can be fatigue, to clarify that. I think it's two  
8 different situations. If you're not in treatment,  
9 sometimes the treatment, the long-lasting effects  
10 can be fatigue. For me, taking iron supplements  
11 helps with that. I have iron deficient blood so  
12 my hemoglobin can be fine yet I can still have  
13 some types of fatigue left over but the iron does  
14 take care of that.

15 MS. GIAMBONE: Okay, very good to know.  
16 Thank you very much. Okay. So let's try to move  
17 on to another symptom unless -- does anybody have  
18 anything else? Yes, Jonca.

19 DR. BULL: Another -- a clarifying  
20 question on the fatigue and weakness. Are people  
21 able to sleep? Where does insomnia fit into this  
22 or lack of being able to get good quality rest?

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1 MS. GIAMBONE: Okay. So I'm seeing a  
2 lot of nos here. Would anybody like to share  
3 their perspective? How about right here, Sarah.  
4 Thank you, Jonca, for your question.

5 MS. WRIGHT: First, I don't have  
6 metastatic breast cancer so I'm fortunate but I  
7 was diagnosed with breast cancer back in '95, so  
8 whatever treatment I had worked. But I would like  
9 to say with regard to this fatigue issue, the type  
10 of fatigue we're talking about -- I heard some  
11 people say they do have trouble sleeping,  
12 sometimes you're so fatigued that you can't sleep  
13 but even when you do get a good sleep, you are  
14 still fatigued. So it's not a tiredness or a  
15 fatigue that goes away with rest and that's the  
16 difference between someone who has not had cancer  
17 and has not had treatment, that when they've  
18 overdone it or they've stayed out late and you're  
19 healthy and you have always been healthy, you get  
20 a good rest and you're rearing to go again.

21 This is not a type of tiredness that  
22 will go away after a few nights of good sleep and



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1 good eating. This is something that is always  
2 present and you might have a good day or two but  
3 it's always there. It's here right now. I mean  
4 you just can't get rid of that. It's hard to  
5 explain if you haven't experienced it and I don't  
6 know if there is a word to describe it. It just  
7 doesn't go away with a good sleep and if you  
8 haven't experienced it, you just -- it's hard to  
9 understand.

10 MS. GIAMBONE: Pervasive exhaustion?

11 MS. WRIGHT: Oh, I'm sorry. I'm told I  
12 didn't say my name. My name is Kim Wright (ph).

13 MS. GIAMBONE: Kimberly. Thank you so  
14 much, Kim. I appreciate it. So I'm going to --  
15 oh, yes. Let's take one more comment.

16 MS. HOLLOWAY: Hi. My name is Jamie  
17 Holloway. I was diagnosed in 2012 with triple-  
18 negative breast cancer and had a complete response  
19 to neoadjuvant chemotherapy. And I will say the  
20 fatigue is definitely a lot stronger when you are  
21 undergoing treatment and we've heard from a lot of  
22 women who have metastatic disease so they're still

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1 undergoing treatment.

2           I was not thrilled to find that I still  
3 have fatigue now two years later and it's not  
4 nearly as bad and it's not the one a day thing  
5 like when I was in treatment. I have young  
6 children so I likened it to when you have a  
7 newborn baby. You can do what you want in the  
8 morning but you must be home at noon because you  
9 have to sleep or you can't function. And it's not  
10 as bad as that but it's -- there are a lot of  
11 times in the evening where I feel like it's just  
12 too much energy to open up my computer and like  
13 get something off of Amazon. That's just too much  
14 energy and I don't want to do it.

15           And so -- and there are definitely  
16 afternoons where I'm just so sleepy and it feels  
17 like sleepy but it doesn't go away just because I  
18 sleep and I think that's something that we've kind  
19 of talked about. And I'm guessing it's still  
20 lasting effects from treatment. You know, I'm not  
21 on any hormonal therapy now or anything but, you  
22 know, it's been a good two years and it still

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1 lingers.

2 MS. GIAMBONE: Okay. Thank you very  
3 much, Jamie. Okay. So to recap, we're hearing  
4 you summarize that it's a pervasive exhaustion.  
5 We heard that it can be worse during treatments  
6 but that it's still lingering post treatments. In  
7 some cases, it sounds like it's sort of worsened  
8 over time, as you mentioned earlier, that, you  
9 know, you had treatment several years ago but  
10 you've kind of -- you feel as though it's getting  
11 worse now. And you mentioned that it is something  
12 that with the tiredness and sleepiness, that it's  
13 not something that's -- it's not just you sleep it  
14 off or anything, it kind of lingers and continues  
15 to be there. So thank you for sharing those  
16 thoughts with us.

17 Any follow-up questions regarding the  
18 fatigue? Yes, Geoff.

19 DR. KIM: I'm just curious. Actually,  
20 for Katy, while you were on KADCYLA and you had --  
21 you said that it seemed to be a very positive  
22 experience, did you have that lingering fatigue

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1 during the treatment, too, or was it put away for  
2 a little bit?

3 MS. McRAE: No, not on KADCYLA. It was  
4 an absolutely amazing drug for me and -- but I  
5 also feel I'm sorry of very positive and I walk.  
6 I love to walk and so sometimes I would choose to  
7 just push myself a little bit --

8 DR. KIM: Yeah.

9 MS. McRAE: -- and go out and do that  
10 walk. I think a lot of this has sort of a  
11 psychological component as well and that was my  
12 way of dealing with it. Right now I'm --

13 MR. THOMPSON: Right.

14 MS. McRAE: -- fatigued since I've been  
15 off KADCYLA and going through some more stuff but  
16 -- so no, KADCYLA was an amazing drug.

17 DR. KIM: Right. And I wonder if you  
18 have a shared experience with the Xeloda, too, for  
19 5-1/2 years. Did you have the same type of  
20 fatigue, too, as well or did that somehow abate a  
21 little bit during the treatment while you're  
22 having a prolonged response and then it came back

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1 after the treatment didn't work as well or upon  
2 progression?

3 MS. GIAMBONE: Ginny.

4 MS. KNACKMUHS: Yeah. I didn't  
5 experience a lot of fatigue when I was on Xeloda.  
6 It's really only been in the last year-and-a-half  
7 when my blood counts really took a hit and, you  
8 know, that is a side effect of being on chemo for  
9 a long time.

10 DR. KIM: Right, right.

11 MS. KNACKMUHS: And now I just can't  
12 seem to get beyond it even though I'm off the drug  
13 and it, you know, points to maybe, you know,  
14 something a little more serious than just the  
15 effect of the -- of being on the drug so

16 DR. KIM: Thank you for sharing that.

17 MS. GIAMBONE: Thank you, Ginny. Thank  
18 you, Geoff. Are we hearing anything on the web  
19 specifically regarding the fatigue?

20 MR. THOMPSON: Yes. We heard very  
21 similar perspectives. One person saying that in  
22 her experience, the most common thing she's heard

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1 patients talk about is fatigue, second being  
2 sleep. One person saying that fatigue can vary  
3 very much among patients depending on what  
4 treatment they are on, and another person echoing  
5 something we heard about sleeping saying that she  
6 feels sleepy all the time and it doesn't go away  
7 when she does sleep.

8 MS. GIAMBONE: Thank you. Okay. Let's  
9 move on to some of the other symptoms that you've  
10 all identified. So I believe pain was also  
11 identified by several of you. So would anybody  
12 like to talk about how their pain manifests and  
13 how do you experience it? Yes.

14 MS. JONES: Hi. I'm Thelma and I was  
15 diagnosed in July of 2007. The pain that I  
16 experience can be sometimes almost from head to  
17 toe. In the beginning, I had very mild arthritis  
18 or either carpal tunnel syndrome and then over  
19 time, it's gotten worse so there -- my fingers are  
20 sort of now lumping up and on some days, it's  
21 excruciating with the pain or there are days that  
22 my hand is in so much pain that I literally have

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1 to pry my fingers open. And so that affects my  
2 daily activity because I'm a very active person.  
3 And there are times that I get the pain in my  
4 breasts and when it happens often, I mean,  
5 naturally, I think, oh, has the cancer returned,  
6 so I return to my doctor and they may say that it  
7 could be, it's probably the side effects of the  
8 radiation.

9           And then on a daily basis -- I think one  
10 of the panelists mentioned about the lower back  
11 pain -- and you have these pains so much that it's  
12 either you do some type of medication or drug,  
13 which I'm trying to stay away from except the ones  
14 that I'm on, exemestane, the hormonal therapy.  
15 But I'm really trying to focus more on  
16 complementary therapies because I keep thinking  
17 about the toxicity of the drugs. I'm HER2-  
18 positive with an unknown primary so I underwent a  
19 lot of drugs in the beginning and I'm just always  
20 concerned about the long range implications of  
21 those drugs.

22           MS. GIAMBONE: Okay. Thank you very

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1 much for sharing that. So head to toe pain, pain  
2 in the hands. You mentioned pain in your breasts.  
3 Okay. Anybody else? Yes, Karen, let's hear from  
4 you.

5 MS. DURHAM: Well, mine is bone,  
6 particularly joints and also muscles and it's not  
7 just one place. It moves around. One day my left  
8 knee may just hurt really, really bad for two-  
9 three days and then all of a sudden it's gone and  
10 then it's something in my right arm. It's -- it  
11 just moves all over.

12 MS. GIAMBONE: Okay. Thank you for  
13 sharing that. Anybody experience that sort of  
14 pain that moves throughout the body? Katy, yes.

15 MS. McRAE: I -- it's kind of  
16 interesting because for the first -- I've only had  
17 pain for two weeks. It started two weeks ago it  
18 was and after six years of metastatic and it was  
19 just excruciating. I couldn't believe it but the  
20 types -- like even in the one episode, it's --  
21 there's a sharp skewer type pain. There's a dull  
22 ache. There's a throbbing pain and it comes out



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1 of -- I mean the intensity and the sudden onset  
2 has just shocked me, you know, in the last two  
3 weeks. And I thought -- when you said, Karen,  
4 about the muscle pain, I thought I'd pulled a  
5 muscle or whatever because, you know, I walk four  
6 miles a day and I thought, okay, I've pulled a  
7 muscle or whatever. Well, now it turns out that  
8 it's all because of, you know, the nerve damage  
9 across my -- the sacral ileac and into the sacrum,  
10 but it's just the intensity. I look at my body.  
11 I'm saying, who are you, where's this stuff coming  
12 from in two weeks?

13 MS. GIAMBONE: Right.

14 MS. McRAE: I can actually almost  
15 physically feel the cancer just -- you know, just  
16 pinging me. It's going to do with it wants to do  
17 and you're just along for the ride.

18 MS. GIAMBONE: Okay. Thank you for  
19 sharing that perspective. Is there anything that  
20 leads to the worsening of the pain, any -- is  
21 there an activity or is there something about a  
22 particular day, is there an average day of pain

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1 versus a more severe day of pain, or is it sort of  
2 always there? Would anybody like to -- yes,  
3 Debbie.

4 MS. DUNNE: I was just going to say it's  
5 always there, it just kind of moves around. But  
6 again, to your point about not really wanting to  
7 take the drugs, I've done a lot of holistic things  
8 myself and doing exercise and hands-on healing,  
9 acupuncture and all of those really do help.

10 MS. GIAMBONE: Okay, great. Yeah. So  
11 let's take one more comment.

12 MS. JONES: And I also detect when I'm  
13 extremely tired, the pain is greater as well so  
14 the two sort of are intertwined.

15 MS. GIAMBONE: Okay. So you see a  
16 correlation between the pain and the tiredness or  
17 the fatigue or weakness?

18 MS. JONES: Exactly.

19 MS. GIAMBONE: Okay, very good to know.  
20 Yes, we'll take -- Sandy.

21 MS. FINESTONE: I think it's very  
22 confusing to women is the pain they're

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1 experiencing due to treatment, due to aging, due  
2 to hormonal manipulation, so it's very confusing.  
3 Should they act on this pain and go to see their  
4 physician because possibly it's a recurrence of  
5 their cancer or progression of their cancer, or is  
6 it just a natural sort of aging kind of thing  
7 because the lack of estrogen and the  
8 manipulations? It's very confusing and as well as  
9 hurting.

10 MS. GIAMBONE: Okay. So I think that's  
11 a good place to do a show of hands. So it sounds  
12 like it is difficult then to tease apart whether  
13 it's due to the disease or whether it's due to the  
14 treatments? I see a lot of heads nodding. Can you  
15 -- could you all raise your hand and say -- is  
16 that a fair statement, that it's difficult to  
17 tease that apart? Okay, great. Okay. Thank you  
18 for sharing that with us.

19 Okay. And then what we'll do is -- I  
20 know you've all mentioned -- you identified  
21 several of these symptoms. I do want to ask is  
22 there a particular symptom that you didn't know to

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1 expect or something that has really sort of  
2 surprised you that, you know, it sounds like  
3 you've all done lots of research and you've talked  
4 to all your doctors, but did something come up  
5 that you just didn't know to expect? Yes.

6 MS. JONES: One of the challenges I had  
7 very early was dental. I've had -- I mean bought  
8 everybody's dental four or five times over and in  
9 the beginning, in 2007 when I presented this to my  
10 doctor, my dentist, he wasn't very receptive to  
11 the idea that that's what was causing it. And  
12 that was very important for me to -- for him to  
13 understand that because the copayment on my  
14 insurance would have been less and so was the out-  
15 of-pocket expense. But when I asked him to  
16 document that, he couldn't seem to agree with me.  
17 So as a result, I ended up paying thousands of  
18 dollars out-of-pocket and now because I'm a  
19 patient navigator and talk to a lot of people, one  
20 of the things that I strongly encourage is that if  
21 you have dental challenges now, you want to make  
22 sure that you've corrected that before you go into

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1 serious treatment because it does have an  
2 implication.

3 MS. GIAMBONE: Okay. Thank you. Dental  
4 effects. Yes.

5 MS. CAPPEL: Living with metastatic  
6 disease and doing it for a while now -- I'm going  
7 on 9 years, 12 years all together and 9 years  
8 metastatic -- they're finding that there are more  
9 side effects that they were not aware of because  
10 people weren't living as long as this. So what's  
11 recently happened in the last year was that I have  
12 a hole in my septum in my nose, and they said that  
13 that is from prolonged use of chemotherapy and the  
14 blood vessels aren't receiving enough blood in my  
15 septum and it actually caused it to erode. So  
16 there's nothing they can do for it. It doesn't  
17 really bother me. It feels a little weird but it  
18 doesn't bother me. But that's one thing that I  
19 definitely did not anticipate was that my nose was  
20 going to fall apart but the rest of it's still  
21 okay, so it's hanging in there.

22 MS. GIAMBONE: Okay.

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1 MS. CAPPEL: So just finding more and  
2 more things since you're living long-term with  
3 breast disease.

4 MS. GIAMBONE: Right, okay. So nasal  
5 issues.

6 DR. IBRAHIM: Can I ask a follow-up  
7 question?

8 DR. IBRAHIM: Oh, sorry, go ahead.

9 MS. DURHAM: I was just going to say  
10 that I think anybody that goes through treatment  
11 understands that they're going to have some degree  
12 of nausea, diarrhea, constipation, and a few of  
13 those things. And if you read what side effects  
14 are, even on over-the-counter medications, there  
15 are so many of them there, and I don't think any  
16 of us that have been treated or are being treated  
17 for breast cancer know the magnitude that we're  
18 going to have the majority of those side effects  
19 and how much we're going to have them.

20 MS. GIAMBONE: Okay. I saw a lot of  
21 heads nodding to what you just said, Karen, so  
22 that sounds like it's a shared perspective. Yes.

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1 MS. FARIS: Hi. My name is Susan Faris  
2 and I just want to echo. You know, I recently  
3 read a study that talked about how the doctors  
4 will underestimate what kind of -- how severe the  
5 side effects are going to be for a medication, and  
6 I hear that repeated by nurses and oncology units  
7 all the time, that the doctors do underreport  
8 them. They -- for me, it was the severity of -- I  
9 mean I looked at the list and I did not realize  
10 how bad it was going to be so that's really what  
11 the surprise to me was, like, you know, it was  
12 sort of like I thought I was going to go on a  
13 roller coaster ride but instead I did the straight  
14 drop down and it was not fun so, you know, that  
15 kind of thing.

16 MS. GIAMBONE: Okay, thank you. So the  
17 severity or the intensity of what you are  
18 experiencing, there's nothing to prepare you for  
19 that. Yes, Amna.

20 DR. IBRAHIM: So I'd like to tag a  
21 question onto that. Some patients say that if  
22 they knew that they are going to have hair loss,

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1 they would have wanted a different kind of  
2 treatment whereas others are willing to take much  
3 more toxicity. So I'm wondering are there any --  
4 is there any toxicity that you can identify which  
5 you think would have changed the treatment that  
6 you were seeking, that if you knew that that  
7 toxicity was going to occur, you would have  
8 actually gone for another treatment?

9 MS. GIAMBONE: Yes, let's go ahead and  
10 hear from Katherine.

11 MS. O'BRIEN: My answer will be slightly  
12 maybe outside of what you asked but when I was  
13 given the anti-estrogen treatment, tamoxifen, I  
14 was told, you know, I would be in -- and also had  
15 ovarian suppression -- so early -- premature  
16 menopause. And my doctor said almost certainly I  
17 would have hot flashes and so on. And so I did  
18 have some symptoms but I waited -- you know, I  
19 waited in dread for these hot flashes and I am on  
20 the minority in that but thankfully, it didn't  
21 happen. But overall, it shows you how difficult  
22 it is to evaluate treatment because you can now



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1 that these are side effects. What you don't know  
2 is how is it going to happen to you specifically  
3 and what is your tolerance for what the treatment  
4 may be.

5           So I think it is extremely difficult to  
6 quantify because even -- I have not had a  
7 treatment that causes hair loss but I know it's a  
8 very important issue for, I would say, all  
9 patients but even -- some patients have found --  
10 they were told they were going to lose their hair,  
11 maybe they had thinning and if they had -- and  
12 they had good results with the drug, so if they  
13 went strictly by "I will lose my hair," they would  
14 not -- they would have missed out on a drug that  
15 proved to be well for them.

16           So I think what I am saying is the other  
17 side effects is the -- this ties into the anxiety.  
18 You don't know what is going -- you don't -- there  
19 is -- you don't know what the treatment will mean  
20 for you specifically.

21           MS. GIAMBONE: Thank you, Katherine.  
22 And I'd like to just make a call-out. For those

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1 of you who are on the web, if you'd like to dial  
2 in to share any phone comments, please go ahead  
3 and do so now. And we'll take just another comment  
4 and then we'll check in with the web. Yes,  
5 Debbie.

6 MS. DUNNE: So despite all the research  
7 I was doing, I really wasn't considering toxicity  
8 because again, my mindset was I'm fighting for my  
9 life so if I lose my hair and I feel pain and I  
10 don't even know if I'm going to be alive in a  
11 year, so I'm not going to worry about toxicity.  
12 So that's where I was coming from.

13 MS. GIAMBONE: Thank you, Debbie.

14 MS. FINESTONE: I would just like to add  
15 as well. Women -- when you're diagnosed, you  
16 think you're going to die. Now is there concern  
17 about losing your hair? Absolutely. And will  
18 some women make the decision not to treat? They  
19 will but those women are few and far between.  
20 Most women will actually do more -- at least  
21 that's been my experience -- the maximum in order  
22 to save their lives. But everyone starts from a

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1 very naive position. When you say "nausea," well  
2 there's nausea and there's nausea and each of us  
3 are our own little, you know, clinical trials, how  
4 we respond and how we don't. I don't think that -  
5 - we're not informed enough. You know, it's like  
6 being dropped into a foreign country and I'm not  
7 pointing a finger at anyone, but physicians,  
8 clinicians use language we as patients don't  
9 understand, and you're asked to make decisions  
10 without the information you need to make that  
11 decision, and you don't have time, you don't have  
12 time to educate yourself about the language of  
13 cancer, the effects of cancer or how, as someone  
14 mentioned, how am I going to respond.

15           Now I didn't have chemotherapy or  
16 radiation therapy or any therapy but I have hot  
17 sweats -- hot sweats -- what are they -- hot  
18 flashes that are --

19           UNIDENTIFIED SPEAKER: And sweats.

20           MS. FINESTONE: -- they are sweats --  
21 that are horrible. I have joint pain and that all  
22 comes with aging but I would have done whatever it

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1 took to save my life. I was diagnosed young and  
2 had two small children. That's what was foremost  
3 in my mind. Losing my hair, no one wants that to  
4 happen but I don't think -- a very, very, very  
5 small majority of women will opt not for treatment  
6 for something like that. That's my experience.

7 MS. GIAMBONE: Thank you, Sandy. Thank  
8 you. So Sandy -- yes, it looks -- let's hear from  
9 -- I don't think we've heard from you.

10 JOANNE: Yes. I'm listening to  
11 everybody and I'm relating to what everyone's  
12 saying and I'm a survivor of two years now. And  
13 the thing that I would -- you know, if I -- my  
14 wish -- my wish is that we could know what to  
15 expect, you know, onset, duration and intensity of  
16 any of these side effects, whether they happen.  
17 You know, you hear oh, it's going to -- you know,  
18 you're fatigue's going to get worse with each  
19 cycle, right? Well, I wasn't quite prepared for  
20 how fatigued I would be by my sixth cycle, just  
21 wasn't. I fell flat on my face. I literally did  
22 and have recovered well. I'm doing well, wasn't

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1 quite prepared for, hmm, I still am very active  
2 with lots of energy and yet I have less energy  
3 than I had before I was treated. So no one would  
4 really notice that I may be more fatigued than I  
5 was before.

6           And so, you know, I'm thinking about,  
7 boy, I would love some research out there that  
8 looks at for whom, under what circumstances, under  
9 what conditions can we expect, you know, that  
10 someone would be feeling, you know, tired,  
11 exhausted, or fatigue, pain, because I think more  
12 than anything, I want to be able to plan. If I  
13 know when I'm going to be experiencing that, then  
14 I can work around that, I'll feel less out of  
15 control. And that's one of the other themes I'm  
16 hearing, too, just feeling -- that's part of the  
17 anxiety, what -- you know, when I'm going to feel  
18 what.

19           MS. GIAMBONE: Okay. Thank you. And  
20 you're name?

21           JOANNE: I'm Joanne.

22           MS. GIAMBONE: Joanne. Thank you,

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1 Joanne. So correlating the lack of -- or the -- or  
2 not understanding right away what to expect or the  
3 intensity or severity of what to expect,  
4 correlating that to the anxiety that you feel.  
5 Okay.

6 MS. JONES: And can I just share because  
7 I think that's an interesting question but a  
8 paradigm shift on the way we are addressing it,  
9 because the women here, I get the impression we're  
10 all fairly well read but then there is that  
11 segment of the population that a, you have  
12 challenges in just getting them to a mammogram  
13 because of fear. So then if you start telling  
14 them after they've gotten a diagnosis from that  
15 fearful mammogram that has taken them years to  
16 get, if you start telling them about the  
17 challenges that they are going to experience, then  
18 I can assure that that's going to delay their  
19 treatment even greater.

20 MS. GIAMBONE: Okay.

21 MS. JONES: So we have to find a way to  
22 not only mitigate their fears but to help them to

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1 understand their treatment choices in a way that  
2 they will reach out to -- and that's very  
3 difficult when the fear factor is very pervasive,  
4 because they've heard everybody in their  
5 neighborhood say all of the horrible things about  
6 it. They rarely hear the benefits of undergoing  
7 any type of cancer treatment.

8 MS. GIAMBONE: Thank you very much. And  
9 we'll take another comment.

10 MR. THOMPSON: Just want to point out  
11 we're going to be going to a break pretty soon but  
12 we will talk much more about treatments and  
13 treatment considerations in the afternoon, so

14 MS. GIAMBONE: So we'll take one more  
15 comment and then we'll check in with the phone and  
16 we'll go to break. Yes.

17 MS. KNACKMUHS: Ginny Knackmuhs again.  
18 I was just thinking when Sandy made her comment,  
19 and I thought it was a very good one, that in  
20 early stage cancer, you know, you're trying to  
21 save your life so losing your hair in the, you  
22 know, long-term is not that big a deal. And I

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1 think that's a great point to illustrate the  
2 difference between early stage and metastatic. I  
3 mean, you know, early stage, yes, you're trying to  
4 save your life and, you know, you'll put up with  
5 just about anything, you know, because what is it  
6 going to be, six months a year, you can get  
7 through it.

8           When it comes to considering symptoms  
9 and side effects for metastatic, it's quite a  
10 different decision. You know, you're going to go  
11 on this drug. You're going to lose your hair.  
12 Well, for how long? Will I ever get it back? So,  
13 you know, it's a different -- obviously, it's a  
14 different perspective but I'm a patient but I'm  
15 also a patient advocate for a metastatic breast  
16 cancer network. We're a patient group and what  
17 I've noticed is that -- and I just want to say  
18 this for all the young women out there,  
19 particularly those that are raising families that  
20 are metastatic -- they are willing to put up with  
21 so much more toxicity just for the sake of being  
22 there as long as they possibly can for their



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1 children.

2 MS. GIAMBONE: Thank you, Ginny. So  
3 let's go to the phones and do we have any callers  
4 on the line? Operator, do we have anyone lined up  
5 for a phone?

6 THE OPERATOR: Jennifer, your line is  
7 open.

8 JENNIFER: Hi. This is Jennifer. Can  
9 you hear me?

10 MS. GIAMBONE: Yes, we can hear you.  
11 Hello.

12 JENNIFER: Hi. So, yes, I was diagnosed  
13 about two years ago at the age of 34, very active  
14 person. I am triple-positive. I had double  
15 mastectomy, 13 lymph nodes removed and there was  
16 cancer found in the lymph nodes. Had no problems  
17 with chemotherapy, didn't need any kind of  
18 radiation or anything like that -- I was actually  
19 a stage three -- but have severe problems with  
20 tamoxifen including very bad hot flashes,  
21 depression for the first time in my life,  
22 bloating, abdominal pain that just -- that would

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1 have me sometimes double over, so I have chosen to  
2 stop taking tamoxifen. And I have also chosen to  
3 not go in an AI because my quality of life is more  
4 important to me than living with something that  
5 makes me feel less like a woman. And being young,  
6 the other thing, too, is I lost the ability to  
7 want to be intimate or sexual with anyone, and  
8 that's something that's very important to me and  
9 if I can't have that, I would rather go through  
10 chemotherapy and other treatments again if the  
11 cancer comes back versus go through something  
12 that's going to take away my quality of life.

13 MS. GIAMBONE: Thank you so much for  
14 sharing that. Thank you.

15 JENNIFER: Thank you.

16 MS. GIAMBONE: And no more -- okay, so  
17 there's no more -- okay. And can we just get a  
18 summary of anything else we've heard on the web  
19 for Topic 1?

20 MR. THOMPSON: Just two small points  
21 from an earlier conversation, so one person was  
22 talking about pain and tingling where their lymph

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1 nodes were removed and also just getting pain over  
2 random body parts after the surgery. And somebody  
3 else was talking about suffering from cataracts  
4 and thrombophlebitis after tamoxifen treatment and  
5 wasn't sure if it was a side effect or something  
6 related to the cancer.

7 MS. GIAMBONE: Okay. Thank you. I know  
8 there is so much more that we could discuss for  
9 Topic 1, but we'll take a short break now, let's  
10 say 10 minutes. We'll take a 10-minute break and  
11 then we'll come back and talk about Topic 2.  
12 Thank you, again.

13 (Whereupon, off the record at 2:45  
14 p.m., and back on the record at 2:55  
15 p.m.)

16 MS. GIAMBONE: So we're going to get  
17 started and how about I just have our Topic 2  
18 panelists come on up and have a seat. Okay. So  
19 we will go ahead and get started again.

20 We had such a great discussion for Topic  
21 1, for the first half of the meeting, and I think  
22 that the one theme that just kept coming up --

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1 again, I think my FDA colleagues would agree is  
2 that biggest part of your life or the biggest  
3 impact of living with breast cancer is the  
4 treatments and the management of your breast  
5 cancer, the doctors' appointments, the decision-  
6 making as it has to do with treatments, so thank  
7 you for bringing up this very, very important part  
8 of your life and sharing that with us. And we're  
9 going to go into much further detail with this  
10 topic which focuses on treatment and I know we  
11 already -- we started bringing that up. You know,  
12 you shared so much of that in Topic 1 and it's  
13 very understandable. So we're looking forward to  
14 exploring that even more in this discussion.

15           And certainly, if there are other  
16 aspects, you know, or downsides or side effects  
17 that you are experiencing with your treatment that  
18 you mentioned in Topic 1 that we didn't get to  
19 explore too much, I encourage you to continue to  
20 bring those up now and share those with us.

21           Okay. So just to reiterate again how  
22 our topic will look -- so for Topic 2, we're going

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1 to be discussing treatments: So, what are you  
2 doing to manage your breast cancer, to treat your  
3 breast cancer and how do you experience the  
4 treatments; what are the benefits that you see;  
5 what are the downsides that you're experiencing?  
6 And we're also -- as I mentioned, we're going to  
7 spend a portion of this discussion talking about -  
8 - and we already brought this up a bit -- is the  
9 decision-making, the factors that you consider in  
10 deciding what treatments you will be taking.

11           So with that, let me turn it over to our  
12 panelists and, Colleen, if you could just get  
13 started. And we'll have each one of you introduce  
14 yourselves and then you can start your  
15 presentation.

16           MS. DUFFEY: So Good afternoon. I'm  
17 Colleen Duffy. I'm a 34-year-old wife, mother,  
18 and engineer. I was diagnosed with stage four  
19 breast cancer which is HER2-positive in December  
20 of 2012. It was just four months after my second  
21 baby was born. It has since spread to my bones,  
22 skin, lymph nodes, lung and my brain. I have

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1 completed a variety of treatments and am very  
2 grateful for the opportunity to share my  
3 perspective on the current approaches with you  
4 all.

5           My cancer has recently progressed and I  
6 started a new drug, KADCYLA, on Monday. I will  
7 continue infusions of that drug every three weeks  
8 until the cancer progresses again. It's just been  
9 a few days since I started this new drug so I'm  
10 going to focus on the treatments that I have had  
11 up to this point. So my first treatment after  
12 diagnosis was a traditional chemo and a targeted  
13 therapy. So I started on Taxotere, Herceptin, and  
14 PERJETA. I completed six cycles with the Taxotere  
15 and stopped it but continued the Herceptin and  
16 PERJETA until about two weeks ago. I have an  
17 infusion of ZOMETA every six weeks and I've also  
18 taken an oral chemo pill, Xeloda, had a  
19 mastectomy, undergone whole brain radiation and  
20 heat therapy, and a targeted radiation.

21           The most significant downsides of all of  
22 these treatments are that they stop working. The

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1 tumors outsmart them and grow. Then there becomes  
2 the need to switch. I would be happy to tolerate  
3 the side effects and inconveniences caused by any  
4 of the treatments if they worked forever. This  
5 issue affects my life by not allowing me to make  
6 long-term plans, interrupting my routine, my work  
7 schedule, and my family's routine.

8 I do many supportive care treatments to  
9 manage my side effects. I currently attend a  
10 support group, participate in therapy, take a  
11 prescribed antidepressant, Lexapro, to manage my  
12 mental health. I have also attended many seminars,  
13 end-of-life preparation, healthy eating, coping  
14 strategies, future research and therapies.

15 As far as my physical side effects, I  
16 take Imodium A-D and/or Lomotil to control my  
17 diarrhea. For pain management, I have taken  
18 OxyContin, Percocet, and Fentanyl patches but I  
19 try to stick to the ibuprofen and getting  
20 massages. I had to take steroids for the swelling  
21 in my brain. I had hyperbaric oxygen treatments  
22 for the wounds I had following the heat and

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1 radiation therapies. I have also done acupuncture  
2 but following the mastectomy, my oncologist does  
3 not recommend it due to the risk of lymphedema.

4           So my mental health has been very well  
5 managed thanks to the support networks in my  
6 community. The diarrhea is mostly manageable by  
7 the medication but depending on my chemotherapy,  
8 it has become extreme. At that point, I go to the  
9 oncologist's office and get fluids. Pain  
10 management is a challenge because there is a fear  
11 of becoming addicted to the pain pills. I am also  
12 adversely impacted by impairment when I take  
13 Percocet, OxyContin, and Fentanyl patches. The  
14 steroids greatly negatively impacted my emotions  
15 and my self-control. The hyperbaric oxygen  
16 treatment worked very well but it was a daily  
17 therapy that required driving.

18           The only side effect that hasn't been  
19 addressed through drugs or alternative therapy is  
20 fatigue. I am always so tired.

21           I weigh the importance of prolonging my  
22 life much higher than improving the symptoms I



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1 experience due to breast cancer. Staying alive is  
2 my main goal in treatment. I have found that most  
3 of the side effects I have experienced will pass  
4 in time. Since my diagnosis, the good days, days  
5 when the side effects don't consume me, have  
6 outnumbered my bad days, and there are many  
7 reasons why staying alive is so important to me.  
8 One is that I'm a mother to young children. My  
9 will to live for my children is worth suffering to  
10 me. I will take on many more side effects if I  
11 get to stay on a particular drug longer. This is  
12 one more month I get to participate in the raising  
13 of my children, one more day I get to see their  
14 smiles, hear their laugh, and show them my love. I  
15 am also young and I still have a good immune  
16 system. I try to prolong each drug I am on for as  
17 long as possible. I have yet to encounter a side  
18 effect that would be bad enough for me to ask to  
19 stop taking the drug or to end a treatment earlier  
20 than recommended.

21           There are many factors I use when making  
22 treatment decisions. My overall strategy is to

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1 stay on each chemo drug for as long as I can. I  
2 try to stretch the use by including other  
3 treatments. When I was diagnosed with a brain  
4 metastases, it was determined that my current  
5 systemic treatment was still controlling the  
6 cancer in the rest of my body. Instead of  
7 abandoning Herceptin and PERJETA, I underwent  
8 whole brain radiation, added Xeloda to the drug  
9 regimen. Instead of switching targeted therapy  
10 drugs for the skin metastases, I added heat  
11 therapy and targeted radiation. Instead of  
12 switching targeted therapy for the lymph node  
13 progression, I added a local radiation. So far  
14 this has given me an additional year on the same  
15 targeted therapy drugs.

16 My overall goal is to prolong my life  
17 and I am doing this by carefully considering other  
18 approaches with my oncologist before abandoning  
19 systemic treatments I take that may still be  
20 somewhat effective. Common and uncommon side  
21 effects from these drugs do not play a major role  
22 in my treatment decisions. Their effectiveness in

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1 prolonging my life is the most important criteria  
2 that I consider when choosing a treatment plan.  
3 As long as I stay on my targeted therapy, I can  
4 endure the side effects of the other treatments.

5           As a stage four breast cancer patient  
6 with major progression, I am much more likely to  
7 die from the breast cancer than a side effect of  
8 the treatment. I'll take my chances in regards to  
9 the serious risks. I would much rather try a  
10 treatment in the hopes of prolonging my life long  
11 enough to see a cure.

12           Thank you so much for allowing me the  
13 opportunity to share my experience.

14           MS. GIAMBONE: Thank you, Colleen.  
15 Susan?

16           MS. FARIS: My name is Susan Faris and  
17 good afternoon, ladies and gentlemen, and thank  
18 you so much for letting me speak today. I really  
19 appreciate it.

20           I -- 30 percent of women who are  
21 diagnosed with early breast cancer will move on to  
22 metastatic status. I am the six percent who was

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1 diagnosed right out the door as metastatic. I am  
2 HER2-positive and I was diagnosed on January 2012  
3 at age 47. The cancer had not only formed in my  
4 breast but it had encumbered my entire liver. I  
5 was immediately put onto weekly Taxol and  
6 Herceptin treatments that lasted for 24 weeks.  
7 The side effects of this were severe and got worse  
8 over time. I experienced extreme neuropathy of my  
9 hands and feet so bad that I would often fall over  
10 and I could not button my own shirt or pick up  
11 small items or put on jewelry. I had extreme  
12 pervasive fatigue. I had steroid-induced bouts of  
13 mania and acne covered my body due to steroids. I  
14 had acid reflux, constipation, edema in my legs,  
15 muscle aches, renewed sciatica, insomnia, loss of  
16 taste, hair loss, and nails that lifted, infected,  
17 and fell off. These are typical side effects of  
18 systemic chemos.

19           The result was that I was disabled. I  
20 was barely able to leave my house or care for  
21 myself and I was increasingly isolated. I became  
22 hopelessly depressed in spite of counseling and

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1 antidepressants. The chemo that I was on was  
2 extended several times from 15 weeks to 20 to 24  
3 weeks and finally, I demanded that it be stopped  
4 because it was killing me.

5           After this, I was considered stable. I  
6 had scar tissue on my liver and I was maintained  
7 on Herceptin, and I could go back to working full-  
8 time and the neuropathy went away. The side  
9 effects of Herceptin are minor. I had some sinus  
10 issues. I had some fatigue. That was about it.

11           But then in November 2013, I had what I  
12 call a "flare-up." I refuse to use the word  
13 "progression." Anyway, when I was told that I had  
14 a five-centimeter mass on the dome of my liver at  
15 the appointment with my oncologist, I began to ask  
16 questions. I had a list of questions but instead,  
17 I broke down into sobs and I told her repeatedly I  
18 did not want to go onto a systemic chemo again.  
19 The treatment that she put me onto was KADCYLA,  
20 which is a targeted chemo. The negative impacts  
21 of this chemo are mostly limited to the cancer  
22 itself although it does have some systemic

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1 effects. There is no such thing as no side  
2 effects. It is a question of severity. So I  
3 experienced minor fatigue, mild neuropathy, acid  
4 reflux, minor constipation, elevated liver  
5 enzymes, and lowered platelets. My oncologist has  
6 reduced the dosage a few times to minimize the  
7 neuropathy and the elevated liver enzymes and the  
8 lowered platelets but the treatment, knock on  
9 wood, is continuing to work.

10           These side effects are easily treated  
11 with Prilosac for the acid reflux, constipation is  
12 treated with a stool soften, and I use supplements  
13 such as alpha lipoic acid and vitamin B6 for the  
14 neuropathy.

15           As long as I can live my life and  
16 continue to work full-time, that is my goal. My  
17 focus is on quality of life when I am choosing a  
18 new treatment. The average survival time for a  
19 metastatic breast cancer patient is 2.5 years.  
20 I've exceeded that. So, I, in the time that I  
21 have left, would like to live a quality life, not  
22 one where I'm suffering.

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1 I judge potential treatments based on  
2 high potential benefit but also significant  
3 immediate negative side effects. If a treatment  
4 has higher immediate negative impacts that would  
5 severely limit my life, I will not choose that  
6 treatment, even if the treatment would prolong my  
7 life. Neuropathy is one of my greatest fears.  
8 Medicines or supplements can do little to treat  
9 neuropathy at this point and since I am very prone  
10 to this side effect, if the treatment has that as  
11 a side effect, I will experience it. I would  
12 rather my oncologist reduce the dosage on a  
13 treatment and risk the cancer growing than to  
14 continue on a higher dosage and risk permanent  
15 neuropathy.

16 The factors I consider when choosing a  
17 treatment are the possible long-term impact  
18 against the severity of immediate side effects,  
19 the likely length of my life, and the percentage  
20 of patients who may suffer that long-term side  
21 effect. Acceptable risk for me, for instance, is  
22 the heart toxicity of Herceptin. Thirty-four

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1 percent of patients treated with Herceptin, you  
2 know, have that experience but it has a  
3 significant progression free survival time, plus  
4 the heart toxicity fits into my goal of dying of a  
5 heart attack instead of cancer.

6 I've announced this goal to my  
7 oncologist and when I first met my cardiologist, I  
8 told him this was my plan. His response was to  
9 ask to -- was for him to ask me to let him know  
10 when I would like to schedule that.

11 (Laughter.)

12 MS. FARIS: I knew I'd met my man. And  
13 if a side effect is manageable with medicines that  
14 do not themselves have significant side effects,  
15 then that is acceptable as well. I balance  
16 between staying alive and living with quality of  
17 life. I focus on targeted treatments because of  
18 the minimal side effects and high benefit of  
19 targeted therapies such as Herceptin, pertuzumab,  
20 TYKERB, and KADCYLA, these are my focus. My hope  
21 is that they are -- these type of treatments are  
22 moved quickly into market so that I can continue



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1 to live. I regularly search clinicaltrials.gov,  
2 PubMed and scan Twitter looking for the current  
3 research on these therapies, things that have not  
4 even made it to PubMed yet.

5 My goal is to stay away from systemic  
6 chemos. That's just my preference due to their  
7 extreme side effects for me and their disabling  
8 qualities. When I've exhausted targeted  
9 treatments and only have systemic chemotherapy as  
10 a choice, I will try one or two of these treatment  
11 types. But if my quality of life is greatly  
12 minimized by these treatments, I will turn these  
13 systemic chemos down and I will choose the right  
14 to die.

15 MS. GIAMBONE: Thank you, Susan. Any  
16 final remarks?

17 MS. FARIS: Nope.

18 MS. GIAMBONE: Thank you very much.  
19 Elizabeth?

20 MS. CAPPEL: Good afternoon. My name is  
21 Elizabeth Cappel. I was diagnosed with early  
22 stage two invasive ductal carcinoma. I have no

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1 family history of breast cancer or of any type of  
2 cancer whatsoever. Like Susan, I was supposed to  
3 die of heart disease but instead I have breast  
4 cancer. I was checked for the BRCA1 and 2 gene  
5 and I am negative for that. I was diagnosed in  
6 March of 2003. I have four children. I had four  
7 young children at that point and my youngest was  
8 three months old. She's now 12. And I am triple-  
9 positive for HER2.

10 I had a lumpectomy and radiation in the  
11 beginning with the stage two invasive ductal  
12 carcinoma. I had no lymph node involvement and I  
13 had clean borders so I was looking pretty good.

14 I was fine for about 3-1/2 years. When  
15 I first was diagnosed, I had Adriamycin and  
16 Cytoxan AC which is the normal thing, four rounds.  
17 The reactions were hair loss -- I have actually  
18 lost my hair three times from chemo -- mouth  
19 sores, nausea, vomiting, fatigue, low blood  
20 counts, the usual, radiation fatigue and skin  
21 blistering.

22 I was on Tamoxifen for 3-1/2 years and

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1 then I had a recurrence. When I had a routine  
2 mammogram, they found DCIS of my right breast. It  
3 was in my right breast to begin with and I asked  
4 for a PET scan, which they didn't think was  
5 important but I demanded a PET scan and it showed  
6 a benign hemangioma on my liver. So we went ahead  
7 with a bilateral mastectomy with reconstruction.  
8 A week later, I had a deep vein thrombosis of my  
9 right leg. Three days later, I passed out in the  
10 doctor's office with a bilateral pulmonary  
11 embolism. I needed a Greenfield filter which I  
12 was very young for since I was early 40's.

13           A few months later, my blood work showed  
14 that I had increased liver enzymes and, in fact, I  
15 did have liver metastasis, so the mastectomies  
16 were not actually need. I had an MRI of the  
17 liver. It showed that about three-quarters of my  
18 liver was involved with only a few liver cells  
19 that were actually viable. I was told at that  
20 point that I would have, at best, two years to  
21 live -- that was from Fox Chase and my primary  
22 doctors -- oncologists -- two years, at best, to

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1 live; during that time, I would be on chemo  
2 continuously and quality of living would be really  
3 bad and that I would no longer ever have hair  
4 again. As you can see, I have a really nice head  
5 of hair right now.

6           So that was almost nine years ago which  
7 is pretty incredible. What I had for treatment  
8 would be Nevelbine and Herceptin right after that.  
9 I had extreme reactions to that, loss of finger  
10 and toenails also, which my toenails are still not  
11 normal, very bad reaction, shaking on infusion --  
12 they all it shake and bake -- increased blood  
13 pressure, red face and neck -- they slowed the  
14 infusion, added Benadryl and Decadron -- mouth  
15 sores, vomiting, fatigue, body pain, neuropathy.

16           I went onto TYKERB, Xeloda, also loss of  
17 nails, bad, bad joint pain, and then we just went  
18 on Doxal and Herceptin. Doxal actually was one of  
19 the more gentle drugs for me. I had hair loss,  
20 nausea, fatigue, infusion reactions; we used  
21 Zofran a lot. But then we continued on with  
22 Herceptin.

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1           With Doxal, we got to a point about 2-  
2 1/2-3 -- well, no, three years ago where the --  
3 everything was progressing and the liver mets were  
4 still growing and we couldn't get them under  
5 control, so we used Doxal and we threw in  
6 something unusual. We threw in CyberKnife. Now  
7 with metastatic breast disease, you don't  
8 typically do CyberKnife or radiation to the site  
9 of the problem with the liver, but we decided that  
10 why not try it. So we did the CyberKnife.

11           Problem with the CyberKnife was I was  
12 coming off of Doxal so there was a lot of fatigue  
13 but also that I had three to four ribs that were  
14 broken. Now that plays into would you have chosen  
15 a different alternative to treatment. They  
16 weren't aware that this could happen so I now have  
17 three -- definitely three ribs that are broken  
18 permanently, which means that they disintegrated.  
19 So I need to have things for pain management. So  
20 I have nerve ablations done every three to four  
21 months to manage that pain because my ribs flail.

22           I stayed on Herceptin after that but I

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1 became very toxic to Herceptin which is unusual  
2 and I couldn't stay on it any longer. And that is  
3 the plan, that you stay on the Herceptin but I had  
4 one of the worst reactions they've ever seen and I  
5 went to Sloan and saw Larry Norton, who is one of  
6 the people who did, you know, work on Herceptin  
7 from the beginning and he said it's one of the  
8 worst reactions he's ever seen. I completely dump  
9 all of my histamine and get terrible body pain  
10 where I can't move. So we decided to stop it and  
11 that was over two years ago.

12           So I am on no treatment whatsoever right  
13 now. I get checked every four weeks for my cancer  
14 markers, my 2729s. I get scans every three  
15 months. Right now I have zero to one circulating  
16 tumor markers which means there's no sign of  
17 cancer in my body. My liver mets are completely  
18 gone. It comes back no sign of metastatic  
19 disease, and my bone scans have been clean for  
20 years. So, right now I just stay on this course  
21 of treatment or non-treatment I should say. And I  
22 think it's really important to get that

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1 information out there, because it's scary as  
2 anything to have metastatic disease and to have  
3 four young children and to just want to live. So  
4 there's absolutely a chance for everyone to have  
5 survival and you just have to keep plugging away,  
6 and research and development is key to this and I  
7 thank you for that.

8 MS. GIAMBONE: Thank you very much,  
9 Elizabeth. Shirley?

10 MS. MERTZ: Hello, everyone. My name is  
11 Shirley Mertz. Before I begin, I want to pay  
12 tribute to the 108 women and men who will die  
13 today of metastatic breast cancer.

14 My journey with breast cancer began 24  
15 years ago when I was diagnosed with early stage in  
16 1991. Because I wanted to survive, I decided to  
17 have a bilateral mastectomy and 12 years later, my  
18 metastatic disease appeared in 2003 and I received  
19 treatment then consisting of capecitabine as the  
20 chemotherapy, targeted therapy, Herceptin and  
21 palliative radiation. My metastatic disease  
22 presented in my spine and quickly spread

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1 throughout my skeleton and into my liver. After  
2 about a year of treatment, I went into complete  
3 remission and remained so for 7-1/2 years.

4           Approximately a year ago, I had a  
5 progression of my disease into a lymph node and  
6 after biopsy, it was discovered that my cancer had  
7 mutated and I started -- I added a different  
8 treatment. Because of having only one lesion in my  
9 body, I decided to undergo stereotactic radiation  
10 therapy which removed the lymph node, and so I now  
11 have a treatment regimen that includes the  
12 Herceptin or I should say trastuzumab,  
13 bisphosphonate for bones that I've been on for  
14 quite some time, and a anti-estrogen agent called  
15 Exemestane.

16           To me, the most significant downsides of  
17 an anti-hormonal agent are what we've heard so  
18 far, bone and joint pain, difficulty sleeping, and  
19 as I've learned recently, a negative impact on  
20 one's immune system. Trastuzumab has had some  
21 issues on my heart but I am able to continue  
22 receiving that treatment. Of course, my kidneys



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1 have to be watched because of the zoledronic acid  
2 and for radiation, stereotactic radiation, I did  
3 experience three weeks of intense fatigue which  
4 we've all tried to explore today of what that  
5 means. For me, it was difficulty doing household  
6 chores, taking care of my elderly mother whom I'm  
7 responsible for, and going anywhere outside the  
8 house.

9           So while treatments have certainly  
10 lengthened my life -- I have lived now 11-1/2  
11 years with metastatic breast cancer and I truly  
12 feel blessed -- at the same time, I know that they  
13 can have a significant impact on my internal  
14 organs, my vital organs and my daily system. Of  
15 course, I still feel that I am glad to be here as  
16 opposed to not and as a side effect, of course, I  
17 guess an inconvenient side effect, one's life, as  
18 we've heard today for metastatic patients, has to  
19 be arranged around weekly visits to the hospital  
20 for infusions, medical tests and visits with  
21 doctors. I chose to be treated at a comprehensive  
22 cancer center which is an hour from my home and

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1 I've visited that place every three weeks for the  
2 last -- since 2004.

3           Because treatment as well as the mental  
4 challenges of metastatic disease have had an  
5 impact on my ability to fall asleep, I take  
6 prescription medication each night to fall asleep.  
7 I do take a daily vitamin D to strengthen my  
8 bones. I can -- I try to walk each day to support  
9 my bone care as well as to help with fatigue,  
10 though that was counterintuitive to me when  
11 someone told me that.

12           I also participate in cognitive therapy  
13 with a social worker to try to cope with the fact  
14 that I worry about progression and I also have to  
15 deal with the fact that I -- my life will be  
16 shortened by this disease. I practice daily  
17 meditation and visualization and prayer. Those I  
18 consider all a part of my supportive integrative  
19 medicine to my clinical treatments.

20           While I consider -- I consider my goals  
21 in treatment to live as long as possible with the  
22 best quality of life. However, I must say that my

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1 -- in making treatment decisions, when I reflected  
2 on preparing for today, when I first heard I had  
3 metastatic disease, I was so angry, so shocked  
4 because I thought what more could I have done with  
5 -- my initial diagnosis in '91 was ductal  
6 carcinoma in situ. And I thought, okay, how could  
7 this be that it came back. So when I met with my  
8 first oncologist and he suggested a treatment, I  
9 was ready to go; sure, whatever you say; you know,  
10 I want to take action and now.

11 I've since discovered -- well, I had  
12 really no information about metastatic breast  
13 cancer at the time. I relied on my doctor to make  
14 the first decision and then I started going on the  
15 internet, finding sources of information which are  
16 not always available back then for metastatic  
17 patients. Things are somewhat better today but  
18 still most oncologists do not hand anything to a  
19 patient about their disease. And so now I approach  
20 decision-making a little different. For example,  
21 with my lymph node, even though it was biopsied  
22 and I could have entered a clinical trial, because

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1 of the mutation, I decided not to because of the  
2 severe toxicity that I read about. So I chose to  
3 go in another direction with the radiation,  
4 CyberKnife, or whatever you would like to call it.

5 I think it's important for patients to  
6 consider what the doctor is suggesting, why is he  
7 or she suggesting a treatment, is there an option,  
8 what toxicities can I expect, can those toxicities  
9 be addressed by over-the-counter medication or in  
10 many cases, the dosage can be reduced or a  
11 treatment stopped for a while. If there are  
12 really serious -- in the questions, it was asked  
13 what would you do about very serious potential  
14 toxicities like liver or kidney failure, blood  
15 clots or heart attacks, those would be deal-  
16 breakers for me because I, for example, have heart  
17 disease in my family and you can't live without a  
18 working liver or kidney.

19 MS. GIAMBONE: Thank you, Shirley.

20 MS. MERTZ: I just have one more  
21 comment.

22 MS. GIAMBONE: Okay, sure.

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1 MS. MERTZ: And I understand the time.  
2 I think for each of us, metastatic disease is  
3 unique. I just want to say to the panel  
4 metastatic patients are used as the participants  
5 in clinical trials to find out if the drugs that  
6 pharmaceuticals are exploring will reduce the size  
7 of a tumor. For us, you asked what would be your  
8 ideal treatment in the future. We would like to  
9 see treatments that prevent the outgrowth of our  
10 metastatic spread and that is different than the  
11 reduction of a tumor, because we feel that if --  
12 until a treatment can be found -- a cure can be  
13 found, we are willing to live with this disease if  
14 it doesn't spread any further than where it is  
15 when we find it, when it's found. And so long as  
16 we can keep it from attacking organs, that's the  
17 type of drug that metastatic patients would like.  
18 And we would like the FDA to support clinical  
19 trials for that.

20 And final point, when I've asked  
21 pharmaceuticals why don't you develop drugs like  
22 this, we have -- I have been told that clinical

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1 trials do not permit that type of endpoint. So I  
2 want to use this platform to please ask you to  
3 reconsider endpoints that prevent metastatic  
4 outgrowth. And I thank you the opportunity today  
5 to comment.

6 MS. GIAMBONE: Thank you, Shirley.

7 (Applause.)

8 MS. GIAMBONE: Thank you again to all of  
9 our Topic 2 panelists for sharing these stories  
10 again and as I said with the Topic 1 panelists,  
11 you are all just very, very strong and brave  
12 people for coming here and sharing such personal  
13 stories with us so thank you. So could we give  
14 everyone -- could we give our panelists a round of  
15 applause?

16 (Applause.)

17 MS. GIAMBONE: And similar to what we  
18 did in the first half of the day, can we see by a  
19 show of hands how many of you felt as if your  
20 experiences are -- that you shared similar  
21 experiences to those shared by the panelists?  
22 Okay. So we see a few hands raised here. Thank

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1 you.

2           Okay. So what we'll do now is we'll do  
3 another polling question. Are the clickers  
4 working?

5           (No audible response.)

6           MS. GIAMBONE: Okay. So we're going to  
7 give the clickers a try. Okay. Have you ever  
8 used any of the following cancer treatments to  
9 help reduce or control the spread of your breast  
10 cancer -- and we definitely have touched upon many  
11 of these so let's just get a count for what we're  
12 seeing -- a) chemotherapy; b) radiation therapy;  
13 c) surgery to remove the tumor or tumors or any  
14 part of the breast; d) targeted drug therapy; e)  
15 hormone therapy; f) other; g) I have not undergone  
16 any cancer treatments; or h) I'm not sure.

17           So I think they can choose multiple --  
18 okay, so you can choose multiple responses here.  
19 Thanks, Theresa.

20           Okay. So here's what we're seeing for  
21 the perspectives in the room. Looks like the  
22 majority of you, over 90 percent of you have

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1 undergone chemotherapy and surgery followed by  
2 radiation therapy. And then we're seeing about  
3 over half of the people in the room that responded  
4 also used targeted drug therapy or hormone  
5 therapy. And then we also have some "other  
6 treatments" listed here.

7 Is that similar to what we're seeing on  
8 the web?

9 MR. THOMPSON: About 66 percent,  
10 chemotherapy; 90 percent surgery; 45 percent  
11 radiation therapy; 22 percent targeted drug  
12 therapy; and 55 percent hormone therapy.

13 MS. GIAMBONE: Okay, great. Thank you.  
14 So as I mentioned, you all have brought up many of  
15 your experiences using these range of therapies.  
16 So what I'd like to ask is instead of focusing on  
17 -- instead of me asking a question focusing on  
18 just one of these particular treatments, could one  
19 of you begin to share with us how you have -- how  
20 this particular treatment, whatever treatment it  
21 is that you have used that you'd like to comment  
22 on, how is that managing your breast cancer? Yes,



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1 Katherine.

2 MS. O'BRIEN: I was diagnosed with  
3 metastatic breast cancer. I was a de novo  
4 presentation. As we learned, that's unusual.  
5 Only about 10 percent of patients have this.  
6 Surgery is not standard of care for metastatic  
7 breast cancer. At the time that I was diagnosed  
8 in 2009, it was thought that there was some  
9 benefit, so after I had been stable on my  
10 treatments for, I think it was like, six months, I  
11 was given the option of having a unilateral  
12 mastectomy. It was stressed this would not -- was  
13 not curative, it was not known if it would be  
14 beneficial for me. So I did research. Another  
15 patient with a similar diagnosis really did the  
16 research. She had collected all of the scholarly  
17 papers. I read the papers. I felt confident in  
18 my decision.

19 One thing that was hard to quantify was  
20 psychologically, I wanted the surgery. I think  
21 that's hard to understand even though logically no  
22 benefit potentially, no promises, I wanted this

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1 cancer out of me. So I did have the surgery;  
2 close margins so I also had radiation.  
3 Reconstruction was not an option. The reason --  
4 and as far as I know, I don't -- you know, I don't  
5 think it particularly harmed me. I don't know if  
6 it helped me.

7           Meanwhile, last year, I believe, at the  
8 San Antonio Breast Cancer Symposium -- at the time  
9 of my surgery, there was no prospective data on  
10 mastectomy in the metastatic setting. At the San  
11 Antonio conference, they presented the results of  
12 the first prospective study and basically, they  
13 found there really wasn't much benefit or it  
14 wasn't sufficient benefit. So I look back on that  
15 and I try to think, well, you know, first of all,  
16 it shows you how things change, even in such a  
17 short time period. But also, I look back on that  
18 and I think it illustrates the difficulty of  
19 making a decision but also, I think -- I have no  
20 regrets about the decision. I believe it was the  
21 correct one for me.

22           I think one of the hardest things to

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1 quantify is patient preference and I was grateful  
2 that that was given to me. But, you know, I do --  
3 I can't prove that it helped me. I hope that it  
4 did but again, when we are talking about the  
5 decision-making process, I think my experience  
6 illustrates some of the challenges.

7 MS. GIAMBONE: Thank you, Katherine.  
8 Would anybody else like to share their experiences  
9 on the treatment that they've undergone?

10 CINDY: Hi. I'm Cindy and I'm very  
11 fortunate to be a 20-year breast cancer survivor.  
12 I was diagnosed with an early but very aggressive  
13 cancer 20 years ago that was treated very  
14 aggressively. Respectfully, I really think we need  
15 to look at the differences between metastatic  
16 patients and early breast cancer patients because  
17 it's one disease but there are many forms of it.  
18 I likely had triple- negative disease which still  
19 has not targeted therapy but it wasn't  
20 consistently tested for back then.

21 Twenty years later, I have all of the  
22 symptoms that were listed on the chart before.

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1 Would I have made decisions differently? I don't  
2 know because nobody told me what those outcomes  
3 might be and I don't know that it would have  
4 mattered when I had two young children. But now  
5 that I am who I am, I might make a different  
6 decision.

7           So I just want to say we need to think  
8 about all the different types of breast cancer.  
9 We need to think about the context, so metastatic  
10 patients make different decisions than early stage  
11 patients. And we also need to think about the  
12 diversity and age, ethnicity. So these questions  
13 are important and I really appreciate the  
14 opportunity to talk about them, but we -- I mean  
15 these were the most amazing stories I've heard and  
16 I've been doing this for a long time. I think we  
17 need to keep that in context.

18           MS. GIAMBONE: Thank you so much, Cindy.  
19 And in fact, to your point, in just a short while,  
20 we'll do exactly that, we'll explore more of the  
21 decision-making and we'll ask -- we have some  
22 questions for you on how you make those decisions

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1 based on, you know, various aspects of your life,  
2 your age, your family, whatever it may be.

3           Okay. So let me ask you this question.

4 I know that in Topic 1 or in the first part of the  
5 day, you brought up a range of, you know, side  
6 effects or downsides that you experienced because  
7 of the treatment that you're on or that you have  
8 taken. And I want to see if you'd like to  
9 elaborate on those further and can you tie them to  
10 specifically one of these treatments? For  
11 example, you mentioned the loss of sexual  
12 interest. You talked about acne. I mean there is  
13 a full range. You talked about pain. I know that  
14 one of our panelists mentioned blisters on the  
15 feet. So can you explore these further and maybe  
16 tell us after you tried one of the -- or, you  
17 know, you underwent one of these treatments, what  
18 was that experience like and explore those  
19 symptoms or explore that downside a little bit  
20 further? Would anyone like to comment or comment  
21 on any one of these treatments and how you  
22 experienced it?

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1 MS. HOLLOWAY: I'm Jamie. I had stage  
2 two breast cancer and currently no evidence of  
3 disease. You know, I had chemo and it ended a  
4 couple of -- two years ago, a little more than  
5 that, and I still have some fatigue that I think  
6 has to be related. All of my symptoms are so  
7 minor that in the -- one of them is I can't always  
8 think of the word that I'm trying to think of and  
9 this is one of those times -- in light of what  
10 everyone else is saying here, it's a lot more  
11 minor, but I think it is important to see that  
12 there's a whole range and it's not all terrible  
13 all the time. I do have some cognitive problems  
14 where I can think of the letter that the word  
15 starts with but I can't think of the word, like  
16 it's just so close but it's not there.

17 And I still sometimes have neuropathy in  
18 my feet. It's not like I'm going to trip and fall  
19 neuropathy but it's just like my toes reminding me  
20 that I had breast cancer. It's just one more  
21 thing. It doesn't happen all the time but it's  
22 that same like weird feeling that I had when I was

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1 on Taxol.

2           And surgery, I opted to have a bilateral  
3 mastectomy. I would echo what Katherine said so  
4 much. There's so much personal choice and just how  
5 you feel about it. It has -- I was very aware  
6 there was a lot of talk -- I think it was maybe at  
7 San Antonio last year -- that women were not  
8 informed enough and that's why they were choosing  
9 bilateral mastectomy even though there's no  
10 survival benefit, and that kind of hurt my  
11 feelings because I didn't make that decision  
12 because I was not smart enough to know what effect  
13 my decision was going to have on me. It's because  
14 I knew that I would be worried about that  
15 mammogram every six months, and I have little  
16 kids, and I didn't want it to be one more thing  
17 that I worried about. And I knew cosmetically, it  
18 would look better if I had the reconstructive done  
19 bilaterally at the same time. You know, I've got  
20 some aging left to do and it wouldn't turn out the  
21 same if one breast was aging and one was not. And  
22 I was really thankful that my doctor could realize

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1 that even though I knew it wasn't a survival  
2 thing, it was a quality of life thing that was  
3 important to me.

4           That being said, the side effects that I  
5 noticed the most are because of the surgery. I  
6 wouldn't change anything. I think maybe Debbie  
7 made the comment that she went through a lot and  
8 she wouldn't change it but she didn't love it.  
9 You know, I still have nerve sensation issues. I  
10 don't like the seatbelt to touch me so I have  
11 actually worn a grove in the car where I pull it  
12 out and the seatbelt has like cut through the  
13 plastic of the seatbelt thing because I just  
14 always pull it out because it just bugs me. And  
15 so there are a lot of things like that. None of  
16 them are deal-breakers by any means but there are  
17 a lot of long-term things that you don't think  
18 about when you're first diagnosed because you just  
19 want it to be gone. And it wouldn't have changed  
20 my mind at all but it's definitely things to  
21 consider.

22           MS. GIAMBONE: Thank you, Jamie. Thank



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1 you. Yes. Let's see, why don't we go to Sandy.

2 MS. FINESTONE: I just want to make a  
3 comment about decision-making in that my  
4 experience has been for most women, they think  
5 this is a one-time issue. They're diagnosed and  
6 they're willing to do almost anything for -- to  
7 get through it. But the majority of women don't -  
8 - they think it's going to be over, that once the  
9 surgery is done, the treatment is done, then my  
10 life is going to go back the way it was. They're  
11 not prepared for the long-time -- long-term  
12 inconveniences or after effects. They're just not  
13 prepared for that and I think that we need to  
14 educate women more about it that, yes, for many  
15 women it is, it's over, their life just goes back  
16 but for many, many other women, it does not.

17 Reconstruction is an issue that's really  
18 not talked about a lot. I'm 30 years and I'm  
19 still dealing with issues of reconstruction. I  
20 have pain from that surgery from 30 years ago.  
21 That shouldn't be and no one ever told me that was  
22 going to happen.

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1 MS. GIAMBONE: Thank you, Sandy. FDA  
2 panel, any follow-up questions? Jonca, go ahead.

3 DR. BULL: Okay. It might be a quick  
4 one.

5 MS. GIAMBONE: Okay.

6 DR. BULL: I was just wondering if we  
7 could get some elaboration on the supportive care  
8 treatments. I was particularly intrigued, Ms.  
9 Cappel, as -- if you're not on anything, are there  
10 other supportive things that you're doing even  
11 though you're not on chemotherapy now?

12 MS. GIAMBONE: So let me actually  
13 interject here and say we're going to go onto  
14 that. We're going to actually do a polling  
15 question so I'll make sure I get to Elizabeth to  
16 answer that question for you and also others in  
17 the audience.

18 DR. BULL: Okay.

19 MS. GIAMBONE: -- but let's -- great  
20 question. We'll definitely address that one.  
21 Suparna, did you have one that you wanted to ask?

22 DR. WEDHAM: No. I mean one of the

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1 questions was supportive meds. It was regarding -  
2 - I think I talked to one of the panelists during  
3 the break -- that I was very interested in the  
4 patients' decisions regarding holistic and  
5 complementary meds and how many have chosen that  
6 and if that's something that you actually discuss  
7 with your oncologist or things that people are  
8 doing independently just out of curiosity.

9           The other question that I just did want  
10 to ask is, you know, we hear about the side  
11 effects a lot which we know that all of these  
12 treatments have and we're kind of hearing both  
13 camps of people willing to take anything, quality  
14 of life versus the side effects. Bt I was just  
15 curious by maybe even a show of hands how many  
16 people have actually changed therapy -- I know  
17 there are a couple of patients up here at the  
18 panel -- but how many have actually changed  
19 therapy because of the side effects or is it  
20 something that you kind of just push yourself  
21 through knowing that it kind of sucks, you don't  
22 like it, it's there and you -- but, you know, how

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1 many actually changed the therapy because of the  
2 side effects?

3 MS. GIAMBONE: Let's do a show of hands.  
4 How many have changed therapies because of the  
5 side effects?

6 UNIDENTIFIED SPEAKER: Sometimes you can  
7 change therapies because you're forced (inaudible)  
8 choosing (inaudible).

9 DR. WEDHAM: Exactly, not because of,  
10 you know, progression of disease or, you know,  
11 something but, you know, simply because of the  
12 side effects. I'm just, you know, curious.

13 UNIDENTIFIED SPEAKER: (Inaudible) --

14 MS. GIAMBONE: Okay.

15 DR. WEDHAM: Right. No -- right.

16 UNIDENTIFIED SPEAKER: -- (inaudible)  
17 because of toxicity.

18 DR. WEDHAM: Yes, because of toxicity.

19 MS. GIAMBONE: Okay, great. And we saw  
20 about five hands raised there. So I think with  
21 the questions that have been raised, it's actually  
22 a good segue to our next polling question. So

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1 let's get our clickers out again.

2           Besides your cancer treatments, what  
3 therapies have you taken to help manage your  
4 symptoms you have experienced because of your  
5 breast cancer or your breast cancer medication?

6 And here again, you can select multiple responses:

7 a) pain medications; b) dietary supplements or  
8 diet changes; c) complementary or alternative  
9 therapies such as massage or acupuncture; d)  
10 herbal remedies such as soy supplements; e) other  
11 therapies; or f) I am not doing or taking any  
12 therapies to treat symptoms. Okay.

13           Okay. So it looks like c, complementary  
14 alternative therapies such as massage or  
15 acupuncture is what we see the most of in this  
16 room followed by pain medications and dietary  
17 supplements or diet changes. And then there's  
18 also some "other therapies," so let's make sure we  
19 definitely touch on some of those also, followed  
20 by herbal remedies. What are we seeing on the  
21 web?

22           MR. THOMPSON: One hundred percent say

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1 they take pain medications and then about two-  
2 thirds, dietary supplements or complementary  
3 alternative therapies, and about one-third say  
4 herbal remedies or other therapies.

5 MS. GIAMBONE: Okay. Thank you very  
6 much. So let's come back to Jonca's question and  
7 Suparna's question and Elizabeth, why don't we  
8 start with you and can you talk to us a little bit  
9 more about some of these supportive care  
10 therapies?

11 MS. CAPPEL: Okay. The pain medications  
12 I take for the ribs but I'm not on any of them now  
13 that we found that we can do the nerve ablation so  
14 then I don't need the pain medication so I'm not  
15 on that anymore. There are no dietary supplements  
16 other than iron because my iron stores are low.  
17 I've done massage but because of the broken ribs,  
18 I can't do massage anymore. They have me on  
19 Lupron to keep me in medically induced menopause  
20 since I'm triple-positive. We're going to do that  
21 for at least another year or two and that's about  
22 it.

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1 MS. GIAMBONE: Would anybody else --  
2 thank you, Elizabeth. Would anybody else like to  
3 share? Yes.

4 MS. DUNNE: So actually, as a result of  
5 my breast cancer, one of the positive impacts was  
6 all the changes that I made to my lifestyle. So I  
7 significantly changed my diet, stopped drinking  
8 alcohol, and did a lot of complementary therapies:  
9 acupuncture, hands-on healing. The pain  
10 medication or anti -- I don't remember exactly  
11 which pill it was but I want to touch on this  
12 because I was very concerned about becoming  
13 addicted and so I just stopped taking it and after  
14 two or three days, I thought I was hallucinating  
15 and I actually happened to go to my acupuncturist  
16 who said, "Well, the drug you're taking is  
17 actually withdrawals are as bad as heroin." And  
18 so I think in taking some of these medications, it  
19 would be helpful to have a better understanding of  
20 the full life cycle of those drugs and once you  
21 take them what you need to do to come off of them  
22 and some of the other effects. So I am big

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1 proponent of these complementary and alternative  
2 therapies.

3 MS. GIAMBONE: Thank you very much.

4 MS. FARIS: I can talk if you want to --

5 MS. GIAMBONE: Yes, Susan.

6 MS. FARIS: Susan Faris. I don't know  
7 if you can hear me. So during my chemotherapy, I  
8 mainly sought out complementary therapies by  
9 myself. I had acupuncture to deal with the  
10 sciatica. I would say, "stab me in the ass," and  
11 I would feel better. It worked. Anyway, so I  
12 also took up yoga which makes a huge difference  
13 and I use -- and I now work with a supportive  
14 care-palliative care doctor -- I prefer supportive  
15 care and when she brought the priest in the room,  
16 that freaked me out. But anyway -- but -- so she  
17 knows that I really don't want the side effects of  
18 further medication so for my neuropathy, she told  
19 me to put capsaicin on the bottoms of my feet for  
20 two weeks and that really helped a lot. And we  
21 use, you know, the combo of the vitamin B6 and the  
22 alpha lipoic acid to deal with, you know, that



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1 sort of thing. So I try to sue as many  
2 complementary therapies as I can just because they  
3 have a lower side effect. And if I do ever get to  
4 the point of needing pain meds, God help me,  
5 because of all the side effects of the opioids,  
6 the constipation, the fact that it just knocks you  
7 out -- I luckily live in DC which has now legal  
8 marijuana and I hope it stays that way, but we  
9 also have medicinal marijuana and I would want to  
10 try that first before anything else.

11 MS. GIAMBONE: Thank you, Susan. So I  
12 think we had one other comment here.

13 MS. JONES: Thank you. So I've tried a  
14 number of complementary therapies having gone  
15 through chemotherapy, radiation and now on  
16 hormonal therapy. So I've done yoga quite a bit.  
17 As a matter of fact, I was just with a group at  
18 Smith Center and we were doing a whole yoga  
19 filming. And so not only have I tried through a  
20 support group, which is in many ways a type of  
21 therapy for some people, that I host a support  
22 group monthly and I share these things to try and

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1 encourage others to try them because when you look  
2 at it from an ethnicity standpoint, African  
3 Americans still are reticent about many  
4 complementary therapies and it's, in part, the way  
5 it's presented. If you think of yoga, 9 times out  
6 of 10, when you see a display or advertisement on  
7 yoga, it's not a person who looks like me.

8           And it brings up the point, not  
9 criticizing, but I am a little curious as to how  
10 the panel on this side as well as the women who  
11 spoke were chosen because, again, when I look  
12 around -- and if I don't see many people that look  
13 like me, it makes me wonder then are my concerns,  
14 issues really being addressed, because we all know  
15 that breast cancer or cancer in general is not  
16 monolithic. It affects everyone differently and  
17 so when we have these type of forums, I really  
18 feel it's important that it's representative of  
19 the population that we're serving and particularly  
20 since we're here in the Nation's Capitol where the  
21 numbers and the statistics on breast cancer are  
22 off the chart.

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1           And then the other kinds of cams (ph) or  
2 complementary therapies I've tried, of course, is  
3 exercising, massaging, acupuncture. Because I  
4 have lymphedema -- decided not to wear my sleeve  
5 today -- I have to do a lot of lymphedema therapy.  
6 As a matter of fact, when I was undergoing  
7 radiation treatment daily, I had to do lymphedema  
8 therapy weekly. And I've done water aerobics and  
9 the other ones, some -- so this is chemo brain now  
10 that I can't think of the other ones but I am  
11 really interested and big on pushing complementary  
12 therapies because of the amount of toxicity that's  
13 not involved with them.

14           MS. GIAMBONE: Thank you so much for  
15 sharing those comments. Thank you. So let's take  
16 a few more comments and I'll also check in with  
17 the web before we move on to our next discussion.  
18 I know several of you chose "other therapies."  
19 You chose "other" not only for these, you know,  
20 supportive care therapies but you also chose  
21 "other" for the first polling question that we had  
22 on treatments that you're undergoing. Would

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1 anybody like to share some of these "other"  
2 therapies that you are trying or that you're using  
3 that are or are not working for you?"

4 MS. McRAE: Was that included in the  
5 "other," the bisphosphonates, because they're  
6 quite commonly used now but I didn't see it here?  
7 Is that -- would that be in this polling question  
8 or would that be in the one previous to this one  
9 like with the bone strengthening and stuff because  
10 I mean that's -- I mean I've been taking that and  
11 I think it's probably --

12 MS. GIAMBONE: It can actually go under  
13 probably both, you know.

14 MS. McRAE: Okay.

15 MS. GIAMBONE: Yeah, it's going to be  
16 both because it's helping strengthen the bones and  
17 treating the disease, you know, from the  
18 metastatic disease but it's also helping with the  
19 symptoms --

20 MS. McRAE: Exactly.

21 MS. GIAMBONE: -- so the pain and  
22 everything so I think you're absolutely right, it

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1 could be in both. Yeah.

2 MS. McRAE: So I take that. I would  
3 consider it, you know, one of the other therapies  
4 and it has been, I think, quite -- you know, I  
5 feel it's helped me.

6 MS. GIAMBONE: Okay. Thank for  
7 bringing that up and I'm sorry, I didn't catch the  
8 name of what you just said. What was the name of  
9 the --

10 MS. McRAE: Bisphosphonates.

11 MS. GIAMBONE: Oh, okay. Does anybody  
12 else in the audience -- by a show of hands, is  
13 anybody else taking that therapy? Three. Okay.  
14 So we have about three people in the audience  
15 doing that. Okay. Anything else before we move on  
16 to any other therapies? Yes, Jamie.

17 MS. HOLLOWAY: When I was undergoing  
18 chemotherapy treatment, I did go into early  
19 menopause because of the chemotherapy and had hot  
20 flashes. And, you know, since I didn't have a lot  
21 of the other symptoms really bad, I just kind of  
22 thought it was not a big deal and am thankful that

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1 my oncologist really prodded me and instead of  
2 trying to sort of underreport the side effects  
3 wanted to be sure that I mentioned anything that  
4 was manageable, and so I did take gabapentin at  
5 night for the hot flashes and then eventually took  
6 an antidepressant in the morning because  
7 apparently, the antidepressant wouldn't let me  
8 sleep well so I take that in the morning and then  
9 take gabapentin that would knock you out at night,  
10 and that made it a lot more manageable. And so,  
11 you know, it was not a complementary therapy but  
12 it really made some of the side effects so much  
13 more manageable for me that I think that was  
14 important.

15           And in the support group that I attend,  
16 there are a lot of -- it's for women who have  
17 young children and there are several women there  
18 who take antidepressants just to manage the  
19 anxiety of the diagnosis with -- especially the  
20 women who have very, very little children. That's  
21 a lot of energy expended and it's very tough for  
22 them. And I think being very proactive about the

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1 use of antidepressants and, you know, keeping in  
2 mind that a lot of times, it's a short-term thing  
3 but it's an important thing for quality of life.  
4 For one of my friends, it made a huge difference  
5 so

6 MS. GIAMBONE: Thank you, Jamie. So  
7 let's actually move on to our next -- what we're  
8 going to do here because many of you have brought  
9 up this -- we've talked about decision-making and  
10 the factors that you consider and what's important  
11 to you in choosing a particular treatment. So  
12 what we would like to do is pose a scenario  
13 question for you, and we've already sort of  
14 touched on -- you've already sort of touched on  
15 some of these aspects but let's spend some time  
16 exploring it further.

17 So let's go to this one. And I'm going  
18 to read this to you and let you know beforehand  
19 that we're not providing you with a whole lot of  
20 information here, but we want to hear the first  
21 things that come to mind after we finish reading  
22 this.

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1           So drug x is a chemotherapy drug being  
2 developed for patients with breast cancer and it  
3 was studied in a clinical trial comparing standard  
4 of care chemotherapy plus drug x versus standard  
5 of care alone. The clinical trial's result showed  
6 that the addition of this drug x prolonged  
7 survival on average two months longer. In  
8 addition to toxicities related to standard of care  
9 chemotherapy, patients treated with drug x had  
10 more diarrhea and rash and had more rare but  
11 serious toxicity such as liver injury and lung  
12 inflammation. So again, we know there's not a lot  
13 of information here but can you tell us what are  
14 the first things that come to mind, even if that  
15 first that comes to mind is a question?

16           UNIDENTIFIED SPEAKER: (Inaudible).

17           MS. GIAMBONE: Okay, sure. So let's go  
18 through this again. Drug x is a chemotherapy drug  
19 being developed for patients with breast cancer.  
20 It was studied in a clinical trial comparing  
21 standard of care chemotherapy plus drug x versus  
22 standard of care alone. In the clinical trials,



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1 it showed that the addition of drug x prolonged  
2 survival on average two months longer, so the  
3 median survival was 12 months on drug x plus  
4 standard of care versus 10 months for standard of  
5 care alone. However, in addition to toxicities  
6 related to standard of care chemotherapy, patients  
7 treated with drug x had more diarrhea and rash and  
8 had more rare but serious toxicity such as liver  
9 injury and lung inflammation. Okay., so --

10 UNIDENTIFIED SPEAKER: Okay. I was  
11 thinking we were talking about metastatic. I'm  
12 curious if --

13 MR. THOMPSON: Please use the microphone  
14 so that people on the webcast can hear you.

15 MS. GIAMBONE: Let's use the microphone.

16 UNIDENTIFIED SPEAKER: I'd like to know  
17 how this is being used. Is it a first line  
18 treatment or is it something for metastatic  
19 patients who've undergone prior treatments? I  
20 think that makes a difference.

21 MS. GIAMBONE: Okay. So, okay. Let's  
22 see, Shirley?

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1 MS. MERTZ: Well, you're not going to do  
2 it first? You don't mind if we have comments?

3 MS. GIAMBONE: Oh, go ahead.  
4 Absolutely, please share your comments.

5 MS. MERTZ: Okay. Well, I mean I think  
6 it shouldn't matter whether it's early stage or  
7 advanced stage. Only two months more, that's, to  
8 me, not enough to warrant the added cost. And I  
9 have yet to meet a cancer drug that doesn't cost  
10 much, so

11 MS. GIAMBONE: Okay.

12 MS. MERTZ: And secondly, I think a  
13 significant point here is the added toxicity, more  
14 diarrhea. How much, it doesn't tell us. Rash and  
15 serious toxicities are possible so I mean if I was  
16 presented with this option even though I want to  
17 live a longer time, I would say this is not an  
18 option for me, what else do you have.

19 MS. GIAMBONE: Okay. Thank you,  
20 Shirley. Yes, Elizabeth.

21 MS. CAPPEL: Well, I'd like to know --  
22 it's saying two months longer. However, I think

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1 that that could very much be wrong because in my  
2 situation, they said in certain drugs, I would get  
3 six months longer and I'm 8-1/2 years out. So if  
4 you're saying the average person; what if you're  
5 not the average person? What if you're the  
6 outlying person? Then you're not going to take  
7 that chance of two months where maybe you would  
8 end up being me and not being two months. So I  
9 think that it's skewed, the numbers are skewed.  
10 You're saying that there's maybe an 80 percent  
11 chance that you won't go longer but what if you're  
12 in that 20 percent chance that you can live  
13 longer? Then it's worth that. So the two months  
14 may necessarily not be you. You may be the 20  
15 months and in that case, it is worth it. So I  
16 think that's very skewed.

17 MS. GIAMBONE: Okay, very good to know.  
18 Yes, Shirley.

19 MS. MERTZ: Can I just -- I have to add  
20 this --

21 MS. GIAMBONE: Yes.

22 MS. MERTZ: -- because this is what I

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1 dream about, sitting in front of the FDA panel and  
2 being able to say this. I kid you not, okay; I  
3 kid you not.

4 (Laughter.)

5 MS. MERTZ: What I want you to think  
6 about -- we have genomic sequencing now. Why  
7 can't clinical trials, within the context of a  
8 clinical trial, a pharmaceutical be required to  
9 follow its patients who do well and know something  
10 about their genetic makeup that distinguishes  
11 between good responders -- I know I shouldn't say  
12 good -- efficacious responders and those that are  
13 not so that in the case of like an Elizabeth,  
14 maybe there are 10 more Elizabeths out there who  
15 would respond and when my doctor and I looked at  
16 this -- the results of this clinical trial that  
17 ultimately the drug was approved by the FDA but  
18 now as a patient, knowing my genetic sequence or  
19 my makeup of my tumor, I then can make a more  
20 intelligent decision of whether would I be  
21 benefitted, would I be an outlier, or would I  
22 really not gain much other than two months? And I

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1 mean that's the promise of the future. It will  
2 require more but the cost of genetic sequencing  
3 has come down so it is doable. It would mean that  
4 clinical trials would be more -- I think could  
5 have fewer people in them, less costly, and be  
6 more informative to both the doctor, the  
7 physician, and the patient. So thank you, one of  
8 my bucket list has been fulfilled.

9 (Laughter.)

10 MS. GIAMBONE: Oh, thank you, Shirley.

11 MS. CAPPEL: I need to respond to  
12 Shirley also.

13 MS. GIAMBONE: Yes.

14 MS. CAPPEL: She's absolutely right  
15 because I've just had genetic testing and they  
16 said that they would like to do some studies on me  
17 to find out if there is something different in me  
18 that is actually working, and so that's what we're  
19 looking into. And I said I would more than be  
20 happy to be a test subject, you know, because if I  
21 can help with that, that's extremely important.  
22 So I am willing to take all my blood and figure it

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1 out.

2 MS. GIAMBONE: Okay. Thank you,  
3 Elizabeth. We have several more hands here so,  
4 let's just go in order.

5 MS. DUNNE: I just want to reinforce  
6 what both Shirley and Elizabeth said because my  
7 first question would be who's in the clinical  
8 trial and how do they compare to me. And to some  
9 of the earlier points, for folks of different  
10 ethnicities and races, they are so  
11 underrepresented in clinical trials, so I just  
12 want to highlight that. I mean I've actually been  
13 doing some research on that for a class I'm taking  
14 and I was actually shocked to see the numbers, and  
15 I actually got my data by going on  
16 clincialtrials.gov. So again, who is in the  
17 clinical trial and how do I know if I'm the high  
18 or low end of the average or not affected at all?

19 MS. GIAMBONE: Okay. We'll have Katy  
20 and then we'll come this way. Okay.

21 MS. McRAE: Ladies, I have been in  
22 contact actually with a woman who is in Harvard, I

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1 think associated with Harvard. They are doing --  
2 they're trying to do a huge database at the  
3 moment. I'll give you some information here where  
4 you can contact her. And they're actually using  
5 the breast cancer cohort of patients because I  
6 guess, you know, we're easy to contact and  
7 whatever. And they will take your information  
8 from you and use it for that very purpose, and  
9 this thing is being sort of spearheaded as we  
10 speak, so it is out there. It's being done.

11 MS. GIAMBONE: Thank you, Katy. Yes,  
12 Ginny.

13 MS. KNACKMUHS: Hi. I absolutely agree  
14 with what Shirley and Elizabeth said but I just  
15 have like a general statement I wanted to make  
16 that, you know, I think for too long we're  
17 accepting these drugs that, you know, show two or  
18 three months of progression-free survival, maybe  
19 not even overall survival and, you know, they're  
20 more expensive. You know, they're not -- you  
21 know, I don't care if you happen to be an outlier,  
22 you know, it's just not acceptable. You know,

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1 there really -- for the cost of drugs and for what  
2 patients have to go through, we can't be happy  
3 with a couple of months and think that this is  
4 really progress. You know --

5 MS. GIAMBONE: Thank you, Ginny.

6 MS. KNACKMUHS: -- I mean I think that's  
7 got to end.

8 MS. GIAMBONE: So I'm seeing a lot of  
9 heads nodding to that. Okay. And we'll take  
10 another comment here. Yep.

11 MS. JONES: Hi. Thanks. And when we're  
12 talking about a dream of getting before FDA, not  
13 just before FDA but NCI, CDC and all of them, I'd  
14 really to see more people of color in clinical  
15 trials. The data is significantly skewed and when  
16 we think about how long we've been dealing with  
17 breast cancer or cancer in general, and in 2015,  
18 the percentage of African American or people of  
19 color is less than two percent, there's something  
20 wrong with that and we are all intelligent people  
21 so we don't have to wonder why but we need to look  
22 at the methodology, the way we are approaching



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1 people, and really think about how serious are we  
2 in eradicating the disease period. And if we have  
3 to do that, we have to look across the board. We  
4 have to look at more evidence-based information as  
5 to why people of color are not involved and then  
6 we have to actually take those steps based on what  
7 has been said to ensure that they're involved.

8 I have never -- I'm a community  
9 navigator -- I have never been asked by any of my  
10 doctors "would you like to be in a clinical  
11 trial," so I've had to explore that on my own. So  
12 no one has asked me and I'm articulate and  
13 educated. What about little Miss Mary in public  
14 housing or Rosetta who has a language challenge or  
15 a Japanese or other nationality who have all of  
16 their cultural barriers? There's something wrong  
17 with that and the FDA want to spend more time and  
18 money looking at that so that we can have better  
19 representation in this if we want to really get  
20 rid of the disease. Thank you.

21 MS. GIAMBONE: Thank you very much. So  
22 we've heard some really, really great comments

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1 about diversity in clinical trials, perhaps  
2 genomic testing to understand how people that are  
3 in the clinical trials relate to you as a patient  
4 and how it would impact you specifically if you  
5 took this particular drug. Any other comments  
6 before -- yes, let's do Karen and then we'll move  
7 on to a polling question.

8 MS. DUNNE: Mine goes back to the  
9 genetic testing, the genomic testing on that.  
10 When I was in my first clinical trial, the average  
11 time to disease progression was about eight  
12 months. They had one person go 24 months. I went  
13 six years on it and the drug manufacturer was not  
14 interested in genomic testing to see why I was the  
15 one that responded for six years out of 240  
16 people.

17 MS. GIAMBONE: Thank you, Karen.

18 MS. DUNNE: Probably because of the  
19 expense of the drug.

20 MS. GIAMBONE: So Geoff, I believe you  
21 had a question?

22 DR. KIM: Right. I think it ties into

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1 this perfectly because I think we are at the  
2 genomic age certainly, but it's also interfacing  
3 with the immunology age and along with the  
4 proteomic age along with every other "omic" and  
5 we're finally getting the sense of check the tumor  
6 out. And I think we kind of take it for granted  
7 but breast cancer actually is leading personalized  
8 medicine, all -- HER2 is one of the key innovative  
9 discoveries in cancer development in over -- in  
10 the last decade and really has changed the poorest  
11 prognosis subgroup to one of the better prognosis  
12 because of accurate drug development and accurate  
13 selection of the patients.

14           But it also comes at a cost, too,  
15 because a lot of the genomic material that we want  
16 is from the tumor and so in order to do that, you  
17 know, across the standard of care in clinical  
18 practice, when someone is diagnosed with  
19 metastatic disease in the setting of previously  
20 diagnosed, clinical practice says go get a biopsy  
21 to make sure that the markers are the same as it  
22 was in the (inaudible). And then each subsequent

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1 progression or flare, as you eloquently put it --

2 UNIDENTIFIED SPEAKER: (Inaudible).

3 DR. KIM: -- yes, exactly -- you want to  
4 check to see whether resistance mutations are some  
5 type of character mutations but I was wondering if  
6 we could get like the patient experience with all  
7 these biopsies and undergoing multiple biopsies  
8 and the uncertainty and the risk and anxiety that  
9 comes along with that, especially has there been  
10 any negative aspects to undergoing biopsies just  
11 for the sake of determining mutation status or  
12 biomarker status?

13 MS. GIAMBONE: Thank you, Geoff, for  
14 your question. Shirley.

15 MS. MERTZ: I do considerable advocacy  
16 work with the Translational Breast Cancer  
17 Researchers Consortium and it has like 19  
18 comprehensive centers, etcetera, and the patient  
19 advocates -- and I happen to be metastatic but  
20 most of them are not metastatic -- there's one per  
21 center -- we have all said to oncologists, If you  
22 explain to your patients the value of a biopsy and

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1 the fact that treatment is impacted by the  
2 information you get with a biopsy, that patients  
3 will willingly undergo it assuming it's not, the  
4 biopsy itself is not a dangerous place where you  
5 can't get to it or it could have some really bad  
6 affect.

7           I mean you've heard in the room here  
8 today how strong women are to survive not only for  
9 themselves but for their families, their partners,  
10 their spouses, and I mean we're strong enough that  
11 once we hear that there is a possibility that your  
12 progression could be different than your previous  
13 cancer or even in early stage without an accurate  
14 diagnosis, you don't get the personalized or  
15 precision type of treatment. So I don't think  
16 biopsy -- requiring biopsies in clinical trials,  
17 that is a must, too.

18           And so you can tell I'm very passionate  
19 about it. I happen to be one person who's mutated  
20 twice now, different in my -- presented  
21 differently in my metastatic setting and the last  
22 progression I've talked about, I'm different

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1 again. So -- and I know I'm in the minority but  
2 it does happen. Thank you.

3 DR. KIM: And your experiences with the  
4 biopsies, were things carefully explained to you;  
5 were they carefully laid out for you; were there  
6 any areas of confusion that should have been  
7 better delineated in your experience?

8 MS. MERTZ: Well, I happen to be treated  
9 in a comprehensive cancer center where the  
10 oncologist did explain the value of a biopsy. In  
11 fact, the -- she said to me initially, I will not  
12 -- I came to her as a second opinion -- she said,  
13 "I will not recommend any treatment until I know  
14 more about your tumor." And so I think that is  
15 helpful and it doesn't always happen in community  
16 settings and so there's really a need for  
17 educating the oncologists about what they can do  
18 better so they just don't throw a treatment at the  
19 patient but rather really select carefully. Thank  
20 you.

21 MS. GIAMBONE: Thank you, Shirley. Yes,  
22 Jonca.

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1 DR. BULL: Hi. Just wanted to share  
2 with our audience that FDA does take the issue of  
3 diversifying clinical trials very seriously. We  
4 have an action plan that was announced last August  
5 that has three priority areas, the first being to  
6 improve data quality, get people in the trials;  
7 second, to look at what the barriers to  
8 participation are and work with regulated industry  
9 to advance this; and the third is greater  
10 transparency of data. And I just want to  
11 highlight an initiative that CDER has in place,  
12 the drug snapshots site that does bring greater  
13 transparency to inclusion. We're not going to fix  
14 the is problem overnight. The Agency will not fix  
15 this alone but working with stakeholders, with  
16 regulated industry, with advocates, I think we can  
17 really, looking ahead, make a big difference. So  
18 I just want to make sure that everyone's aware  
19 that the Agency is actively engaged in this and  
20 looking for solutions.

21 MS. GIAMBONE: Thank you, Jonca. Okay.  
22 We'll take one more comment and then we'll move on

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1 to our next question.

2 MS. McRAE: For me, having the bon  
3 biopsy was transformational. I mean I had been on  
4 the anti- hormone treatments because of my  
5 previous ER-positive -- PR-positive cancer as a  
6 primary. But, you know, I think about that year's  
7 time, you know, where I was on those treatments  
8 and it was kind of -- you know, I was never really  
9 satisfied that treatments were going well, but I  
10 was the one who had to talk to my oncologist. She  
11 was fantastic. She listened to me. You know, we  
12 made an informed decision. I actually went to Dr.  
13 Lisa Carey in North Carolina who did the research.  
14 The biopsy itself, I had absolutely no problems  
15 with it but I think it's so important and I think  
16 it's still being left too much to the oncologist.  
17 I think patients are not informed enough and I  
18 don't know what the insurance status is for  
19 people. I was able to get it paid by my insurance  
20 but, you know, it's this constant battle between  
21 what we can do, what we can afford to do and  
22 patients are kind of, a lot of the time, left in

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1 the dark. I think we need to be more informed.

2 MS. GIAMBONE: Thank you, Katy. So I've  
3 been the okay that we have 10 more minutes so  
4 within those 10 minutes, what I'd like to do is we  
5 have two more questions for you, polling questions  
6 for you and then we'll check in with the web and  
7 see if anybody would like to dial in. So on that  
8 note, for those of you on the web, if you'd like  
9 to call in, please go ahead and do so.

10 So again, we've touched on some of these  
11 already but we'll explore this just a little bit  
12 more.

13 So here's the question for you and  
14 please have your clickers out. Of the following  
15 factors, which two would you rank as most  
16 important to your decision about using treatments  
17 to help reduce or control the spread of your  
18 breast cancer; please select up to two options --  
19 responses: a) whether the treatment is expected  
20 to help relieve the symptoms I experience because  
21 of my cancer; b) the small but significant risk of  
22 serious side effects associated with treatment

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1 such as blood clots or kidney failure; c) how long  
2 the treatment would probably prolong my life; d)  
3 how long the treatment could possibly prolong my  
4 life for longer than expected; e) the expected  
5 side effects of the treatment such as nausea, loss  
6 of appetite or other; or f) how the treatment is  
7 administered such as how long the treatment takes,  
8 whether it requires hospitalization, requires  
9 doctor visits and so on?

10           Okay. Did everyone have a chance to  
11 enter their responses? Okay. So it looks two-  
12 thirds of those of you responding selected c) how  
13 long the treatment would probably prolong my life  
14 followed by d) how long the treatment could  
15 possibly prolong my life, and e) the expected side  
16 effects of treatment such as nausea or loss of  
17 appetite. How about on the web? What do we see  
18 there?

19           MR. THOMPSON: Three-quarters of  
20 participants chose how long the treatment would  
21 probably prolong my life and the expected side  
22 effects of the treatment such as nausea, and then

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1 one-quarter chose how long it could possibly  
2 prolong my life and how the treatment is  
3 administered.

4 MS. GIAMBONE: Okay. Thank you very  
5 much. So let's just spend -- let's have a few  
6 comments on why you made -- why you selected what  
7 you did. So what is it based on? What does this  
8 weighing depend on, for example, your age or your  
9 prognosis? Would anybody like to share a comment?  
10 Yes.

11 UNIDENTIFIED SPEAKER: Every patient  
12 wants to survive and I kind of had struggled with  
13 the difference between c and d, like what's the  
14 different data between those two.

15 MS. GIAMBONE: Okay.

16 UNIDENTIFIED SPEAKER: So I think if you  
17 added those, you'd have 100 percent.

18 MS. GIAMBONE: Okay, okay. And  
19 Elizabeth, I think I heard you ask what was the  
20 question that I asked which is why did you choose  
21 what you did; what factors weigh into that  
22 decision. So would you like to respond?

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1 MS. CAPPEL: I think I speak for most of  
2 us here is we want to live so we base our  
3 treatment on what is the best probability of  
4 living and c and d are kind of -- they work  
5 together in my mind. So I think that's pretty  
6 much, if we put those together, again, 100 percent  
7 of us would like to live longer.

8 MS. GIAMBONE: Okay. Yes, let's -- we  
9 have two comments on this side.

10 MS. O'BRIEN: So I guess I had two  
11 things. As one of the -- as part of my treatment,  
12 I get a bisphosphonate because I have bone mets  
13 and originally, the bisphosphonate that I got was  
14 a 20- minute infusion but it requires a blood test  
15 and it will be a, you know, hour or two hours at  
16 the hospital. And then there was research that  
17 came out that found that you could -- it was  
18 quarterly rather than the monthly that I had been  
19 getting it. So I then switched -- oh, I'm sorry -  
20 - when it was monthly, a new bisphosphonate came  
21 out that was a shot, a shot that you got -- after  
22 you had your monthly oncologist visit, you get the

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1 shot. It was a considerably more expensive but I  
2 felt my time was worth it so I opted for the shot.  
3 Then when the dosing guidance changed that you  
4 could have this drug quarterly, I think switched  
5 to -- I switched back to the more time- consuming  
6 yet cheaper infusion because I only had to do that  
7 -- quarterly I could deal with. Monthly, it was a  
8 pain.

9           But the other thing I would also say  
10 that is not perhaps widely understood is that a  
11 patient often perceives a drug's effectiveness on  
12 how harsh the side effects are and that is not  
13 always true, but patients are not doctors.  
14 Patients perceive, you know, I lost my hair, I  
15 feel nauseous, I have diarrhea, this is one  
16 fantastic drug and that's not the case.

17           And I know many times I'm asked to speak  
18 to newly diagnosed stage four women and with stage  
19 four, it's the least toxic option first. And I  
20 recall even in my own experience having to tell my  
21 insurance company I wasn't going to -- first, I  
22 wasn't going to have surgery and the

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1 administrator, you know, no surgery. "You're not  
2 going to have chemotherapy? "No, you know, I  
3 won't. I'll take t his daily pill." And she just  
4 goes, "Well, they don't seem to be doing very much  
5 for you, are they?" And it has -- it's not  
6 understood that a non-chemotherapy and anti-  
7 estrogen can be equally effective as a  
8 chemotherapy, but sometimes doesn't have that  
9 choice. If they have an aggressive disease, if  
10 they have a disease like triple-negative where  
11 there is no receptor to act upon, then  
12 chemotherapy is essentially their only option.  
13 But if it's six of one, half dozen of another,  
14 oftentimes, again, the patient goes through a  
15 motion of, you know, this drug -- you know,  
16 they're not looking at the little printout that  
17 came with the drug. They're going, "Well, you  
18 know, I look terrible, I feel terrible, this drug  
19 is really doing the trick."

20 MS. GIAMBONE: Thank you.

21 MS. O'BRIEN: And I think that  
22 clinicians struggle perhaps to communicate that.

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1 MS. GIAMBONE: Thank you, Katherine.  
2 Let's do -- let's go on to our next polling  
3 question and then we'll be sure to hear you  
4 comment. Okay. So the purpose of this question,  
5 it's to hear the other side now. So we're going  
6 to ask the contrary question here.

7 Of the following factors, which one  
8 would you rank as least important to your  
9 decisions about using treatments to help reduce or  
10 control the spread of your breast cancer: a)  
11 whether the treatment is expected to relieve the  
12 symptoms I experience because of my cancer; b) the  
13 small but significant risk of serious side effects  
14 such as blood clots or kidney failure; c) how long  
15 the treatment would probably prolong my life; d)  
16 how long the treatment could possibly prolong my  
17 life; e) the expected side effects of the  
18 treatment such as nausea or loss of appetite; or  
19 f) how the treatment is administered such as how  
20 long the treatment takes, whether it requires  
21 hospitalization or required doctor visits? So  
22 here you're going to select one that you would

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1 rank as the least important.

2           Okay. So, the least important to your  
3 decision was "f," how the treatment is  
4 administered. And again, we acknowledge and  
5 appreciate that there are many, many factors into  
6 your decision-making so we appreciate that you're,  
7 you know, choosing with one of the options here.  
8 So, okay, let's make sure we hear your  
9 perspective.

10           MS. JONES: Thank you. I really think  
11 that's interesting because on the previous ones,  
12 in addition to what others have said about "c" and  
13 "d," "f," how the treatment is administered was a  
14 great concern of mine because it was so how long  
15 is this going to take. If I have long-term,  
16 temporary employment, is this going to impact that  
17 or maybe my insurance; am I going to lose that or  
18 is this going to be a free clinical trial kind of  
19 thing; whether it requires hospitalization; where  
20 will I be hospitalized, and about the doctors;  
21 will I lose the relationship that I have with my  
22 current doctors that I'm still kind of struggling



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1 with and developing a trust, so when this comes  
2 in, do I have to get used to all new doctors  
3 again. So those are -- and just the  
4 transportation issue. Let's say, live in  
5 Southwest. I may have to go Bethesda or NIH.  
6 That's a huge stretch so those are the kind of  
7 concerns I have.

8 MS. GIAMBONE: Thank you very much. So  
9 let me turn to the web and if you could -- what  
10 polling results do you see there and perhaps you  
11 could summarize what you're hearing on the web and  
12 then we'll take some phone calls.

13 MR. THOMPSON: Similar to what we had in  
14 person. We had three-quarters saying "f" as the  
15 most answered thing. Nobody currently on the  
16 phone, so I'm going to summarize some of the  
17 comments I'm getting.

18 Going back to something we've been  
19 talking about earlier about what do you keep in  
20 mind when you're thinking about treatments, in  
21 several comments, we had one person saying it  
22 would be nice to be informed ahead of time about

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1 side effects, but you're never going to be able to  
2 know how your body is going to respond to them.

3 Another person said it would be nice to  
4 know which side effects would not go away after  
5 you're done with the treatment.

6 There was one person who said her main  
7 concern was her fertility because she was  
8 diagnosed when she was 31, but there was no  
9 information, no studies that were going to talk  
10 about how this would impact her fertility.

11 There was one person who was talking  
12 about the difference between metastatic and non-  
13 metastatic patients, when they're considering  
14 treatment.

15 In terms of other therapies are taking,  
16 people also talked about exercise and yoga and  
17 about support and the importance of peer sharing  
18 things with other patients to help them overcome  
19 isolation and depression.

20 And in response to the question about  
21 biopsies, one person said it's different between  
22 diagnostic and investigational purposes. So if

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1 you're getting a biopsy, if it's investigational,  
2 he would probably consider where the metastatic  
3 lesion was located, for example, skin and bone  
4 would be a lot easier than a liver biopsy and then  
5 one person talking about genomic medicine said  
6 that while they're promising, they're still early  
7 so it's -- people need to keep in mind that some  
8 of these treatments -- some of these approaches  
9 are very limited right now.

10 MS. GIAMBONE: Okay. Thank you very  
11 much. So we're going to wrap up this portion of  
12 the meeting today and we're going to be moving on  
13 to open public comment. But I would just like to,  
14 on behalf of all of my FDA colleagues, just thank  
15 you all so much for sharing these stories with us  
16 and really teaching us so much today. I think --  
17 yes, Geoff -- yes.

18 DR. KIM: I had a quick question. Just  
19 a really quick show of hands. Has anybody ever  
20 ready the little thing that comes with the  
21 medicine also called the drug label? If you have,  
22 can you -- and any feedback? I know we're

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1 probably going to get a lot but was it helpful in  
2 describing the side effects and expectations or --  
3 I think we're going to get a lot of comments but  
4 just kind of get a -- it helps us a lot to --

5 MS. FARIS: Can I address that real  
6 quickly?

7 MS. GIAMBONE: Let's do a show of hands.  
8 Can we do a show of -- okay, yes, Susan.

9 MS. FARIS: Just real quickly. I  
10 definitely read the side effects on it and I, you  
11 know, try not to freak out but the thing is, for  
12 instance, when I started KADCYLA, it is so new, it  
13 was so -- I like to pronounce it "KOD-ZILLA,"  
14 like, you know, Godzilla. Anyway, but I definitely  
15 read what the drug company was putting out but the  
16 fact is that with any of these drugs, they do not  
17 talk about everything that is really going to  
18 happen. There is stuff that I think either they  
19 don't want to admit, you know, and a prime example  
20 would be Paxil which is still not admitting how  
21 hard the withdrawal off of Paxil is. And so a lot  
22 of times, I have to look not only at what the drug

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1 company provides but then go off into the forums,  
2 to trusted forums and hear what other people are  
3 talking about to find out the real story. You  
4 know, I mean there are books that are written on  
5 how to withdraw from Paxil and that's still like  
6 not -- that's a secret. Anyway, so

7 MS. GIAMBONE: Great. And so -- okay,  
8 let's -- we'll take one more comment.

9 MS. JONES: We discussed that just sort  
10 of over the break and with my last label, I  
11 thought, "oh my God, this looks different than the  
12 last one," but I didn't have the last one to  
13 compare. I think the information is -- it's quite  
14 technical, it is a lot to consume and most people,  
15 I don't think -- well, let me retract that -- the  
16 population that I serve, I can assure you a lot of  
17 them do not read that and if they do, their health  
18 literacy is not at a level that they can totally  
19 comprehend it so it could be to their advantage.

20 MS. GIAMBONE: Thank you. Thank you,  
21 Geoff, for your question. So thank you all again  
22 so much for being part of today's meeting.

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1 (Applause.)

2 MS. GIAMBONE: Pujita, I'll turn it over  
3 to you.

4 MS. VAIDYA: Hello, everyone. I'd like  
5 to thank you all for coming here today. We are  
6 now moving into the open public comment session  
7 and for those of you who are not aware, the  
8 purpose of this session is to allow an opportunity  
9 for those who have not had a chance to speak on  
10 issues that are not related to the topic  
11 discussion questions today. This is an  
12 opportunity for folks who are not a patient or a  
13 patient representative to comment. Please keep in  
14 mind that we will not be responding to your  
15 comments but they will be transcribed and be a  
16 part of the public record.

17 Since we would like to -- like this  
18 process to be transparent, we encourage you to  
19 note any financial interest that you have that are  
20 related to your comment. If you do not have any  
21 such interest, you may state that for the record.  
22 And if you prefer not to provide this information,

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1 you can still provide your comments.

2           So we have collected signup before the  
3 meeting and during break. We have four people  
4 signed up and about 15 -- 10 minutes for this  
5 session, so please be respectful of your other  
6 colleagues here and other patients and stick to  
7 the two-minute limit. We won't have a timer but I  
8 will be using my phone here to keep track just so  
9 that you don't go over. And if you do approach  
10 the two-minute mark, I will have to ask you to  
11 wrap up.

12           So I'll run through the order of  
13 speakers and I apologize if I mispronounce your  
14 name. So the order will be first, Joanne Buzaglo,  
15 Katherine Crawford-Gray, Kimberly Beer, and then  
16 Katherine O'Brien. So first, may I have Joanne  
17 Buzaglo to the mic?

18           MS. BUZAGLO: Hello. Thank you. I do  
19 not have any financial disclosures to present.  
20 Okay. I applaud you for hosting this meeting  
21 today and I'm very grateful and applaud all the  
22 people who spoke up. It is not easy to do so.

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1 I bring the voice of over 3500 patients  
2 who have shared their voice in the cancer  
3 experience registry. I bring that with me. I  
4 would encourage you to strongly consider the  
5 comments the cancer support community has  
6 submitted to you about integrating distress  
7 screening and follow-up into the clinical trial  
8 design to ensure that the types of patient-  
9 reported outcomes that we've been discussing are  
10 collected in real time and over time and over the  
11 course of disease and treatment so that it can  
12 inform your ultimate decisions about medical  
13 solutions.

14 One question I would like to  
15 specifically respond to is the question about  
16 toxicity and risk- benefit tradeoff decisions. It  
17 is clear from our data that patients, especially  
18 with metastatic disease, have unique needs in  
19 their cancer journey and each is willing to  
20 tolerate a benefit-risk profile based on very  
21 personal considerations. We do know from our  
22 cancer experience registry that over 50 percent of



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1 women living with metastatic breast cancer are  
2 unable to work due to their cancer. Meanwhile,  
3 they are balancing other very real life  
4 commitments, child care, elder care, etcetera.  
5 Additionally, we know that they have different  
6 definitions of value depending on their  
7 experience.

8           As you consider your definition of an  
9 appropriate risk-benefit scenario, I encourage you  
10 to ensure that it is based on the data emerging  
11 from the voice of the patient and move further to  
12 collect it in real time and allow it to inform  
13 your thinking in ways it may not have been done in  
14 the past. So we look forward to partnering with  
15 you on this. Thank you.

16           MS. VAIDYA: Thank you, Joanne. Next we  
17 have Katherine Crawford-Gray.

18           MS. CRAWFORD-GRAY: Thank you. Thank  
19 you so much. On behalf of the Metastatic Breast  
20 Cancer Alliance, I appreciate this opportunity to  
21 make a short statement and thank you particularly  
22 to all the women who have spoken here today.

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1           The Metastatic Breast Cancer Alliance is  
2 comprised of more than 30 member organizations,  
3 many who are in this room or are online today, and  
4 these include the three largest private funders of  
5 breast cancer research in the U.S., 16 leading  
6 advocate non- profits providing information and  
7 support services for breast cancer patients and  
8 caregivers, 6 pharmaceutical corporations invested  
9 in treatments for metastatic breast cancer as well  
10 as individuals who advocate for and work with  
11 patients on a daily basis. And the Alliance  
12 applauds the FDA's work today and its commitment  
13 to expanding treatment options for people living  
14 with metastatic breast cancer, and we also commend  
15 the FDA's dedication to continuous education of  
16 its reviewers so that they can focus on the  
17 different needs of opts that arise from the  
18 various types and stages of breast cancer and  
19 particularly, the differences between early stage  
20 and metastatic breast cancer.

21           Last year the Alliance undertook  
22 research which was published in October in their

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1 report, "changing the landscape for people living  
2 with metastatic breast cancer," and based on this  
3 research, we are advocating that in order to  
4 accelerate research and treatment benefitting  
5 metastatic breast cancer patients, the following  
6 aspects of clinical trials be a priority for the  
7 FDA. The first aspect is updating clinical trials  
8 for metastatic breast cancer including new trial  
9 designs with meaningful endpoints. For example,  
10 tumor shrinkage may be but one endpoint relevant  
11 to tumor spread or metastasis. Additional  
12 endpoints such as time to next metastasis need to  
13 be introduced. Quality of life measures that are  
14 valued by patients living with the disease and  
15 inform their treatment decisions need to be  
16 additionally standardized and required in all  
17 phase three trial designs.

18           The second aspect is that there is also  
19 a need for multi-center collaborative phase two  
20 trials. By helping to incentivize multi-  
21 institution, multi- investigator trials,  
22 metastatic breast cancer research will be

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1 accelerated. Barriers to clinical trial design  
2 include there being too many "me too" trials in  
3 industry and reward systems for single  
4 investigators conducting single institution phase  
5 two trials. These, along with other barriers, need  
6 to be removed for research benefitting metastatic  
7 breast cancer patients and for the research to be  
8 conducted at a faster pace.

9           Accelerating the speed of research and  
10 the development of new treatment that extend the  
11 lifespan of, while maintaining a high quality of  
12 life for people living with metastatic breast  
13 cancer, is a primary goal of the Alliance. And we  
14 appreciate the opportunity to have had input to  
15 this process today as well as the public docket  
16 coming up and trust our views are helpful for FDA  
17 staff and reviewers and the progress of research  
18 for patients. Thank you.

19           MS. VAIDYA: Thank you, Katherine.

20 Next, I have Kimberly Beer.

21           MS. BEER: Thank you. I'm Kimberly  
22 Beer. I'm the Director of Public Policy at Susan

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1 G. Komen, and I want to thank the FDA for giving  
2 us this opportunity to invite patients to come and  
3 share their stories. And we have had the pleasure  
4 of working with the FDA to ensure proper  
5 representation; however, I am significantly  
6 disappointed that the breadth of the diversity in  
7 the breast cancer community is not represented  
8 here. And so Komen is committed to ensuring that  
9 during the public docket period that we really,  
10 really emphasize outreach to those folks who are  
11 not women, only women -- breast cancer impacts  
12 men, diversity in ethnicity, diversity in health  
13 literacy, diversity in stage and type of disease.

14           This meeting is critically important and  
15 so we look forward to working with you in ensuring  
16 that we have patients comment on the docket as  
17 well as we look forward to hearing what those  
18 folks on the web also submit. Thank you.

19           MS. VAIDYA: Thanks, Kimberly. And  
20 lastly, we have Katherine O'Brien.

21           MS. O'BRIEN: Thank you. When Shirley  
22 started here remarks, she mentioned that today 108

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1 U.S. people will die from metastatic breast  
2 cancer. That is 40,000 per year. One thing that  
3 we don't know is how many people are currently  
4 living with metastatic breast cancer. We say that  
5 there are 150,000 U.S. people living with  
6 metastatic breast cancer but that is an estimate  
7 only because our U.S.

8 cancer registry does not count  
9 metastatic recurrence. Women are counted when they  
10 die or when they are de novo presentation such as  
11 myself. But we know that only 10 percent are  
12 people like me, people who are metastatic from  
13 their first diagnosis. Most people join the  
14 metastatic breast cancer ranks having been treated  
15 for early stage cancer but we do not track that,  
16 and what we do not count, the pole we do not  
17 count, we do not provide for.

18 Finally, I'm reminded of an advocate, a  
19 late advocate whom I had much respect and  
20 admiration for, Susan Davis. Susan had many, many  
21 chemotherapy regimens and she always said she  
22 could handle the worse side effects, the harshest

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1 drug, and Susan said, "I live in hopeful dread. I  
2 hope that my next set of scans that I have every  
3 three months will be good but I dread that they  
4 will be not, they won't, that they will not." And  
5 that is the reality for the estimated 150,000 U.S.  
6 people living with metastatic breast cancer. They  
7 live in uncertainty.

8           Oftentimes in popular parlance, when we  
9 talk about breast cancer treatment, we talk about  
10 slash, burn, poison. For the metastatic  
11 community, another way to put it would be scan,  
12 treat, repeat because every three months for most  
13 people, you have a set of scans which determines  
14 whether your treatment is working. If it is not  
15 working, you have to try and find another drug.  
16 We've talked today about what the implications of  
17 those drugs might be.

18           So I thank you very much for this  
19 opportunity. Thank you.

20           MS. VAIDYA: Thank you, Katherine. And  
21 so before we get started with our last agenda  
22 item, I'd like to ask Sarah and Kathy to please

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1 pick up the clickers from the tables. And then  
2 I'd also like to remind you that we do have  
3 evaluation forms outside and we would really  
4 appreciate your feedback. So please leave -- if  
5 you could fill it out and please leave them at the  
6 table, that would be great.

7 Now lastly, I'd like to call Dr. Amy  
8 McKee to the stand for our closing.

9 DR. McKEE: So I think I'm going to  
10 summarize with there are two things I've heard  
11 today consistently. One, every patient is an  
12 individual; every patient is going to have their  
13 own story about how their disease responds to  
14 treatment and how they handle the toxicities of  
15 that treatment. And I'll go back into that a  
16 little bit more. And the second thing is that we  
17 have a lot of work to do. There is a lot of work  
18 to be done.

19 So I want to thank you all for sharing  
20 your stories because it's really important for us  
21 to hear, as regulators, how these treatment affect  
22 you both in terms of how they work and how you



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1 think about it when you choose them and how you  
2 have to handle all the toxicities and the doctors'  
3 appointments that go along with those treatments.

4           I think one of the things that we were  
5 really interested in hearing from you because it's  
6 something that we deal with with every drug that  
7 comes before us where we have to make a decision  
8 is how do we describe whether or not you should  
9 pick this treatment for yourself. And so we use  
10 clinical trials to do this and we use statistics  
11 to try to summarize it and you sort of saw a  
12 little bit of that with that question, "If you had  
13 an average two-month improvement in survival but  
14 lots of toxicity, would you choose that for  
15 yourself?" And this is what we have to do every  
16 day. We have to think about for this population,  
17 for these specific patients, do we think that  
18 there's enough benefit that the risks are worth  
19 it, and we use statistics to try to decide that  
20 but that could never answer the question for an  
21 individual patient, and that's where you all have  
22 to come in with your oncologist and your family

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1 and yourselves to make that decision.

2           And then the second thing is there is a  
3 lot of work to be done. We want to continue this  
4 dialogue with you. We encourage all of you to  
5 engage with the FDA and with clinical trials and  
6 with advocacy groups as much as you can. I'm  
7 actually a little bit bleary-eyed because I've  
8 been trying to stay up for the last three nights  
9 to watch PBS's series, "Emperor of All Maladies."  
10 And last night I think the most hopeful thing  
11 about it was there is a lot of work to be done but  
12 we're such an exciting time right now. We know  
13 we've talked about genomic sequencing; we're  
14 talking about immunotherapies. There are so many  
15 more options than some of the women who are in  
16 this room who were diagnosed at a time when there  
17 were almost no options beyond extremely toxic  
18 therapy and surgery and you might not even know  
19 what surgery you were going to get when you went  
20 under anesthesia. And so it's an exciting time  
21 and a hopeful time and I really thank you all for  
22 sharing your perspective because it is very

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1 important when we make decisions and we evaluate  
2 the data about not how it's going to affect the  
3 population but how it's going to affect each  
4 individual patient. So I thank you and please  
5 fill out your evaluations because it's really  
6 important for us to read them because we take it  
7 all into account. Thank you very much.

8 (Applause)

9 (Whereupon, at 4:40 p.m., the meeting  
10 was adjourned.)

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1 CERTIFICATE OF NOTARY PUBLIC

2 I, MICHAEL FARKAS, the officer before whom the  
3 foregoing hearing was taken, do hereby certify  
4 that the testimony appearing in the foregoing  
5 hearing was taken by me in audio recording and  
6 thereafter reduced to typewriting under my  
7 supervision; that said transcription is a true  
8 record of the proceedings; that I am neither  
9 counsel for, related to, nor employed by any of  
10 the parties to the action in which this deposition  
11 was taken; and, further, that I am not a relative  
12 or employee of any counsel or attorney employed by  
13 the parties hereto, nor financially or otherwise  
14 interested in the outcome of this action.

15

16

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22

A handwritten signature in black ink, appearing to read "Michael Farkas". The signature is written in a cursive, flowing style.

MICHAEL FARKAS  
Notary Public in and for the  
DISTRICT OF COLUMBIA

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1 CERTIFICATE OF TRANSCRIPTION

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

9

10

11

12

*Lucy T. Turnbull*

13

-----  
LUCY T. TURNBULL, CET-743  
Transcriptionist

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