

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

1

FOOD AND DRUG ADMINISTRATION (FDA)  
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)

LUNG CANCER PUBLIC MEETING ON  
PATIENT-FOCUSED DRUG DEVELOPMENT

Friday, June 28, 2013

8:23 a.m.

Food and Drug Administration

White Oak Campus

10903 New Hampshire Avenue

Silver Spring, MD 20993

Reported by: Natalia Thomas

Capital Reporting Company

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

2

1 MEETING ROSTER

2 FDA STAFF

3 Gideon Blumenthal, MD  
4 Medical Officer, Lung Cancer Team Leader  
5 Division of Oncology Products II  
6 CDER, FDA

7 Sara Eggers, PhD  
8 Office of Strategic Programs  
9 CDER, FDA

10 Andrea Furia-Helms, MPH  
11 Health Programs Coordinator  
12 Office of Health and Constituent Affairs  
13 CDER, FDA

14 Patricia Keegan, MD  
15 Director  
16 Division of Oncology Products II  
17 CDER, FDA

18 Dickran Kazandjian, MD  
19 Medical Officer  
20 Division of Oncology Products II  
21 CDER, FDA

22 Sean Khozin, MD, MPH  
23 Medical Officer  
24 Division of Oncology Products II  
25 CDER, FDA

26 Robert Le, MD, PhD  
27 Medical Officer  
28 Office of Cellular, Tissue, and Gene Therapies  
29 CBER, FDA

30 Shakun Malik, MD  
31 Medical Officer  
32 Scientific Liaison for Thoracic Oncology  
33 Division of Oncology Products II  
34 CDER, FDA

35

(866) 448 - DEPO

www.CapitalReportingCompany.com © 2013

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

3

- 1 MEETING ROSTER (cont'd)
- 2 FDA STAFF (Continued)
- 3 Paivi Miskala, MSPH, PhD  
Study Endpoints Reviewer
- 4 Study Endpoints and Labeling Development  
Office of New Drugs
- 5 CDER, FDA
- 6 Theresa Mullin, PhD  
Director, Office of Strategic Programs
- 7 CDER, FDA
- 8 Pujita Vaidya  
Office of Strategic Programs  
CDER, FDA
- 9
- 10 PUBLIC PARTICIPANTS
- 10 Donna Adkins  
Karen Arscott
- 11 Amy Copeland  
Andrea Ferris
- 12 Shelley Fuld Nasso  
Stephanie Haney
- 13 Denise Hogan  
Montessa Lee
- 14 Kim McCleary  
James Phang
- 15 Ruth Phang  
Sheila Ross
- 16 John Ryan  
Lorren Sandt
- 17 Kathleen Skambis  
Marie Smith
- 18 Susan Warmerdam
- 19
- 20
- 21
- 22

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

4

1	TABLE OF CONTENTS	
2		PAGE
3	Welcome	6
4	Patricia Keegan, MD	
5	Director	
6	Division of Oncology Products II	
7	CDER, FDA	
8	Overview of FDA's Patient-Focused Drug	
9	Development Initiative	10
10	Theresa Mullin, PhD	
11	Director	
12	Office of Strategic Programs (OSP)	
13	CDER, FDA	
14	Background on Lung Cancer and Treatment Options	17
15	Sean Khozin, MD, MPH	
16	Division of Oncology Products II	
17	CDER, FDA	
18	Overview of Discussion Format	26
19	Sara Eggers, PhD	
20	Office of Program and Strategic Analysis	
21	OSP, CDER, FDA	
22	Panel #1 Comments: Topic 1	39
23	Large-Group Facilitated Discussion: Topic 1	62
24	Break	82
25	Panel #2 Comments: Topic 2	84
26	Large-Group Facilitated Discussion: Topic 2	109
27	Open Public Comment	165
28	Closing Remarks	176
29	Theresa Mullin, PhD	
30	Director, OSP, CDER, FDA	
31		

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

5

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

2 DR. EGGERS: Okay. I think we'll go ahead  
3 and get started. We have a very full morning today,  
4 lots of discussion, so I'm going to try to keep my  
5 remarks as brief as possible. My name is Sara Eggers,  
6 and I am in FDA Center for Drug Evaluation and Research  
7 in the Office of Strategic Programs, and I will be the  
8 facilitator for today's discussion. This meeting is a  
9 public meeting on lung cancer as part of our Patient-  
10 Focused Drug Development Initiative.

11 I am just going to go over the agenda and a  
12 few housekeeping things before I turn it over to Pat  
13 Keegan to give some welcome remarks.

14 This morning's agenda -- you should all have  
15 the agenda. We're going to spend a few minutes, about  
16 a half hour, setting the context on the background of  
17 our initiative called Patient-Focused Drug Development  
18 and on

19 Lung Cancer and Treatment Options, and then I  
20 will go over the discussion format. And then we're  
21 going to have two discussions today: the first is going  
22 to be focused on the most significant symptoms of lung

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

6

1 cancer and the impact on daily life, and then we'll  
2 move after a break into a discussion on patients'  
3 perspectives on lung cancer and treatment options. We  
4 will follow this with an Open Public Comment period, so  
5 if there is something that anyone here today, that you  
6 want to say something, make a statement that's not  
7 really relevant to Topic 1 or 2, then I encourage you  
8 to sign up for the Open Public Comment, and I believe  
9 we'll take registrants for that until the break. And  
10 depending on the number of registrants we have, we will  
11 determine the amount of time that's available for that  
12 public comment.

13           There are restrooms located out about as far  
14 away as they can be in this building, straight to the  
15 back and to the right you'll find those, and there is a  
16 kiosk that serves some basic food and coffee. And if  
17 you need anything, there are folks traveling around,  
18 let us know if you need anything, and with that, I will  
19 turn it over to Pat Keegan, who will give some opening  
20 remarks. Welcome

21           DR. KEEGAN: Thank you, Sara.

22           Good morning, and welcome to this meeting on

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

7

1 Lung Cancer Patient-Focused Drug Development. My name  
2 is Patricia Keegan, and I am the Director of the  
3 Division of Oncology Products II in the Center for Drug  
4 Evaluation and Research at FDA.

5           We're excited to see lots of people in the  
6 audience today and on the web, and we have a broad  
7 range of people in attendance today, including  
8 patients, patient advocates, researchers, drug  
9 developers, government officials, and many others, and  
10 we're happy to see such interest in and look forward to  
11 this discussion.

12           Today's meeting is the third of the Patient-  
13 Focused Drug Development meetings. This initiative is  
14 about getting a better understanding of patients'  
15 perspectives on a particular disease and its treatment.  
16 Theresa Mullin will be talking about this initiative in  
17 more detail in a few minutes.

18           Lung cancer has a significant public health  
19 impact in this country. Although it is the second most  
20 common cancer, it is the leading cause of cancer death  
21 in both men and women in the U.S., so we're looking  
22 forward to hearing directly from patients about the

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

8

1 symptoms they experience and how they view existing and  
2 potential therapies for treating lung cancer to help  
3 advance drug development for this very devastating form  
4 of cancer for which effective treatments are still  
5 needed.

6           One of the reasons we initially nominated  
7 lung cancer to be part of this series of meetings was  
8 because our current way of measuring the effects of  
9 lung cancer treatments don't capture some of the  
10 aspects of the disease, specifically how these  
11 treatments affect the way that patients feel either  
12 positively or negatively. One reason for this is that  
13 there is often not a dominant symptom in patients who  
14 are diagnosed with lung cancer that we can rely on.  
15 Also, when cancer metastasizes to different parts of  
16 the body, we have difficulty weighing symptoms from  
17 different sites. Therefore, it's difficult to figure  
18 out how symptomatic changes translate into treatment  
19 benefits because the symptoms often differ from patient  
20 to patient.

21           So what we're hoping to hear today is that we  
22 can really help think through some of these issues and

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

9

1 use that discussion to inform the new and existing work  
2 on drug development tools and do outcome measures for  
3 lung cancer.

4           One reminder for the audience is that while  
5 FDA plays a key role in drug development, FDA does not  
6 actually conduct clinical trials or develop drugs. The  
7 researchers, developers, advocacy groups, and others  
8 might submit applications for new products to FDA, and  
9 our role is, after the applications are submitted, to  
10 carefully evaluate safety and effectiveness of  
11 products.

12           Today's discussion can also enhance our  
13 understanding of the patients' value in potential  
14 treatments. Sometimes we struggle with how to evaluate  
15 treatments that may have a small benefit to patients  
16 and very large risks, and so hearing what patients  
17 think about these issues can really help strengthen our  
18 benefit-risk thinking in those situations.

19           So thank you again for attending. We look  
20 forward to your input, and I will now turn things over  
21 to Theresa Mullin to provide background on the FDA  
22 initiatives. Overview of FDA's Patient-Focused Drug

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

10

1 Development Initiative

2 DR. MULLIN: Thanks, Pat.

3 Welcome. We're very glad that you could make  
4 it to the meeting today, and we're really looking  
5 forward to hearing from our patients who are here  
6 today; that's the whole point of this meeting.

7 And so I was just surprised that my slides  
8 got advanced. I got it.

9 But I want to take a few minutes to give you  
10 a general background on this initiative. As Pat said,  
11 this is the third of our meetings, patient-focused  
12 meetings, and this is a new effort for us, but it's all  
13 tied to our basic approach at FDA and in the Center for  
14 Drugs to doing benefit-risk assessment. And one of the  
15 initial steps or one of the sort of foundational  
16 components of that assessment is to consider the  
17 severity of the condition and the degree to which there  
18 are no good therapies today, so the degree of unmet  
19 medical need, and that comprises what we call the  
20 clinical context.

21 And so this patient-focused effort is really  
22 inspired by the fact that we recognize that patients

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

11

1 are the ones who will be directly experiencing those  
2 benefits and risks. They are uniquely positioned to  
3 inform us about the severity of the condition and the  
4 degree to which current therapies meet their needs and  
5 that we would certainly benefit from a more systematic  
6 way to get that kind of input from patients to help us  
7 have more insight as we approach the review of a  
8 particular drug.

9           And what we have today and prior to this  
10 initiative were a limited number -- we do have some  
11 mechanisms for getting that kind of input, but they  
12 can't cover all the things we would like to discuss.  
13 We have a patient representative program, so a patient  
14 representative can participate in the context of  
15 decision making typically around a particular drug, and  
16 it's often they will participate in advisory  
17 committees. So that's a particular setting. What  
18 we're hoping that this patient-focused effort can do is  
19 give us a more wide- ranging discussion to explore  
20 questions that are of particular concern to the review  
21 divisions, issues that are of particular concern to the  
22 patients outside of the context of a particular drug,

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

12

1 which can limit that discussion a bit, and so that's  
2 what we're doing here.

3           And so we are developing this more systematic  
4 way to capture this input, this getting the patient  
5 perspective. That's what these meetings, these  
6 patient- focused meetings, are about. This is our sort  
7 of exploration of how to do this well. We're learning  
8 in varying things a little bit on each of these  
9 meetings in part, and in large part, to fit the needs  
10 of the questions for a particular disease area but also  
11 trying to test out technologies and ways that we can  
12 maximize our ability to learn from the patients who are  
13 experiencing that disease.

14           Under PDUFA V, we have committed to convene  
15 at least 20 such meetings over the next 5 years, and,  
16 as I said, we are in this kind of learning mode both  
17 about how to do this well and about the particular  
18 diseases that we'll be discussing in those meetings.

19           In trying to figure out, well, what 20  
20 diseases should we focus on in this initial effort?  
21 here are the criteria that we developed and worked on  
22 with the review divisions to try to see what would be a

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

13

1 good place to start, and this is the list of criteria  
2 that we used to develop that initial list that we're  
3 working with. So we're looking at diseases that are  
4 chronic, symptomatic, affect activities of living,  
5 affect patients' lives, ones where these aspects of  
6 disease may not be very well captured in clinical  
7 trials today, where there may not be good therapies or  
8 therapies that work in all populations, there may be  
9 subpopulations that are not well served by the current  
10 therapies. Covering the set of 20 should cover a range  
11 of severity, and we hope to cover a wide range of  
12 affected patient populations and maybe conditions where  
13 there are particularly affected subpopulations, for  
14 example, the pediatric subpopulation or maybe the  
15 elderly.

16           Last September, we published a Federal  
17 Register Notice with a list of potential areas, 39  
18 areas, disease areas, for public comment. We received  
19 about 4,500 comments covering and identifying 90  
20 different disease areas. We reviewed the comments. We  
21 looked at the disease areas that were recommended or by  
22 the public input that we received, went back to our

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

14

1 review divisions to talk about what diseases they felt  
2 they had issues that really were sort of urgent issues  
3 that they were aware of, and there were no other  
4 meetings where they were already trying to capture this  
5 kind of input. So there were a variety of  
6 considerations that we tried to put together to come up  
7 with a set of 20, and so far, we've identified 16 for  
8 the first 3 years, and we'll come back and try to  
9 revisit and figure out what diseases to do in the last  
10 2 years of this 5-year reauthorization.

11           And just to go over this quickly, this is the  
12 set of diseases we're covering in this fiscal year.  
13 Now, the fiscal year ends at the end of September, and  
14 so, as you can see, we're in our third meeting, we'll  
15 cover narcolepsy in September, and then we have -- this  
16 is just the set, I'm not going to go through it, and  
17 you can, I'm sure, get these slides later if you want  
18 to see this. We have a Federal Register Notice we  
19 published on April 11th with the list, all the list, of  
20 diseases, but these are the ones we're going to be  
21 covering in the next 2 fiscal years.

22           And so in planning these meetings, we are

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

15

1 trying to tailor each meeting format and questions to  
2 really fit the context of that disease, so the current  
3 state of development for that disease, particular  
4 questions or issues the review division may be  
5 grappling with and they would like the benefit of  
6 patient input on those issues, the needs of the patient  
7 population. Some populations we know are having a  
8 harder time with mobility or travel issues and other  
9 things, sometimes fatigue can play a role, so we're  
10 trying to really tailor our format to the needs of the  
11 patient, the information needs of the review division,  
12 and so on.

13           So, for example, with chronic fatigue  
14 syndrome, we focused on patients' daily lives and the  
15 experience that they have. How are they treating their  
16 condition today? There are not very many therapies  
17 available, so how are they dealing with it today?

18           With HIV, we focused more on the experience  
19 of living with current treatments and also trying to  
20 get the patients' perspective on whether or not they  
21 would be willing to participate in cure research  
22 because there is talk of cure research now, and how did

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

16

1 they see that?

2                   what were their views on cure research? And  
3 that was very helpful to us.

4                   In both of these meetings, we got the input  
5 from patients' caretakers, patient advocacy groups, and  
6 they provided us a lot of really helpful insights that  
7 we hadn't heard before, so these venues are providing  
8 us with really helpful additional information. And the  
9 stakeholder involvement going into these meetings and  
10 afterwards has been critical to their success as well,  
11 so we've really found that to be just incredibly  
12 helpful to us.

13                   In addition to these, we've been having  
14 periodic meetings with patient groups just to help us  
15 think through our process on how to do these meetings  
16 well. So we're exploring different methods. We've  
17 been trying clicker technology, we have interactive  
18 webcasts, and to see how well these things work.

19                   After each of these meetings, we're going to  
20 be producing a relatively short, we think, very  
21 readable meeting report that we intend to have  
22 faithfully captured the words of the patients, the

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

17

1 perspectives of the patients, that will provide insight  
2 to our reviewers and may be of use to other  
3 stakeholders as well, and so that's the immediate work  
4 product that comes from these efforts.

5           And so with that, I'll turn it over to the  
6 next speaker. And Sean is going to give a background  
7 on lung cancer and its current treatment options.

8 Background on Lung Cancer and Treatment Options

9           DR. KHOZIN: Hello. I'm Sean Khozin. I'm a  
10 Medical Officer in the Division of Oncology Products.  
11 And I'm going to give a brief background on lung cancer  
12 and current therapeutic options.

13           So, as Dr. Keegan mentioned, lung cancer is  
14 the second most common cancer in the United States. It  
15 comes after prostate in men and breast cancer in women;  
16 however, it is the leading cause of cancer deaths in  
17 the United States. There are more than 200,000  
18 diagnoses a year and about 160,000 deaths each year, so  
19 the burden of disease is high.

20           In general, there are two broad categories of  
21 lung cancer: small cell lung cancer, which is about 50  
22 percent of the diagnoses; and non-small cell lung

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

18

1 cancer, which is about 85 percent. Now, these are  
2 histological diagnoses, meaning the diagnosis is made  
3 based on essentially what a tumor looks like under the  
4 microscope. And non-small cell lung cancer is further  
5 subdivided into squamous cell carcinoma,  
6 adenocarcinoma, and other categories.

7           This is an overview of the staging and  
8 treatment for non-small cell lung cancer. So  
9 traditionally we have four stages for non-small cell:  
10 Stage I to IV. And Stage I is essentially localized  
11 disease. It's when the disease can potentially be  
12 cured by surgery. Stage II can also be localized, but  
13 there is usually spread to the nearby lymph nodes, and  
14 the treatment modality for Stage II is surgery plus or  
15 minus chemotherapy depending on the extent of the  
16 spread of the disease and the size of the tumor. As  
17 you go into Stage III and IV, the treatment goal  
18 changes from potential cure to palliation, and what I  
19 mean by that is the treatment goal for advanced stage,  
20 Stage III and IV, is usually aimed at improving the  
21 patients' symptoms or prolonging their life. And Stage  
22 III, we often use a combination of chemotherapy and

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

19

1 radiation therapy. And Stage IV, which is the  
2 metastatic stage, when the cancer has spread beyond the  
3 lungs and to other organs, systemic therapy is a  
4 primary way of treating the disease.

5           Small cell lung cancer tends to be very  
6 aggressive, and it has a tendency of metastasizing  
7 early, so rarely you catch it at a stage where you can  
8 fully resect it. So there are essentially two  
9 different stages of small cell lung cancer: a limited  
10 stage and an extensive stage. In both cases,  
11 chemotherapy is used to treat the disease. In limited  
12 stage small cell lung cancer, we use radiation therapy  
13 in addition to chemotherapy, and they are thought to  
14 work synergistically. And limited stage is essentially  
15 small cell lung cancer that is limited to one radiation  
16 port, and once the cancer goes beyond one single  
17 radiation field, we call it extensive stage and we use  
18 chemotherapy.

19           So early on, the symptoms of lung cancer can  
20 be few and often none and difficult to detect. That's  
21 one the reasons that most patients present in the  
22 advanced stage. Once symptoms develop, you can have

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

20

1 respiratory or what we call constitutional symptoms.  
2 Respiratory symptoms include cough and shortness of  
3 breath. Constitutional symptoms would be loss of  
4 appetite, weight loss, and a general sense of fatigue  
5 and just feeling unwell.

6           So I already talked about surgery as a  
7 primary modality of treatment for lung cancer that's  
8 localized and can be potentially cured if fully  
9 resected, but radiation therapy is also used for both  
10 small cell and non-small cell. So radiation therapy is  
11 essentially high-energy radiation, x-ray or gamma  
12 radiation, and in some cases charged particles, and  
13 they are basically delivered to the tumor site to  
14 reduce the size of the tumor and kill the cancer cells  
15 by damaging their DNA. And, again, it's used both in  
16 small cell and non-small cell lung cancer.

17           Radiation therapy can be used to support or  
18 replace surgery for early stage disease if a patient is  
19 not a candidate for surgery. You can, in some cases,  
20 use radiation therapy to potentially cure the patient,  
21 or in some cases, when the tumor is resected and there  
22 is residual tumor, you can go in and radiate the tumor

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

21

1 to address the residual disease. It can be used  
2 concurrently with chemotherapy; they often work  
3 synergistically. And in the advanced stage of the  
4 disease, in Stage IV, when the tumor has metastasized,  
5 we often use radiation therapy as a palliative measure  
6 to reduce tumor size if the tumor is causing symptoms  
7 such as pain.

8           And systemic therapy is generally comprised  
9 of chemotherapy and the newer so-called "targeted"  
10 therapies. Now, these two different types of therapies  
11 are based on two different views on treatment.

12           So on the left side you see the traditional  
13 view, which bases treatment decisions with chemotherapy  
14 on the tumor histology, and these are histological  
15 classifications that I mentioned earlier. Small cell  
16 and non-small cell, and non-small cell is subdivided  
17 into further categories, and that's the pie chart that  
18 you see on the left side.

19           And the newer view on lung cancer treatment  
20 is called the molecular view, and it attempts to target  
21 treatment to specific genetic abnormalities in the  
22 tumor. So instead of dividing tumors by histological

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

22

1 subtypes, researchers are now dividing tumors based on  
2 their genetic makeup. And on the right side you see  
3 that we've been able to identify many different genetic  
4 abnormalities, so there are many different types of  
5 lung cancer based on the genetic profile of these  
6 tumors. And for many of the abnormalities that you see  
7 on the right side, there are drugs under development,  
8 and few have been approved.

9           The common side effects of treatment  
10 essentially relate to the type of treatment. With  
11 surgery, you have the common surgical complications and  
12 side effects, including pain, weakness, fatigue,  
13 shortness of breath, risk of infection or bleeding, in  
14 the immediate time point after surgery. A lot of these  
15 symptoms resolve or get better as the patient and the  
16 body recuperates. With radiation therapy, most of the  
17 symptoms are related to damage that's done to the  
18 normal tissue and normal parts of the body, so you can  
19 have a localized skin reaction or sore throat,  
20 difficulty swallowing, if, for example, the esophagus  
21 is involved. There can be cognitive impairment with  
22 brain irradiation. And about 5 to 15 percent of

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

23

1 patients who have radiation to the thorax, to the chest  
2 area, experience lung inflammation that can present  
3 itself as shortness of breath and cough.

4           With chemotherapy, nausea, vomiting, fatigue  
5 is very common. You can have nerve damage which causes  
6 what we call neuropathy, numbness and tingling usually  
7 in the toes and fingers, hair loss very common, and  
8 also increased risk of bleeding and infection, which is  
9 usually due to the suppressive effects of chemotherapy  
10 on the bone marrow. Targeted therapies have a  
11 different profile of side effects. Some overlap with  
12 chemotherapy. You can have rash, diarrhea, fatigue,  
13 high blood pressure, increased risk of bleeding, visual  
14 changes, lung injury, and liver injury.

15           Now, in approving new drugs, the FDA requires  
16 substantial evidence from adequate and well-controlled  
17 clinical trials, and the way this evidence is weighed  
18 is by balancing the safety of the drug with its  
19 efficacy. And one way to think of drug efficacy is by  
20 looking at the concept of clinical benefit, which is  
21 defined as an improvement in how a patient feels or  
22 functions or prolongation of survival. So if a drug

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

24

1 can accurately show that a patient feels better or  
2 functions better or it prolongs survival, it has likely  
3 demonstrated clinical benefit.

4           Now, there are times in certain situations  
5 and in some cancer types that a validated surrogate for  
6 one of the metrics that I just mentioned can be used to  
7 define clinical benefit. For example, the way that a  
8 tumor responds to a new drug and the duration of that  
9 response can in some cases be a surrogate for survival  
10 and therefore clinical benefit.

11           And there are two broad categories of review  
12 at the FDA. There is a standard review, which the  
13 review time is within 10 to 12 months for new drug  
14 applications. And also there are expedited programs  
15 that are targeted at major advances to treat serious  
16 conditions such malignancies in cancer, and the review  
17 time for expedited programs is within 6 to 8 months.

18           And this is just a snapshot of the FDA's  
19 current expedited programs: Fast Track, Breakthrough,  
20 which is the newest program available for drugs that  
21 show very promising early evidence of activity, there  
22 is Priority review, and Accelerated Approval.

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

25

1            Now, this is just a partial list of the drugs  
2 that have been approved by the FDA for the treatment of  
3 lung cancer. On the left side, you have common  
4 chemotherapeutics that are used in treating lung  
5 cancer, such as cisplatin, paclitaxel. On the right  
6 side, there are the newer targeted therapies, such as  
7 crizotinib, which is for patients with a specific  
8 genetic abnormality called ALK-rearrangement; there is  
9 erlotinib for patients with certain types of EGFR  
10 mutations; and this category also includes antibodies  
11 that bind to either receptors or other what we call  
12 ligands that are involved in malignant process, such  
13 bevacizumab.

14            A few years ago, the FDA issued a guidance on  
15 patient-reported outcomes, or PROs, to facilitate the  
16 participation of patients in the drug development  
17 process. Now, PROs can represent direct measures of  
18 treatment benefit. They are essentially instruments  
19 that measure or aim to measure how a patient feels or  
20 functions. There are technical challenges with using  
21 PROs in clinical trials. These measurements have to be  
22 done in a very well-controlled clinical trial and

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

26

1 proper measures should be taken, but they are  
2 potentially very useful in capturing how the patient  
3 actually feels when given the new drug. So PROs, in  
4 essence, highlight the patient's unique ability to  
5 contribute to the field of drug development, and the  
6 FDA certainly encourages the development of well-  
7 defined and reliable PRO instruments that capture the  
8 clinical benefit concepts that are important to  
9 patients.

10           That's all I have to say. I would like to  
11 turn the podium back to Sara. Overview of Discussion  
12 Format

13           DR. EGGERS: Thank you very much, Sean.

14           And thank you, Theresa, for giving the  
15 background on the program, and Sean for giving the  
16 background on lung cancer and its treatment.

17           Now it's my job to give a bit of background  
18 on the discussion format. Again, my name is Sara  
19 Eggers, and I will be the facilitator. And this  
20 meeting is run a little bit differently than public  
21 meetings that you may have attended in the past in that  
22 our main goal is to engage patients and patient

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

27

1 representatives in dialogue. By "patients," I'm using  
2 that as a shorthand for people who are living with lung  
3 cancer; and by "patient representatives," I mean  
4 caretakers, loved ones, and patient advocates who are  
5 in the room today and on the web.

6           Let me start first with a discussion format.

7           For each of the two topics that I described  
8 earlier, the first topic is about the most significant  
9 symptoms of lung cancer and its impact on daily life,  
10 and the second is on patient perspectives on treatment  
11 approaches. We will first hear from a panel of  
12 patients and patient representatives, and I would like  
13 to call up the ones who are participating on Panel 1  
14 now: Kathleen, Susan, Sheila, and Lorren. If you  
15 could just sit at the far end of the table and bring  
16 your name tags, please, you little tent cards.

17           The purpose of these first panel discussions  
18 is to really set a good foundation for our discussion  
19 with everyone. The panel members include patients and  
20 advocates, and they reflect a range of experiences with  
21 lung cancer.

22           We'll then broaden the discussion to include

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

28

1 other patients and patient representatives in the  
2 audience. And this is a very important part of our  
3 discussion today, and we encourage you to participate.  
4 The purpose here is to build on the experiences shared  
5 by the panel and see what we can expand upon, maybe  
6 what's different than what was heard from the panel,  
7 and really get at the questions that have been posed.  
8 And by the way, all of the questions are written on the  
9 second half, on the backside, of the agenda.

10           We'll generally be following those questions,  
11 but as this is a facilitated discussion, we will be  
12 straying a bit and focusing on where the conversation  
13 leads us and what is most important to the experts. So  
14 I'll be asking follow-up questions and inviting people  
15 to raise their hand to speak.

16           We tried an experiment before and we're going  
17 to continue this experiment where periodically we will  
18 invite those in person and web participants to respond  
19 to specific questions, and I'm going to ask for the  
20 clickers to be handed out.

21           So you, in-person, we have clickers to  
22 respond to a question, and we're going to practice here

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

29

1 in a minute. So Chad is going to hand out the  
2 clickers. Yeah, in the front there. And so we need  
3 those back at the end, they're not really useful  
4 outside of this room, so please remember to leave them  
5 on the table when you're done.

6           And web participants can respond to the poll  
7 that will be on the webcast, and I wanted to take an  
8 opportunity to give a special welcome to the web  
9 participants. Lung cancer is a very debilitating  
10 condition with a wide range of severity, and we  
11 recognize that it is very difficult for those to come  
12 who are ill, to come in person, and we hope that you  
13 are able to present on the web, and your participation  
14 is very important, and we will try every opportunity to  
15 collect your comments. So although they may not be  
16 read or summarized all today, feel free to use the  
17 comment box that is in the webcast to submit a comment,  
18 and those will be included in our public record, and  
19 we'll try to summarize what we can today, but your  
20 voice will be heard if you're on the webcast. And we  
21 ask for the web polling and for those with the clickers  
22 to only patients and patient representatives, please.

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

30

1           We have a few ground rules to make sure that  
2 this discussion is the most effective and the fairest  
3 for everyone in the room and that we ensure that FDA  
4 and the patients and patient representatives get the  
5 most out of today.

6           So we encourage patients, caregivers, and  
7 other patient representatives to contribute to the  
8 dialogue. We want to hear the patient perspective, so  
9 if you're an advocate and caregiver, we want you to  
10 contribute to the conversation, and we ask that you  
11 provide what you can about the patient's perspective.  
12 Caretakers and loved ones who are here, particularly if  
13 you are here representing someone who is too ill to  
14 travel today, you're very important at giving that  
15 perspective.

16           There are a number of other folks in the  
17 audience today, and we're very excited to see so many  
18 people from industry, from the research community, and  
19 from government here today. We even put out the white  
20 tablecloths for you. We just ask that you stay in  
21 listening mode today and learn. We think this should  
22 be very important for you as well.

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

31

1           Our FDA staff is here to listen, and I'm  
2 going to ask them to introduce themselves in a minute,  
3 but first I'll make my disclaimer. I am not a medical  
4 expert, and my goal today is to try to get by without  
5 saying one of those complicated drug names because I  
6 will mess that up, so I really rely on my colleagues up  
7 here to help me out by asking some follow-up questions,  
8 as they see fit, and so I'll be turning to them.

9           And with that, I would like to ask you each  
10 to introduce yourselves and the office that you're  
11 with. If you push the little button.

12           DR. KAZANDJIAN: My name is Diko Kazandjian.  
13 I'm a Medical Officer for the lung team in Division of  
14 Oncology Products II.

15           DR. MISKALA: My name is Paivi Miskala, and  
16 I'm a Study Endpoints Reviewer in the Office of New  
17 Drugs.

18           DR. MULLIN: Theresa Mullin, Director of the  
19 Office of Strategic Programs, and, like Sara, I'm not a  
20 medical expert, so I'm in listening mode for what I can  
21 understand.

22           DR. KEEGAN: Patricia Keegan. I'm the

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

32

1 Division Director of Oncology Products II.

2 DR. BLUMENTHAL: Hi. I'm Gideon Blumenthal.  
3 I'm the Lung Cancer Team Leader in Division of Oncology  
4 Products II.

5 DR. MALIK: Hello. I'm Shakun Malik. I am  
6 the Medical Officer and the Scientific Liaison for  
7 Thoracic Oncology in the Division of Oncology DOP II,  
8 and I also continue to have my clinic while working for  
9 the FDA. So I am a clinician as well.

10 DR. LE: Hello. My name is Robert Le. I'm  
11 the Medical Officer of the FDA Center for Biologics  
12 Evaluation and Research, Office of Cellular, Tissue,  
13 and Gene Therapy.

14 DR. EGGERS: Thank you very much.

15 Panelists, we'll get to you in a minute.

16 So as part of the facilitated discussion, we  
17 really are going to try to get to everyone who wants to  
18 contribute today, and this discussion is, as I said,  
19 different, it's more I'll be asking follow-up questions  
20 and looking for you to raise your hand to contribute,  
21 and so we're going to ask that you, in your comments,  
22 try to stick to the question that's asked. You'll have

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

33

1 plenty of time to make other statements and provide  
2 your perspective on other aspects of the condition as  
3 well.

4           There may be topics that are not relevant to  
5 our discussions today that you may want to raise, and  
6 again we have that Public Comment Period, so if there  
7 is something that you want to make a statement about,  
8 find the registration table and sign up for that at the  
9 break and we'll accommodate those conversations as well  
10 because we really want to stick to the two topics that  
11 we're discussing today. And we really want to focus on  
12 understanding the common ground regarding those topics.  
13 So, for example, specific treatments may be raised, and  
14 that's appropriate, that's good, but we're not going to  
15 spend too much time on any particular treatment.  
16 Instead, we're going to look for what it is about  
17 treatments in general, what can we learn about  
18 patients' perspectives on treatments in general?

19           Participant feedback is very important to  
20 this meeting, and we have some evaluation forms at the  
21 registration table. It's completely voluntary, but we  
22 benefit from your feedback on this meeting and the

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

34

1 preparation for the meeting and what you liked and what  
2 you think could be improved. That will help us as we  
3 continue on our future meetings of this sort.

4           And above all, respect and courtesy for one  
5 another is important, and so raise your hand to speak  
6 and I'll do my best to get to everyone. Keep side  
7 conversations to a minimum. If you have to take a  
8 phone call, take it outside. And, again, feel free to  
9 leave anytime. If you have to use the restroom or get  
10 something to drink, that's all available outside.

11           With that, I think that is the end of sort of  
12 the ground rules and the format. We're going to try a  
13 few -- can I advance them? Okay. I'm going to let  
14 Pujita advance them because I can't do multiple things  
15 at once. We're going to practice with the clickers,  
16 and on the web you should have polling questions up.  
17 And the reason that we have these quick clicker  
18 questions is really to provide us an indication of  
19 who's in the room and what perspectives are generally  
20 in the room. These are not survey questions, they're  
21 not going to be used for any scientific purposes, and  
22 they're completely voluntary for your answering, but

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

35

1 they do give us a sense of who's in the room.

2           So the first one is an easy one, and that is,  
3 where do you live? So if you're in the room, you press  
4 1 if you live within the D.C. Metropolitan area, and  
5 you press 2 if you live outside of the D.C.  
6 Metropolitan area.

7           (Answering question.)

8           DR. EGGERS: Okay. And then we're going to  
9 advance and see the results. Okay, so we have about an  
10 equal split of local and outside. And for those of you  
11 who have traveled from outside of the metro area, a  
12 special to us, we very much appreciate your commitment,  
13 we appreciate everyone's commitment, but if you  
14 traveled through those thunderstorms yesterday, we are  
15 especially grateful.

16           Okay, how about the next one? Have you ever  
17 been diagnosed as having lung cancer? 1 for yes; 2 for  
18 no.

19           (Answering question.)

20           DR. EGGERS: Okay. We have -- I'm going to  
21 do some math in real time. We have about 10 people --  
22 I believe, if my math is correct -- who are living with

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

36

1 lung cancer. That's great. We really want to hear  
2 from you. And the representatives here, the loved  
3 ones, caretakers, and advocates, we want to hear from  
4 you as well.

5 Do we happen to have the responses from the  
6 web participants?

7 MS. FURIA-HELMS: Yes. On the web, we have  
8 25 people that have not been diagnosed, and 22 people  
9 that have.

10 DR. EGGERS: Okay, great, this is wonderful.  
11 Okay.

12 What we're going to ask for in the remaining  
13 polling questions is that it really focuses on  
14 patients, people living with it answering the  
15 questions. I know we don't have very big numbers, but  
16 it still gives us a sense of who is in the room. And  
17 if you're here representing someone directly, if you're  
18 a loved one and you're representing someone who is not  
19 here, you can think about how they would answer the  
20 questions, too, and answer those questions as well  
21 because what I will say is, as I mentioned, for those  
22 too ill to travel, we don't have their voice directly

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

37

1 here today, and so the panel's experiences may not  
2 reflect the full spectrum of the experiences with lung  
3 cancer, and so we want to acknowledge that, and I will  
4 say, as an example, we had one gentleman who was  
5 supposed to be on the panel today who at the last  
6 minute was too ill to travel, and we just want to  
7 acknowledge that, and we hope he's participating by the  
8 web so we can still hear his voice, but those of you  
9 who are loved ones with someone, then please answer the  
10 questions as well.

11           Okay, we'll move on to the next question.

12 What is your age?

13           (Answering question.)

14           DR. EGGERS: Okay. We have a very nice  
15 spread, primarily with the most prevalent being those  
16 in your sixties.

17           Okay, we'll go on. And are you male or  
18 female?

19           (Answering question.)

20           DR. EGGERS: Okay. This may not be exactly  
21 representative of the men, so the men in the room,  
22 we're going to be calling on you a lot today.

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

38

1 DR. EGGERS: You didn't know you were getting  
2 yourself into that; did you?

3 Okay, do we have one more or a couple more?

4 Okay. What is the length of time since your  
5 diagnosis? Less than 1 year ago, 1 to 2 years ago, 2  
6 to 5 years ago, more than 5 years ago, or if you're not  
7 sure.

8 (Answering question.)

9 DR. EGGERS: More than 5 years ago. I think  
10 that also -- I'll look to my colleagues -- that also  
11 may not be reflective of the entire population, so I  
12 just want to point that out, that we are talking with  
13 more survivors and more with long-term stable condition  
14 today in the room.

15 Okay. Which of the following best describes  
16 your current condition? Your cancer has localized and  
17 has not spread outside your lungs; your cancer has  
18 spread -- when I get nervous, I can't say a word, help  
19 me -- metastasized to the rest of your body; your  
20 cancer is currently in remission; or you're not sure.

21 (Answering question.)

22 DR. EGGERS: Okay. So we have a pretty good

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

39

1 split of the folks in the room. At least we're  
2 representing every perspective with that in that  
3 regard.

4           Okay. All right. That's it for the first  
5 questions. Those polling things are hopefully not too  
6 bad. And on the web, hopefully you were able to work  
7 that as well.

8           Panel #1 Comments: Topic 1

9           DR. EGGERS: Now I'm done talking. I don't  
10 want to hear me, so I'm going to ask my panelists to  
11 introduce themselves right now. We have four  
12 panelists, patient panelists, who will be speaking, or  
13 patient or patient representatives.

14           MS. SANDT: Good morning. Lorren Sandt, with  
15 the Caring Ambassadors program.

16           MS. WARMERDAM: Hi. Susan Warmerdam, partner  
17 at the American Lung Association.

18           MS. SKAMBIS: I'm Kathleen Skambis. I'm a  
19 volunteer with the American Lung Association and a  
20 cancer -- we're both cancer patients.

21           MS. ROSS: Sheila Ross, with the Lung Cancer  
22 Alliance and also a survivor.

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

40

1 DR. EGGERS: Okay, great. So I'm going to  
2 ask each of the panel participants to give three to  
3 four minutes of remarks that answer the questions that  
4 are raised for this morning's discussion. They're on  
5 the back of your sheet, and to summarize them here,  
6 it's really what symptoms that you've experienced  
7 because of your lung cancer, and which ones have the  
8 most significant impact, and are there specific  
9 activities that are important to you but you can't do  
10 it all or as fully as you would like because of your  
11 lung cancer?

12 Now, the women up here do not experience the  
13 disease currently as severely as others, so I've asked  
14 them to either think about what worries them most about  
15 their condition or what they understand from their  
16 peers, the people that they talk to every day who do  
17 more acutely feel the symptoms today, if they can share  
18 that. So they are free to talk about whatever that  
19 resonates with them about this, and I'll ask you to --  
20 let's see, are we starting with Lorren?

21 MS. SANDT: Sure.

22 DR. EGGERS: Great.

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

41

1 MS. SANDT: Thank you. I just want to say my  
2 name is Lorren Sandt. I'm the Executive Director of  
3 the Caring Ambassadors Program, and I am going to be  
4 speaking on behalf of someone living with Stage IV lung  
5 cancer, and I am totally humbled by people living with  
6 lung cancer and what you go through every day, and it's  
7 an honor to be able to sit up here and represent people  
8 living with lung cancer.

9 So I'm going to talk today about a young lady  
10 named Kim. She was diagnosed 2 years ago in May of  
11 2011, and I asked her to tell me what it was like to  
12 live with lung cancer, and here is what she wrote.

13 "Living with lung cancer is no easy task.  
14 It's difficult to decipher which is more difficult, the  
15 physical challenges or the mental challenges. I've  
16 been asked to comment on what it's like to live each  
17 day living with my terminal disease. Honestly, I feel  
18 like my life is better summarized on a monthly basis.  
19 Each day can vary greatly. Is it a doctor appointment  
20 day?

21 scan day? day before a doctor appointment  
22 day? a day of total rest and relaxation? A day of the

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

42

1 thought of me dying before age 40 leaves me  
2 immobilized, weeping in bed, and tightly grasping a  
3 heating pad. In a month's time, I go through all of  
4 these in a typical day and then some.

5           "I'll run you through a Wednesday. This  
6 particular Wednesday is a scan day, a day my cancer is  
7 checked up to see if it's shrinking, staying the same,  
8 or growing. The morning looks like any other morning.  
9 I wake up before 8:00 a.m. to the smell of fresh-brewed  
10 coffee. I have a cup while I make my morning protein  
11 smoothie. For the most part, I eat a very consistent  
12 diet in hopes to eliminate GI issues that are often a  
13 problem.

14           "As a former morning person, my AM's are  
15 slow. After a smoothie is made, I plop myself back down  
16 into bed with my computer and two bottles of pills.  
17 First down is the anti-nausea pill, 30 minutes later is  
18 my daily targeted chemo pill. Once I feel like my  
19 stomach is settled, at least 1 hour after the nausea  
20 pill, I begin to prepare for my day. I dress head to  
21 toe in cotton, give myself my daily blood thinner shot,  
22 pack a light daypack. Today I will perform my new

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

43

1 version of a triathlon. I'm going to have scans, blood  
2 work, and EKG. I'm even going to add a quick stop at  
3 the pharmacy for good measure.

4           "I arrive on time for a 10:00 a.m. check-in  
5 for scans. First is the quick CT of my lungs and  
6 abdomen. Thankfully, the needle went in trouble-free  
7 and my blood work was able to be drawn from the same  
8 injection point. Next is the MRI. This image is  
9 peskier, clocking in at 45 minutes. Once scans are  
10 complete, I venture up a few floors to get my EKG. I  
11 did not get a latte this time before my EKG, I know it  
12 will show my abnormally slow heart rate because of that  
13 and the side effects of my targeted therapy, but, oh,  
14 well.

15           "After 2 hours of actually doing things at my  
16 Care Center and 2 hours of waiting time, my only stop  
17 left is a quickie at the pharmacy. I need to exchange  
18 my full sharps container for my daily blood thinner  
19 shots for an empty one. Finally, I'm ready to leave.

20           "I make it home without too much frustration  
21 after navigating the parking lot. I'm hungry, need to  
22 eat before nausea kicks in. I ate a nice salad and

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

44

1 drank some herbal tea. Naptime it is. Me, laptop, and  
2 cat are ready for afternoon snuggles. Tomorrow I'll be  
3 getting the results of the scans, but I can't help but  
4 to begin to think about it now. Finally, I'm able to  
5 catch my required 2-hour nap. The short snooze gives  
6 me the boost I need to visit with my sweetie when he  
7 gets home from work. We'll chat briefly and then  
8 decide where to go out to dinner. It's a night to  
9 celebrate, and all the running around has made me  
10 unable to spend a drop of energy on what to make for  
11 dinner. I could ask my sweetie to do it, but I would  
12 rather save him for when I'm too ill to prepare my  
13 meals.

14           "Since the blood work has already been taken  
15 earlier, I can have a glass of wine and not fear that  
16 my liver counts will poorly reflect such indulgence.  
17 After returning home from a great meal with meaningful  
18 conversation, we'll end the night with an easy 8-block  
19 walk. Now, I'm ready for bed. I dress in bed clothes,  
20 prepare my evening drug doses. I've learned the hard  
21 way to take them when I still have food in my stomach.  
22 Anti- nausea pill down, antidepressant down, 30 minutes

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

45

1 later targeted chemo down. I am now officially ready  
2 for bed, or put, ready to lay in bed and think of all  
3 the possible outcomes of my scan today. It's difficult  
4 to sleep. Some days are better, some days are worse."

5 Thank you.

6 DR. EGGERS: Thank you very much, Lorren.

7 And I'm going to ask Susan?

8 MS. WARMERDAM: Gosh, how do I follow that?

9 I can relate to a lot of that. Sixteen months ago at  
10 47, I was diagnosed with Stage IV lung cancer as a  
11 never smoker, and it spread to my adrenal gland into  
12 the lymph nodes in my chest and abdomen and tested  
13 positive for the EGFR gene, which is something  
14 completely beyond my control and completely unrelated  
15 to smoking.

16 Last February, a chest x-ray for just a  
17 common cough was what exposed the mass in my lung, and  
18 a month later I started on a daily targeted oral chemo  
19 treatment and an early Phase II clinical trial which  
20 has since been unblinded.

21 I didn't really have any prediagnosis  
22 symptoms except maybe, in hindsight, an annoying and

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

46

1 lingering cough that my doctor had diagnosed, or  
2 misdiagnosed, as an allergy, and insomnia. These lack  
3 of symptoms and lack of early detection screenings are  
4 why 84 percent of those with lung cancer already are at  
5 such an advanced stage like myself by the time we're  
6 diagnosed. My doctor said I had had the cancer in my  
7 body for 5 to 7 years.

8           Since I had started treatment, the physical  
9 side effects that most negatively impact my life are  
10 the fatigue and the what us cancer patients call "chemo  
11 brain." I try to keep as much normalcy in my life as  
12 possible and continue like I'm not sick, but these pose  
13 challenges at work. I still work full-time, and my  
14 inability to sometimes process and remember things get  
15 in the way. Getting up in the mornings, like early  
16 morning meetings like this and getting ready with my  
17 new routines to take care of myself and then making it  
18 through a day of work without escaping into the lady's  
19 room stall for a quick catnap.

20           The visual side effects that I had  
21 experienced like losing 40 percent of my hair, the eye  
22 infections, and a monstrous looking facial skin rash

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

47

1 had an impact on my daily life because I could see  
2 them, and every time I looked in the mirror, I saw a  
3 sick person, and it was always a reminder that, oh,  
4 yeah, I still have Stage IV lung cancer.

5           We have an image in our mind of what a sick  
6 person looks like, and because my tumors are invisible  
7 and I look healthy, people tend to forget that I'm  
8 sick, and even those that know that I am, they forget  
9 or think that I'm cured, and it really feels like they  
10 just don't care anymore.

11           And the emotional and psychological symptoms,  
12 it's difficult managing dying with living -- I don't  
13 really know how else to phrase that -- balancing the  
14 limited time that we have to do great things while  
15 managing work and the daily chores, just to keep things  
16 together because sometimes just keeping it together is  
17 surviving.

18           And telling people I have lung cancer is like  
19 wearing a sign. There is an implicit judgment with the  
20 stigma that lung cancer is a smoker's disease, and  
21 since people's perceptions matter to me, I feel I need  
22 to explain I was never a smoker to validate that I did

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

48

1 not do this to myself and that they can get it, too.

2           Being on Tarceva, or erlotinib, and with my  
3 drastic changes in lifestyle, I miraculously am not  
4 living with symptoms that prevent or limit me from  
5 doing any activities. I'm very fortunate to live my  
6 life like I did before treatment, just scan to scan  
7 now. However, though I don't have physical limitations  
8 today, there are things within my control that I choose  
9 not to do or to do differently. They may be perceived  
10 as an inconvenience to some, but for me, they're  
11 lifestyle choices.

12           Tarceva is keeping my cancer at bay, but I  
13 will inevitably build up a resistance to the drug and  
14 my cancer will begin to progress again. So I worry  
15 about things like suffering, I worry about the added  
16 risk from the excessive radiation that I'm getting that  
17 could cause another cancer. I'm worried about running  
18 out of time to do everything that I want to do. And,  
19 again, I worry about building up a resistance to the  
20 Tarceva. I'm just waiting in the wings hoping and  
21 praying every single day for that Tarceva, as I call  
22 it, rescue drug. I can deal with having lung cancer

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

49

1 and living with a chronic illness, I just need to know  
2 that there is a drug out there without a resistance  
3 that will allow me to live a normal life expectancy,  
4 like diabetes and AIDS.

5           And, lastly, my perspective on currently  
6 available treatments is there are none, for me anyways.  
7 Since there aren't other treatment options out there  
8 for me, I've made drastic lifestyle changes that are  
9 within my control, that I consider treatments, and I  
10 participated in a clinical trial for which I hope to be  
11 able to comment on later because I know I'm probably  
12 getting close to my 4 minutes -- right, Sara?

13           UNIDENTIFIED FEMALE SPEAKER: She waved you  
14 on.

15           MS. WARMERDAM: What does that mean, you  
16 waved me on?

17           UNIDENTIFIED FEMALE SPEAKER: She said go on,  
18 keep on going.

19           DR. EGGERS: (Off mic.)

20           MS. WARMERDAM: Oh, okay. And I know Sean  
21 had already talked about the statistics, so I won't  
22 even reiterate those, but I'm just asking the FDA to

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

50

1 understand the severity and actually everyone, the  
2 severity of a lung cancer diagnosis. For me and other  
3 lung cancer patients that are diagnosed at my stage,  
4 Stage IV, there is only a 3 percent chance that we will  
5 survive 5 years, and according to that statistic, I'll  
6 be dead in 3-1/2 years, so I'm asking you to please act  
7 with some urgency like it was you and your family or  
8 your family member that had received the same  
9 diagnosis.

10 DR. EGGERS: Thank you, Susan.

11 And now I'll go with Kathleen.

12 MS. SKAMBIS: Hi. I'm Kathleen Skambis. I'm  
13 a very, very lucky lung cancer survivor, and I'm here  
14 for myself, but also I'm a member of a lung cancer  
15 support group, and I just will tell you what I did. I  
16 sent these discussion questions to a number of people  
17 and I got back written answers to the questions from  
18 eight different people, all of whom I know well. So  
19 I'm going to tell you a little bit about myself, and  
20 then I'm going to try to synthesize their comments so  
21 that you'll get an idea of the wide range of ways that  
22 people deal with lung cancer and the different types

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

51

1 and how it affects their lives.

2           I was diagnosed in May of 1999, I was 41  
3 years old. I had lung cancer in both my lungs. I had  
4 no symptoms. I had forgotten to get the flu shot  
5 because I was getting married. I got the flu on my  
6 honeymoon. I had a chest x-ray, and I had lung cancer  
7 in both my lungs. I'm a trial lawyer, I'm married to a  
8 trial lawyer, we know how to research. At the time,  
9 the Mayo Clinic retrospective said that people with  
10 what I had, bronchioloalveolar carcinoma in both of  
11 their lungs had a zero percent chance of survival for 5  
12 years. I just decided that that was a small sample.

13           And they had a difficult time staging my lung  
14 cancer because I didn't have lymph nodes where I was  
15 supposed to have lymph nodes, and I did have  
16 chemotherapy, six rounds of chemotherapy, with all the  
17 usual side effects. I still have some permanent  
18 neuropathy. That's the only -- I'm missing a third of  
19 my lungs, but that's come back, that lung function has  
20 principally come back. They say I can't go to high  
21 altitude places; that's such a small thing.

22           Let me tell you a little bit about some of

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

52

1 the other people and I'll go in order of diagnosis.

2           My friend Bill was diagnosed in May of '99.  
3 He had a persistent dry nonproductive cough and a golf  
4 ball size tumor in the back wall of his lung. They  
5 tried to take his lung out. They couldn't do that  
6 because the tumor was wrapped around the pulmonary  
7 artery. He had 6 weeks of chemotherapy, 7 weeks of  
8 chemotherapy and radiation. His only remaining symptom  
9 is that he has, as I understand it, is that he has a  
10 dry persistent cough and some postnasal drip. We are  
11 very lucky. Really, he has no limitations or views  
12 himself as having no limitations on his life.

13           My friend Shelly, in May of 1998, had a  
14 violent outbreak of ulcerative colitis on her legs. It  
15 was biopsied and she had a chest x-ray and it was  
16 determined that she had lung cancer. She had her lung  
17 removed, she had chemotherapy, radiation, and she has  
18 shortness of breath. She also has COPD, she takes  
19 oxygen, but she views herself as having no real  
20 limitations. I know that's not entirely true. She  
21 can't climb stairs; she can't be as active as she would  
22 like to be.

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

53

1           My friend John was diagnosed in August of  
2 2005. His one and only symptom was a tumor on his arm  
3 and on his buttock, and when those were biopsied, they  
4 were lung cancer. He had the lumps removed. He had to  
5 have one of them removed twice. He had radiation and  
6 chemotherapy, and he is now on -- I know there's a  
7 fancy name for this type of drug, but I can't remember  
8 it -- Tarceva, and he had side effects from that  
9 medication, but they are controlled, and he would be  
10 here today, but he is currently hiking the Pacific  
11 Crest Trail as a benefit for lung cancer and to raise  
12 awareness.

13           My friend Gail was diagnosed in 2010. She  
14 had a really bad cough and they did a chest x-ray. It  
15 turns out the cough was completely unrelated to lung  
16 cancer, she had severe acid reflux, but it found her  
17 lung cancer. She had surgery and chemotherapy. She  
18 believes that she has no lingering symptoms, although  
19 she feels fatigued and doesn't know -- she has no signs  
20 of lung cancer remaining and believes the fatigue is  
21 residual from her lung cancer.

22           My friend Pat was diagnosed in November of

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

54

1 2012. She had it inside her left lung, the middle of  
2 her left lung, and outside in the pleural effusion of  
3 her chest cavity. She is on a different targeted  
4 treatment, oral treatment, and she specifically listed  
5 some side effects that she can't do. Because of her --  
6 and I think this is important to know as you look at  
7 this -- everyone said if you are treated for lung  
8 cancer, it very quickly becomes impossible to tell the  
9 difference for a patient between the difference between  
10 your symptoms of lung cancer and the side effects of  
11 your treatment. So that all gets mixed together. So  
12 Pat has shortness of breath, voice hoarseness and  
13 fatigue, and she has some side effects from her  
14 treatment. She can't swim, she gets out of breath  
15 walking on uneven terrain, and she has to sit a lot to  
16 relieve the side effects of the swelling in her leg.  
17 All of these people who have these side effects are  
18 extraordinarily grateful to be having these side  
19 effects and have these treatments available, and I  
20 think that's really important for you guys to know.  
21 I want to end with my friend Lisa, who was  
22 there for me when I had lung cancer in 1999. She was

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

55

1 diagnosed in August of 2011. She had a large tumor in  
2 her right lung and multiple bilateral nodules  
3 throughout both of her lungs, it was inoperable. She  
4 is also on Tarceva. The large tumor has shrunk. The  
5 rest of the cancer has diminished. She had some pretty  
6 significant side effects from Tarceva, but she says she  
7 doesn't seem to be as physically strong, she lost  
8 weight, and she's not sure if that's from having lung  
9 cancer or if that's from the side effects.

10           But I want to read you this. Throughout her  
11 statement, she talks about not being physically strong,  
12 but in response to the question about activities that  
13 keep you from doing things, she wrote this: "I am able  
14 to do everything I have always done. I sleep very well  
15 and continue to work every day as an interior designer.  
16 I am very physically active and continue to stay active  
17 through cycling and power walking every day. I just  
18 finished cycling through Holland," where they carried  
19 all of their gear on their bicycles, "and went  
20 approximately 200 miles on a bike." Lisa is a little  
21 older than I am. "Earlier this year, I rode in the  
22 "Horrible Hundred," which is a 100-mile bike ride

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

56

1 through the hills of Clermont, Florida. This was done  
2 in 1 day." I can't read what I wrote because I copied  
3 it over. "I would say I don't feel as strong as I  
4 would have normally felt prior to the diagnosis. My  
5 physical activity is very important to me, and I will  
6 not allow cancer to take that away from me. Focusing  
7 on something else helps me not to dwell on what is  
8 going on in my body, and I refuse to let it define me."

9           And that sums up what I would say everyone I  
10 know -- and I know a lot of people who have lung cancer  
11 -- they're determined fighters who want options.

12           Thank you.

13           DR. EGGERS: Thank you very much, Kathleen.

14           And, finally, Sheila.

15           MS. ROSS: Thank you, Sara. I would just  
16 like to thank FDA for holding this council. I'm with  
17 Lung Cancer Alliance, an advocacy organization right  
18 here in

19           Washington, D.C. And we basically do two  
20 things: try to change policy, and patient support,  
21 live on-staff patient support. So in doing the policy  
22 work, we work frequently with FDA, and I just want to

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

57

1 say once again you have such a wonderful committed  
2 staff, it's a pleasure to work with you, it really is.

3           And when I was driving over here, I kept  
4 thinking of Patty Delaney, who actually she was at FDA  
5 for quite a while, and she actually started the Office  
6 of Liaison for patients and patient advocacy groups.  
7 She died a few years ago of cancer, but she was  
8 wonderful. So every time I come here I think of Patty.

9           In any event, on with this. I think an  
10 interesting thing about lung cancer is that it really  
11 has few symptoms, or if they have any, they're very  
12 nebulous. The first time that I was diagnosed with lung  
13 cancer, I was 49 years old, and my only symptom was a  
14 pain in my shoulder, which I thought was from some kind  
15 of exertion or maybe I was sleeping a bad way.

16           In any event, I was actually diagnosed by  
17 stethoscope; I think that's very rare these days. But  
18 that was treated surgically, and I was fine for quite a  
19 while. I was told after that surgery, just get a blood  
20 test and a chest x-ray every year, you're fine, and I  
21 did that, of course, faithfully. But I kept feeling  
22 weaker and weaker and coughing more, and the technician

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

58

1 kept saying, "But the chest x-ray is clear, there is no  
2 problem," and then one day when I was babysitting my  
3 grandchildren, I literally started hemorrhaging, and  
4 then I finally got a CAT scan, and it showed that the  
5 right lung, what was left of it, was completely  
6 blocked, the right bronchus, and the tumor was starting  
7 to spread into the left bronchus. I think I was  
8 probably Stage V.

9           But by the good graces of a surgeon who was  
10 brave enough to take it on, they were able to remove  
11 the right lung, patch up the hole in the left bronchus,  
12 and here I am. I'm very grateful to be here. That  
13 came true so hard yesterday. If I'm a little shell-  
14 shocked today, it's because I'm a little tired. I had  
15 the great pleasure yesterday of being all day at the  
16 Naval Academy watching my grandson be inducted into the  
17 Academy as a plebe, and it was so thrilling to walk  
18 into the alumni hall where he dropped off at 8:00 in  
19 the morning, and then see him come back out at 6:00 no  
20 longer my grandson, his hair gone and white uniform,  
21 completely transformed, and I thought, wow, I'm so  
22 happy to see this because that second surgery was 13

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

59

1 years ago, and I am just so lucky and fortunate.

2           And I think part of the thing that keeps me  
3 going is becoming a strong advocate and out there  
4 fighting for other people so that people can be  
5 diagnosed early with this wonderful screening ability  
6 of CT scans to find it early, and new attention to lung  
7 cancer, we had legislation passed in January of this  
8 year that's going to make NCI focus more on lung  
9 cancer. And we have, of course, targeted therapies and  
10 molecular testing. We are really at the turning point  
11 for lung cancer, we're really there.

12           So back to symptoms, very briefly. Since we  
13 do patient support services, I spoke with Maureen  
14 Rigney, who is director of those services, and we were  
15 both kind of surprised at how very nebulous the  
16 symptoms are. The most common one I think is fatigue,  
17 and Maureen mentioned cachexia, which is just like a  
18 general wasting, your muscles waste, your skin wastes,  
19 your skin sags, you just feel tired, and as you said,  
20 these symptoms morph right into -- they stay with you,  
21 I mean, even when you're treated, even post-treatment,  
22 they just don't go away. So it would be wonderful if

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

60

1 drug companies could start targeting particularly  
2 cachexia, see what's going on there, how they can help  
3 patients with that.

4           And the last thing I'll mention because it's  
5 a symptom that people don't like to talk about, but I  
6 had it with both cases of cancer, and most people I  
7 talk to have it, and that's depression. In fact, I  
8 think it should be a symptom of lung cancer and defined  
9 as a symptom, and it certainly should be treated. I  
10 never got around to treating my depression until months  
11 after I finished chemo and radiation, surgery, chemo,  
12 and radiation, and then finally someone said, "Oh, you  
13 might be depressed," you know.

14           Yeah, okay, and it was wonderful to get that  
15 treatment and to be able to change that. And so I  
16 definitely encourage depression as a symptom.

17           Thank you.

18           DR. EGGERS: Thank you very much, Sheila.

19           I am going to save follow-up questions from  
20 the panel, and then we'll get into the large-group  
21 discussions, but we might have some follow-up questions  
22 for you from my colleagues.

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

61

1           And I was going to start this large-group  
2 facilitated discussion part by asking for a raise of  
3 hands about whether the experiences are shared up here  
4 by those of you in the room. But I'm going to start  
5 with a different one, and that is, how many people in  
6 the room felt inspired by the stories that were shared  
7 today of the courage and the strength?

8           (Show of hands.)

9           DR. EGGERS: And I think we should give a  
10 round of applause for that.

11           These are inspiring stories. But as I say  
12 that, I don't know if they are typical, if they are the  
13 typical stories of everyone. And so now I want to ask  
14 for a raise of hands in the room of how many of you  
15 heard yourself in at least one of the experiences that  
16 was shared.

17           (Show of hands.)

18           DR. EGGERS: Okay. And how many have  
19 experiences that are different than what was shared  
20 above?

21           (Show of hands.)

22           DR. EGGERS: Okay. And on the web, I'm going

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

62

1 to make a call out to the folks on the web, too, that  
2 you also share your experiences, maybe not through the  
3 webcast in full detail -- I think I forgot to mention  
4 that we have a public docket that is opened, and this  
5 is very important. I should have mentioned this. If  
6 you go to our meeting webpage, there is a link that you  
7 can click on to submit your full comments, just like  
8 the ladies shared up here today, you can submit your  
9 own comments to that docket, so those on the web and  
10 those here, please submit your comments, and as you  
11 hear the discussion today and it brings up some point  
12 that you think is important, share that as well. We  
13 read all of those comments and they are as important as  
14 what we hear today, so I just wanted to say that.

15           Large-Group Facilitated Discussion: Topic 1

16           DR. EGGERS: And now I am going to start off  
17 with a question that I think will be a good discussion  
18 question that will start our discussion, and I think  
19 we'll follow up on a few things that were mentioned  
20 here today. So can we go to the next question? I know  
21 this is extremely small writing. We had a lot of  
22 symptoms that we wanted to put up here. So if you're

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

63

1 experiencing these or if you have a loved one who is  
2 experiencing symptoms of lung cancer -- and I know it's  
3 hard to tease out the side effects of treatment, and  
4 that's okay if you blur those together, it doesn't  
5 matter.

6           Of all the symptoms you experience because of  
7 your lung cancer, which have the most significant  
8 impact on your daily life? And you can choose up to  
9 three symptoms. So pain, such as chest pain or  
10 shoulder pain; shortness of breath, wheezing, or other  
11 breathing difficulties; coughing or coughing up blood  
12 or phlegm; loss of appetite or weight loss; voice  
13 hoarseness or difficulty speaking; fatigue or lack of  
14 energy; depression or anxiety; other side effects of  
15 your cancer treatments; or other symptoms that are not  
16 mentioned. And let's allow the folks who are not  
17 feeling symptoms at this point right now, since this is  
18 just for discussion, if you want to put the ones that  
19 worry you the most even if you don't experience them.

20           (Answering question.)

21           DR. EGGERS: And I know we don't give much  
22 time, so we don't have to hold you that these are your

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

64

1 exact top three. We'll give a few more minutes -- a  
2 few more seconds.

3 (Answering question.)

4 DR. EGGERS: All right. Let's move on.

5 Okay, now I have to see the numbers here. And we also  
6 are asking the folks on the web. But let's start with  
7 those in person. It looks like there is the whole  
8 range of symptoms, and there is quite a bit of other  
9 side effects. And interesting no one in the room has  
10 anything that's not on this list, so I think we can  
11 stick to this list. So the most prevalent is the  
12 fatigue or lack of energy and the second most is the  
13 shortness of breath, wheezing, or other breathing  
14 difficulties.

15 Can I ask what's on the web just as the top  
16 ones that are raised?

17 MS. FURIA-HELMS: It's very similar with  
18 fatigue and lack of energy as the most and shortness of  
19 breath coming in second.

20 DR. EGGERS: Okay. So let's start with the  
21 fatigue or lack of energy. We heard comments up here  
22 in the front. I just want to see, does anyone have an

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

65

1 experience that they want to share about how fatigue or  
2 lack of energy affects their life or how they  
3 experience it?

4 Yes. We have Montessa?

5 Oh, and someone will be coming around with  
6 microphones. And while she's getting that ready, if  
7 you can state your full name just for the public  
8 record. This meeting is being transcribed and the  
9 public record will be up on our website.

10 MS. LEE: Okay. My name is Montessa Lee,  
11 with the National Lung Cancer Partnership. I was  
12 diagnosed when I was 28 years old, so I'm not in active  
13 treatment now, but I can tell you that the fatigue was  
14 the worst part of any of the side effects, and there  
15 was one point where I couldn't walk from my apartment  
16 over to a neighbor's apartment to ask for a ride, it  
17 felt like I was lifting up weights just to walk there  
18 as well as the shortness of breath. And I had small  
19 cell lung cancer, so a little bit different than  
20 anybody on the panel, but the fatigue was absolutely  
21 horrible.

22 DR. EGGERS: Does anyone want to follow up

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

66

1 with that, on that?

2 Yes, Denise.

3 MS. HOGAN: Hi. My name is Denise Hogan. I  
4 have been cancer-free for almost three years. While  
5 surgery was fine, I was up and running in 5 days, but  
6 with the chemotherapy, I spent the entire -- out of 90  
7 days, I had maybe 10 good days. I went every day to  
8 the oncology office, came home and slept, came off the  
9 couch, went to bed, all I did was sleep, and like she  
10 said, I couldn't -- I had no energy to do anything.  
11 It's very debilitating.

12 DR. EGGERS: Okay. Yes, Stephanie.

13 MS. HANEY: This strikes me because I  
14 specifically remember a story, and, again, that  
15 crossover between whether it's treatment related or  
16 disease related, when I was going through the  
17 traditional chemo, now 5 years ago, my daughter was 2  
18 years old, my youngest daughter, and my fatigue was  
19 very severe, and I remember the whole thing, "Mommy,  
20 can you pick me up? Mommy, can you pick me up?" and I  
21 was just so tired, and I would sit down and I would  
22 hold her in my lap, and I would get, "Mommy, can you

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

67

1 pick me up?" And I specifically remember the first  
2 time she noticed after the traditional chemo was over  
3 when she had this epiphany, "Mommy, you can pick me  
4 up!"

5 And it made such a difference to her, and so  
6 that was a big impact for me, was that I was  
7 disappointing her.

8 DR. EGGERS: Thank you.

9 Does anyone else want to share their  
10 experience with fatigue?

11 Yes, John. You can stay seated.

12 MR. RYAN: Yeah. My name is John Ryan. I am  
13 2 months into this and in Day 12 of my first chemo  
14 cycle. My doctor said the people that stay most active  
15 do better in this, and I knew that fatigue was an  
16 issue. How do I stay with active with fatigue? Work  
17 it. So in my last 2 weeks, I have been taking naps,  
18 sleeping well at night, and trying to get exercise when  
19 I felt best to do that, and then set aside time for a  
20 nap. I commend those that try and live a normal daily  
21 routine working and sneaking naps wherever to make it.  
22 And so the fatigue has been overwhelming in terms of

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

68

1 overarching how the day would work, but working  
2 exercise and meals when I was feeling well and then  
3 paying back the "fatigue god" to get better for the  
4 next cycle was what we've been dealing with lately.

5 Thank you.

6 DR. EGGERS: Does anyone up here on the panel  
7 want to talk more about your fatigue? You shared it  
8 very well.

9 MS. WARMERDAM: So one of the other ladies I  
10 interviewed really talked about fatigue and really was  
11 frustrated that she can't do everything she used to do,  
12 and the shortness of breath and fatigue are both part  
13 of that. And while she still goes to the gym every  
14 day, it's not in the same way. And she still plays  
15 golf every day, but she can't walk, she's got to ride.  
16 And those kind of things really are getting to her  
17 because that's what she loves to do, and she's retired  
18 now.

19 But another young lady who has got two kids,  
20 it's been a real struggle, and I can relate to your  
21 story of picking up the kids, of just how difficult it  
22 is to have two young children and living with lung

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

69

1 cancer and taking care of them and having the energy to  
2 take care of them. And you take some of that from your  
3 kids.

4 DR. EGGERS: So I think what I'm hearing is  
5 that even if you're not bed bound with fatigue, even if  
6 it's not debilitating, even if you can go to work and  
7 you can take care of your children and your  
8 grandchildren and you can do your outside activities,  
9 it doesn't mean it's not a significant impact on your  
10 life. Is that perspective shared?

11 (Heads nodding.)

12 DR. EGGERS: Okay, I see a lot of head  
13 nodding. Okay.

14 I'm going to ask my colleagues if they have  
15 any specific questions about fatigue or how it's  
16 experienced that they want to ask.

17 (No audible response.)

18 DR. EGGERS: Okay. We'll move on. I want to  
19 get a little bit at the shortness of breath, wheezing,  
20 or other breathing difficulties that have been  
21 mentioned. Would anyone here in the room like to follow  
22 up on something they heard or their own experience with

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

70

1 shortness of breath, wheezing, and its impact on daily  
2 life?

3 Yes?

4 MS. ADKINS: Hi. I'm Donna Adkins, and I'm  
5 with National Patient Advocate Foundation, but I'm more  
6 here today as a mother and caregiver of a daughter who  
7 was diagnosed at age 26 with lung cancer. She is  
8 cancer-free from her surgery and deals with the chronic  
9 fatigue. She's a registered nurse. It impairs her job  
10 on a daily basis. She still has a little bit of  
11 wheezing, but I also wanted to mention -- and I forgot  
12 to do it when you did your poll, but one of her biggest  
13 issues is chronic pain from the surgery. She's been  
14 through physical therapy, they've given her bone  
15 stimulators, they can't get rid of her pain.

16 DR. EGGERS: And how does she experience this  
17 pain? What kind of pain is it? Can you give some  
18 specific examples of the --

19 MS. ADKINS: After the surgery, her diaphragm  
20 is not aligned anymore. She has one rib that they  
21 broke in half when they did the surgery and it has  
22 never come back together. So it sort of floats in

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

71

1 there. The bone stimulator was to promote the growth  
2 of that rib. So it's the pain from just that rib not  
3 being in place. She has pain in her side. Her muscles  
4 ache all the time. As a nurse, lifting patients is  
5 very difficult for her at times. I do have to say that  
6 she works a full-time job as a hospice nurse, so she  
7 has not let this get her down, but when she gets home  
8 in the evening, that's her day, that's her day, she's  
9 done. The fatigue, everything, has taken its toll on  
10 her.

11 DR. EGGERS: Okay. Thank you.

12 Anyone else want to follow up on shortness of  
13 breath or even the pain that was mentioned?

14 Yes, Amy.

15 MS. COPELAND: I'm Amy Copeland. I work for  
16 Lung Cancer Alliance with Sheila, but I also want to  
17 talk on behalf of caregivers. I was a caregiver for my  
18 mother for many years, who had lung cancer, and one of  
19 the most difficult things for her was the pain. She  
20 was a landscape designer, and she lived for her job,  
21 she loved her job, it was very active. Because of  
22 peripheral neuropathy from the chemotherapy she went

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

72

1 through, she had a lot of numbness in her feet, which  
2 caused her one day to fall, and because of the  
3 radiation that she had done to hip metastases, she also  
4 had fairly brittle bones, so she ended up with a really  
5 odd fracture in her hip because of this, and luckily we  
6 were able to find an orthopedist at a really well-known  
7 cancer center that was willing to even come near her  
8 and kind of wire her back together in this really  
9 intricate surgery, but it definitely had kind of an  
10 outcome on her ability to work through that pain, and  
11 that was really difficult for her because in a lot of  
12 ways, especially as her progression continued, work was  
13 really what kept her going, and to not be able to do  
14 that really brought her down in a major way. So the  
15 pain and fatigue were really significant parts of her  
16 experience.

17 DR. EGGERS: Thank you very much, Amy.

18 Anyone else have their most -- maybe a  
19 symptom or impact that hasn't been mentioned yet that's  
20 most significant?

21 Karen.

22 DR. ARSCOTT: Thank you. I'm Karen Arscott.

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

73

1 And I've had the fatigue, crawling up the steps, the  
2 shortness of breath, the cough, but the one thing that  
3 I had that hasn't been mentioned yet was kind of  
4 interesting. Prior to my diagnosis seven years ago, I  
5 had my right hand -- and I'm right-handed, and I'm a  
6 physician, my right hand started to become dusky, and  
7 actually became almost claw-like. And I was going  
8 through the workup for Raynaud's, I had three EMGs and  
9 CVs. I had multiple workups to try to find out what  
10 was happening to my hand.

11           I didn't really think about the fact that I  
12 had a nagging cough, especially as a professor, I was  
13 teaching, I would have to stop talking when I was  
14 teaching to take a drink of water and to try to get it  
15 back together so that I could -- and really I thought  
16 it was allergies or something. I had no risk factors  
17 whatsoever for lung cancer, so it never even occurred  
18 to me.

19           In the meantime, I was just going through  
20 this workup for my hand. And finally I had vascular  
21 studies and finally they did an MRI of my brachial  
22 plexus, and they found a nodule in my right upper lobe

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

74

1 which was only 15 millimeters. It did light up and it  
2 was lung cancer, it was Stage IA. When I had my  
3 resection, 16 hours later, my hand was relieved. The  
4 nodule wasn't anywhere near by brachial plexus, they  
5 think that it was probably a paraneoplastic syndrome  
6 associated with it.

7 I can say that losing the ability to use my  
8 right hand was -- I was trying to teach myself to write  
9 with my left hand. It was just doing everyday things,  
10 and that I had my right hand back. I'm going to be on  
11 Panel 2, so I'll talk a little bit more about my  
12 recurrence then, but that's a symptom that I've done  
13 some research, and there have been other people who  
14 have had some paraneoplastic syndromes. But the thing  
15 is that it never even occurred to anybody, including  
16 myself, that there might be a cancer behind it, which  
17 was kind of interesting.

18 Thank you.

19 DR. EGGERS: Thank you, Karen.

20 Anyone else about a symptom that they feel?

21 Go ahead, Lorren.

22 MS. SANDT: Just briefly, I think you guys

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

75

1 need to take this as a new definition, "scanxiety." I  
2 don't think I have to tell you what that means.

3 DR. EGGERS: Thank you very much.

4 We're going to be talking a bit about the  
5 downsides of treatment in the next topic, but I think  
6 since we're exploring that a little bit more now, I'm  
7 going to ask a question about one of the side effects  
8 of treatment, and I think it was Susan who talked about  
9 the chemo brain. Because we don't have as much mental  
10 symptoms, cognitive symptoms, up here, although I did  
11 hear it from up here in the panel, and so I was  
12 wondering, does anyone else want to explain what Susan  
13 means by "chemo brain" or any other mental cognitive  
14 issues?

15 MS. HOGAN: I hope it's "chemo brain."

16 The doctor said it takes five years, but I  
17 just find my memory isn't as sharp as it used to be,  
18 and, you know, I walk into a room to do something and  
19 then I forget why I was there, which happens anyway,  
20 but it seems to be more frequent now. But he said it's  
21 usually five years and you see the difference.

22 DR. EGGERS: Okay. So even five years after

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

76

1 treatment, and you have been --

2 MS. HOGAN: Well, I'm three years, so I'm  
3 giving it two more years. I'm going to use it for the  
4 next two years.

5 DR. EGGERS: Use the excuse.

6 MS. HOGAN: "It's my 'chemo brain,' I swear."

7 DR. EGGERS: Anyone else want to follow up on  
8 these cognitive issues?

9 We'll go with Sheila and then we'll go back  
10 here.

11 MS. ROSS: Actually, it's longer than five  
12 years. Yeah.

13 DR. EGGERS: Sheila, though, in all  
14 seriousness, you have noticed a difference, more than  
15 you might attribute to just --

16 MS. ROSS: Just regular aging?

17 DR. EGGERS: Becoming more distinguished?

18 MS. ROSS: That's a nice way of putting it.  
19 No, I think that there is definitely -- I was never as  
20 sharp again after chemo, never, and even factoring in  
21 aging and whatnot. I don't know what it is.

22 And just to go back to the pain, I really

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

77

1 think it's wrong that there hasn't been a better pain  
2 medication developed. Everyone who goes through that  
3 surgery is in tremendous pain like your daughter. And  
4 I don't mean the VATS surgery. Fortunately we have the  
5 new VATS for particular lung cancers, depending on the  
6 position in the lung, which is wonderful. A friend of  
7 mine just had that and she was out of the hospital in  
8 24 hours and walking up a hill the next day, but for  
9 the regulars, what I call "slash-and-burn" surgery,  
10 it's painful. I mean, that scar is 13 years ago, and  
11 it still hurts. So I just don't understand why there  
12 can't be better pain management for lung cancer  
13 patients. It's wrong.

14 DR. EGGERS: Well, let's save that for the  
15 next topic. We'll revisit that. But I think it's  
16 important, so bring it back up if I don't mention it.

17 I think Pat has a follow-up question?

18 DR. KEEGAN: Either in this session or in  
19 maybe the next panel session because as we're listening  
20 to a lot of the discussion about fatigue, it sounds  
21 like the fatigue of concern is a treatment-related  
22 fatigue more so than a manifestation of the lung

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

78

1 cancer, the underlying lung cancer, and I just want to  
2 make sure if that's the case, that we clarify it in our  
3 future comments because I think the way we would  
4 develop tools to approach evaluation of that would be  
5 different, so if in the next session or in this session  
6 you could elaborate on that because it's important to  
7 us to know which it is so that we get the right kind of  
8 tool to look at that.

9 DR. EGGERS: Okay. I know we have a comment  
10 back here -- and we'll get to you, Montessa -- but let  
11 me follow on Pat's question and ask one. Can anyone  
12 distinctly tell the difference? I mean, are you able  
13 to describe the pain -- and we'll ask this for the  
14 folks on the web, you can put it in your comment box --  
15 describe the pain that you would say, "I can tell this  
16 is not treatment related." Because I think Kathleen is  
17 going to make the point that it's very difficult to  
18 tell, she made that point earlier, but if you can,  
19 elaborate on what that feels like and what you  
20 experience with that. Okay?

21 UNIDENTIFIED FEMALE SPEAKER: The pain?

22 DR. EGGERS: The fatigue that you can say,

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

79

1 "This is really because of my lung cancer, and I don't  
2 think it's because of my treatment." Okay?

3 MS. LEE: Since I have the mic, I think my  
4 fatigue definitely was from the chemotherapy or the  
5 radiation. Now, that I don't know which because I had  
6 radiation and chemotherapy at the same time. But I  
7 couldn't sleep; before I was diagnosed, I could not  
8 sleep. Now, that could have been due to the pain  
9 because at the time they found the tumor, it was 15  
10 centimeters, and it was probably pressing on something,  
11 I couldn't breathe and I couldn't sleep, but after  
12 that, the extreme fatigue and low blood pressure, all  
13 of that, it is a fine line, but I thought some of it  
14 was probably due to the treatment.

15 DR. EGGERS: Well, we'll move on from that  
16 topic, but I'll put a plug in for the docket that if  
17 you can really address this topic in the docket, or the  
18 advocates in the room and listening, if you can think  
19 about what your constituency, what they experience,  
20 what your peers experience, about fatigue that you  
21 think is attributed to the lung cancer.

22 Montessa, did you have a comment about

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

80

1 cognitive?

2 MS. LEE: Yeah. I was going to tell her it  
3 doesn't go away after five years, because I was  
4 diagnosed in -- it gets better, but I totally have to  
5 write everything down.

6 DR. EGGERS: So I think, Paivi has a  
7 question.

8 DR. MISKALA: No, I had a similar comment to  
9 fatigue as it relates to pain. I think we've heard  
10 some patients describe that pain is related to surgery  
11 versus the underlying disease, and I would be  
12 interested in hearing from you further as well.

13 DR. EGGERS: So in the interest of time -- I  
14 think we're going to go to the break soon -- but we'll  
15 put another plug in for the docket to really talk about  
16 the pain that you think is attributed to your lung  
17 cancer separate from the treatment itself.

18 We are almost ready to go to a break. I  
19 think I'm going to look to Pujita for confirmation of  
20 that? Right? And what I want to do before we close  
21 this discussion, this is going to bleed into the next  
22 discussion, but I want to see if anyone has anything

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

81

1 that they wanted to bring up as a symptom of something  
2 that they experienced because of the lung cancer before  
3 we go to a break that maybe hasn't been raised.

4 Yes. Go ahead.

5 MS. WARMERDAM: I'm actually not even sure if  
6 it is related, but Montessa had actually mentioned it,  
7 so I thought I would also. Probably five years before  
8 I was diagnosed, I was dealing with insomnia, sometimes  
9 where I wouldn't fall asleep for two days in a row  
10 literally, and in hindsight, I consider that a symptom  
11 because -- and I don't know if there is any science  
12 behind it, but my cancer had spread to my adrenal  
13 gland, and so for me, it kind of told me that maybe  
14 that was a symptom.

15 DR. EGGERS: Okay. If you feel comfortable  
16 raising your hand that you think that not just fatigue  
17 but sleep problems, insomnia, has been an issue for  
18 you, any raise of hands?

19 (Show of hands.)

20 DR. EGGERS: Okay. We have some hand raises,  
21 about five hand raises here. Okay, thank you.

22 Well, I think we're going to take a 15-minute

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

82

1 break. I want to thank you all so far for a great  
2 conversation and dialogue, and the panelists, I want to  
3 thank you again. When we come back from the break, if  
4 I could ask the folks who are on Panel 2 to work their  
5 way up to the panel with your tent cards.

6 Thank you.

7 And I'll put a reminder, if you want to do a  
8 public comment, sign up for that at the registration  
9 table.

10 (Whereupon, a brief recess was taken.)

11 DR. EGGERS: Okay, as you make your way to  
12 your seats, I'm just going to make an announcement  
13 about the Open Public Comment. We've had five people  
14 register. I'm going to ask a favor of them. If the  
15 five folks who have registered, if you can keep your  
16 comments to 3 minutes, then we can extend the  
17 discussion that we're going to have, which is going to  
18 be a really rich discussion on how you think about  
19 decisions regarding cancer treatments, we can extend  
20 that just a bit if we need to, and if that conversation  
21 comes to a natural close, then we would still be able  
22 to end a little bit early for lunch. So as you're

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

83

1 thinking about your public comments, please 3 minutes.

2           Well, building on the great discussion we've  
3 had so far -- and again I want to thank everyone who is  
4 so courageously sharing your experiences -- we're going  
5 to move into Topic 2, but before we do that, we are  
6 going to summarize some of the comments that we've  
7 heard on the web that maybe we haven't heard that  
8 haven't been mentioned here yet.

9           MS. VAIDYA: Thank you, Sara.

10           So we have someone from the web who wants to  
11 provide a gentle reminder that irrespective of smoking  
12 histories, everyone deserves to live and to be treated  
13 as deserving to live.

14           Participants on the web share similar  
15 symptoms presented in the room, including fatigue,  
16 shortness of breath, lack of concentration, memory  
17 retention, and neuropathy. A different symptom  
18 mentioned includes side effects from a drug which  
19 results in drop in testosterone level. It was also  
20 mentioned that nutrition and physical exercise have  
21 helped with side effects. Web participants also feel  
22 there is a need to also address emotional side effects

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

84

1 which have not been addressed here.

2 Thank you.

3 DR. EGGERS: Thank you, Pujita.

4 Panel #2 Comments: Topic 2

5 DR. EGGERS: So we're going to move into  
6 discussion Topic 2, which is really the perspective on  
7 current approaches to treating lung cancer, and we did  
8 talk a lot about the symptoms of those, and we can  
9 expand upon that, too. I think we're going to hear  
10 some from the panels, but we'll move into talking about  
11 how you really get into making those treatment  
12 decisions and what you think about and how you weigh  
13 different considerations and what's important to you.  
14 So this is going to be a very exciting discussion.

15 We have some great panel participants up  
16 here. They represent patients and patient advocates.  
17 So I'll let you introduce yourselves because I don't  
18 think we have them in order here. So if you could just  
19 state your name and if you want to state what  
20 affiliation you are with or who you associate with,  
21 feel free.

22 MS. HOGAN: Good morning. My name is Denise

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

85

1 Hogan. I work for ALA. I'm part of Power Against  
2 Tobacco. And I have been free of cancer for close to  
3 three years.

4 DR. EGGERS: Can everyone hear Denise? Is  
5 everyone hearing? Okay.

6 MS. HOGAN: Is it on? No? Did you hear me?  
7 Can you hear me now?

8 DR. ARSCOTT: Hello. My name is Dr. Karen  
9 Arscott. I'm a physician, and I have been free of  
10 cancer symptoms for 6 years now, and I am a professor  
11 at a medical school, and I am a member of Lung Cancer  
12 Alliance as a patient advocate.

13 MR. RYAN: My name is John Ryan. I'm at the  
14 front end of this simply as a cancer patient. Nine  
15 weeks ago today I didn't know anything about it. I'm  
16 just finishing my first chemotherapy phase.

17 MS. FULD NASSO: Hello. My name is Shelley  
18 Fuld Nasso, and I'm Senior Director of Policy for the  
19 National Coalition for Cancer Survivorship, and we  
20 advocate on behalf of cancer patients in terms of  
21 quality of care.

22 MS. HANEY: My name is Stephanie Haney. I am

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

86

1 a lung cancer survivor. I was diagnosed at Stage IV  
2 about 5-1/2 years ago.

3 DR. EGGERS: Thank you very much.

4 So we've asked the panelists again to prepare  
5 3 to 4 minutes of remarks, and once we hear that, time  
6 permitting for the panel discussion, we'll see if there  
7 are any follow-up questions, but then we'll move into  
8 the large-group facilitated discussion. And again the  
9 questions are on the back of your agenda, but basically  
10 we want to understand your thoughts on the cancer  
11 treatments you are currently undergoing or have  
12 undergone in the past to help reduce or control the  
13 spread of your lung cancer, as Sean described those  
14 today, what supportive care treatments you're taking to  
15 help or improve or manage the symptoms that you talked  
16 about earlier today, what you're thinking about your  
17 overall goals for treatment and how you weigh  
18 importance specifically of prolonging your life versus  
19 improving your symptoms, and what you really take into  
20 account when you do that, when you think about those  
21 two goals, and what other factors you take into account  
22 when making decisions about using treatments.

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

87

1           So with that, I will stop talking and turn it  
2 over to Denise to begin.

3           Thank you, Denise.

4           MS. HOGAN: Okay. Good morning again. Thank  
5 you to the FDA for having us. I was diagnosed with  
6 Stage II non-small cell lung cancer. It was five  
7 centimeters. My local doctors wanted to do radiation  
8 and chemo. The American Lung Association directed me  
9 to a doctor in New York City who insisted that we take  
10 it out right away. I was very lucky it didn't go  
11 anywhere, it just stayed in my lung, but as a  
12 precaution, we did three months of chemotherapy.

13           The surgery, of course, is no walk in the  
14 park, but compared to chemotherapy, chemotherapy  
15 totally disabled my life. I have numbness from the  
16 surgery, but I feel so lucky, I don't have any bad side  
17 effects. I mean, my breathing -- I can't do a stair  
18 climb, but that doesn't keep me from doing stairs.  
19 Nothing has stopped me from doing what I used to do, I  
20 just might not do it as fast as I used to do it. If I  
21 was ever in need of doing chemotherapy again, I don't  
22 think I would do it. It affected me physically and

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

88

1 mentally because I couldn't accept that it was killing  
2 everything else. If there were any cancer cells that  
3 it was attacking, it was also attacking my bones and my  
4 blood and I just -- my quality of life -- there was no  
5 quality of life, and I did it once, but I'm also  
6 convinced that I'll never have cancer again.

7           Cancer has not consumed my life. I had it, I  
8 had it taken out, I had treatments, and in my opinion,  
9 I don't have it, and I don't say I'm in remission, I  
10 just don't have cancer anymore. I would like very much  
11 for the stigma of lung cancer -- is it me? There is  
12 such a stigma. I was an ex-smoker. I had stopped  
13 smoking for 11 years, and the first thing everyone says  
14 is, "Did you smoke?" I don't think any other cancer  
15 people ask a question, you know, "How did you get it?"  
16 If I didn't smoke, the first thing I would say to  
17 people is, "I got lung cancer and I never smoked." I  
18 think it's an unnecessary question for someone to ask.  
19 It puts the smoker, the ex-smoker, in a position where  
20 they feel people are looking down on them like they  
21 caused their own illness.

22           When I started smoking, no one told me that

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

89

1 there was a cancer of lung cancer, and it's an  
2 addiction just like any other addiction. So I hope  
3 eventually the stigma comes off of it. And I hope  
4 there is more open dialogue about lung cancer because  
5 most people think that you die immediately, you know,  
6 if you have lung cancer, you're going to die, and to me  
7 that's not the case.

8 I had wonderful doctors, I had wonderful  
9 family support, which you have to have a lot of support  
10 around you, but there is a financial burden that -- I  
11 mean, I was going to the oncology office every single  
12 day to be hydrated, so I had to pay a copay. My bill  
13 was \$5,000 just for copays, and that plays on your  
14 mind, especially when they're asking for more money.

15 So there are a lot of things that are going  
16 on besides -- for me, I just felt like I was dead, I  
17 felt like I didn't have any life. I was so happy after  
18 surgery. I mean, I came home, I went for a walk, I  
19 resumed, you know, but the chemo just completely -- and  
20 as I said before, I don't know if I would ever do it  
21 again because the quality of life is far more important  
22 to me.

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

90

1 Thank you.

2 DR. EGGERS: Thank you very much, Denise.

3 We'll go on with Karen.

4 DR. ARSCOTT: Okay, so I was first diagnosed  
5 7 years ago. And I am no longer under any treatment  
6 for my lung cancer. With my initial diagnosis, as I  
7 said before, I was a Stage IA, it was a supposedly  
8 incidental finding, although I probably had the  
9 paraneoplastic syndrome associated with it which helped  
10 find it. I had a surgical resection.

11 Being a physician, and my husband is a  
12 physician, we did a lot of searching to try to find out  
13 whether I should receive adjuvant chemotherapy or  
14 radiation at that time, and I had two opinions, and  
15 along with the literature, agreed that I should have  
16 been a surgical cure and did not require any further  
17 treatment. So I was on the every-4-month CAT scan at  
18 that point, which is another point that I would like to  
19 make a little bit later in the follow-up treatment of  
20 lung cancer, which is sadly -- it varies from person to  
21 person.

22 So I was on an every-4-month follow-up, which

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

91

1 I'm very grateful for because 12 months after my  
2 surgery I had a completely clean CAT scan, 4 months  
3 later I had a 2 centimeter nodule, lymph node, in my  
4 mediastinum, so I had a mediastinal recurrence and it  
5 was a skip metastasis, which is very rare, but I had a  
6 skip metastasis to my mediastinum, and now I'm a 3A.  
7 When that happened, I knew that I was in for the fight  
8 of my life, and I looked at my doctor and I said, "Hit  
9 me with everything you have. I'm 48, I'm healthy," at  
10 that point I was going to spinning class regularly, and  
11 I was in very, very good shape, and I just said, "Hit  
12 me with everything you have," and he said, "We're going  
13 to hit you with everything including the kitchen sink,"  
14 because, along with this panel, my treatment options  
15 were very, very limited at that point.

16                   So this is 6 years ago. And although  
17 targeted therapy was around at that point, I couldn't  
18 really get anybody to check me for any of the  
19 biomarkers because I was a IIIA, I wasn't a IV, and I  
20 did eventually talk them into it, and I am epidermal  
21 growth factor receptor- positive because I said if this  
22 ever recurs a third time, I want to be able to start

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

92

1 treatment immediately and not have to wait for the  
2 results to come back.

3           So what they hit me with was 12 weeks of  
4 carboplatin and Taxotere. I followed with a second  
5 thoracotomy mediastinal resection, and then I had 7-1/2  
6 weeks of radiation and cisplatin. So they did hit with  
7 me with everything. And I was prepared mentally for  
8 the fight, and I did fairly well until the radiation  
9 and chemo combined were pretty hard. I'm going to say  
10 that after that I started to fight my way back, and 11  
11 months after I concluded treatment I walked my first  
12 marathon. I used to run. I don't run anymore, I can't  
13 because of the shortness of breath and such, but I do  
14 walk, and since that time I've walked four marathons  
15 and six half marathons all with Team Lung Love with  
16 Lung Cancer Alliance. I just feel that I have to do  
17 that for all the people who can't participate like  
18 that. Is it easy? No, it's hard, but you know what?  
19 I walk with my husband and my sister, and they give me  
20 encouragement, and I feel that I'm better for it, it  
21 gives me a lot of opportunity to reflect and to talk,  
22 and I'm glad that I'm able to do that.

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

93

1           I would like to comment on -- so for the FDA  
2 and for anybody out there, I think that we have a  
3 couple issues, first of all, treatment options.  
4 Currently targeted therapy is for late stage. IIIA  
5 does not fall into late stage, you have to be IIIB or  
6 IV. There really isn't that much research for early  
7 stage. I'm not sure. There are side effects, I  
8 understand that, the chemo is very hard, and there are  
9 side effects for it. However, I would like to know if  
10 I am epidermal growth factor receptor-positive, should  
11 I have continued on any targeted therapy? I don't know  
12 because there isn't research. So I think that would be  
13 one thing I would like to comment on.

14           The other thing I would like to comment on is  
15 the follow-up. Again, I was very fortunate in that my  
16 doctor chose to do every-four-month CAT scans. I have  
17 known people who were on the six-month, and when they  
18 went back for their six-month scan, already had  
19 metastasis to the other lung.

20           And we are treating the tumor marker positive  
21 as if it's the old-fashioned type of -- lung cancer has  
22 changed over the years. As a physician, I'll tell you

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

94

1 it is not the old-fashioned lung cancer, it is new.

2 There is a more aggressive style of lung cancer. It's  
3 hitting 20-year-olds, 30-year-olds, 40-year-olds, and  
4 it's very, very aggressive, and so if we continue to do  
5 follow-up care as if it's the old-fashioned lung  
6 cancer, we are going to have people develop metastasis  
7 in six months, and they're going to be Stage IV before  
8 we have any option to treat them. So we need to  
9 consider follow-up.

10 I have met people who are getting follow-ups  
11 at 1 year out after surgery for Stage IA. It's  
12 inexcusable, but I have to say that as a physician, the  
13 medical community is as ignorant to the facts as the  
14 general population. I have met many physicians and  
15 nurses who feel the same way as the general population,  
16 that they don't understand lung cancer, they don't  
17 understand the stigma attached to lung cancer, and also  
18 this will take me into my next comment about smoking  
19 and lung cancer.

20 When I received my call from my nurse case  
21 manager from my insurance company after my first  
22 surgery, the first question out of her mouth was, "How

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

95

1 should we begin your tobacco cessation program?" That  
2 was the first thing she said to me. And I said, "Well,  
3 you can start it any way you want, but I never smoked,"  
4 but don't talk about that anyway.

5           So as a physician, I can say that I'm opposed  
6 to smoking, I'm not opposed to smokers. I feel that  
7 you have to help them. Most people begin smoking in  
8 their teenage years, when they're 15, 16, they get  
9 their first job, and they want to be with their other  
10 coworkers and such, and so they take their smoking  
11 breaks, and they go out, and they become addicted very,  
12 very fast, and, you know, although at 18 we think we  
13 know everything, and at 20 we're sure we know  
14 everything, most of us in this room will say that we  
15 really don't know anything until we're in our thirties,  
16 and so by the time somebody hits 30, if they've been  
17 smoking for 20 years, they have a significant smoking  
18 history. It is not their fault that they became  
19 addicted as teenagers to this. The tobacco industry  
20 created this to become an addiction product.

21           So we need to think about this. I had this  
22 discussion with some physicians recently about smoking,

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

96

1 and I said, "You don't realize that 60 percent of  
2 people with lung cancer are those who already quit  
3 smoking," and so, as physicians, we're giving our  
4 patients advice and telling them, "You quit smoking and  
5 all will be rosy," and then we're not following up with  
6 any screening or testing. That is inexcusable. So we  
7 have people who have quit, we have people who are still  
8 smoking, and we have never-smokers, and we need to  
9 treat them all equally. We need to do early screening.  
10 Everybody deserves early diagnosis and adequate  
11 treatment whether they are smokers or non-smokers, and  
12 that's what I would like to say.

13 Thank you.

14 DR. EGGERS: Thank you, Karen.

15 Can we move to John, please?

16 MR. RYAN: Yeah, good morning. My name is  
17 John Ryan. As I said earlier in my intro, I had no  
18 visibility to this 9 weeks ago. I went into an  
19 emergency room at my doctor's direction due to a self-  
20 induced coughing up of about a teaspoon of blood and  
21 phlegm. The emergency room did their normal checks,  
22 and my x-ray showed nothing. If it wasn't for a

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

97

1 radiologist who said, "We need a C scan," I would still  
2 be wandering around in the dark on this.

3           In the ensuing weeks, I was informed by very  
4 capable oncologists saying that, "You're in Stage IV.  
5 We can treat you. We cannot cure you. This will kill  
6 you. And depending on how lucky you are with our  
7 pathology, if you have some positive mutations, you get  
8 to go oral at directed. If that's not the case, we  
9 need to get moving into chemotherapy." I had my first  
10 chemotherapy injection last Monday.

11           And after reading everything that the Cancer  
12 Institute put out about side effects -- it was a very  
13 detailed account about all the side effects with  
14 chemotherapy -- I was energized to the nines waiting  
15 for everything to hit. In fairness to the process, the  
16 advances that were made on treating my situation where  
17 I have had this spread to a rib and they're looking at  
18 major bone strengthening things through injections of  
19 bone enhancement, I'm taking a medication for that,  
20 getting an overkill on everything that could make you  
21 avoid the "bucket brigade" of 30 years ago with nausea  
22 and vomiting, taking B-12 to offset maybe the fatigue,

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

98

1 folic acid. I didn't decide I was going to take this,  
2 the team did, and here we are on Day 12.

3           It is my greatest concern as a patient, and,  
4 believe me, and my family, since you can't cure, what  
5 are the options for treatment? I went through a double  
6 -- or a second opinion verification through Bethesda  
7 and then Vanderbilt with Dr. Powell, and my family is  
8 at peace knowing that they both concluded that I didn't  
9 have positive EGFR or ALK and that where I am is where  
10 I need to be. I see evening news marketing of great  
11 things that are happening at the Cancer Center on the  
12 genomes, the directed. Research has put us to the  
13 Foundation One, so we would like to see that product.  
14 I asked both oncology teams in Tennessee and Bethesda,  
15 would that product today, of me and my genetic  
16 molecular profile be helpful to you today as a  
17 potential assistance on what treatments might augment  
18 my first-line or second-line and beyond? And both said  
19 yes. My discussions here would suggest, with others,  
20 would suggest that we're not ready to do that because  
21 although you may have a lot of matchable pairs, so what  
22 are the possibility links to viable clinical trials

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

99

1 that may help? So my voice in the dark is be sensitive  
2 to the patient that's out there that is gripping for  
3 access to the viable treatments that are available to  
4 enhance the life and make the best shot for the finish.

5 Thank you.

6 DR. EGGERS: Thank you, John.

7 We'll move with Shelley next?

8 MS. FULD NASSO: Thank you. And I want to  
9 thank the FDA for hosting this meeting and for  
10 listening to patients and patient advocates and their  
11 perspectives about to help inform the drug review and  
12 approval process. We really appreciate your listening  
13 to us, and I just want to thank all the patients who  
14 have shared their stories here today.

15 I'm not a lung cancer patient, but my  
16 organization advocates for patients of all types of  
17 cancer for quality care. But I want to share the story  
18 of my father-in-law, who made a different decision from  
19 what we've heard today. He was diagnosed very recently  
20 with small cell lung cancer. He has made the decision  
21 not to undergo any treatment, any disease-directed  
22 treatment. And he and his wife are both very at peace

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

100

1 with this decision. He turned 79 last month, or as he  
2 likes to say, he's in his 80th year, and he has  
3 advanced emphysema. He has lost a significant amount  
4 of weight in the last year and can't keep weight on  
5 despite his best efforts. He is frequently out of  
6 breath and tires easily. He lives in rural central  
7 Texas and would have to travel about three hours to  
8 Austin or Dallas for treatment.

9           He told me he doesn't want to spend the money  
10 and the time undergoing treatments that may or may not  
11 help reduce his cancer burden but will certainly make  
12 him feel worse and will not address his emphysema. He  
13 would rather enjoy his peaceful life for as long as he  
14 can. As his disease progresses, he will have  
15 supportive care to alleviate his symptoms and ensure he  
16 is comfortable. It is not one single factor, but the  
17 combination of factors, the effectiveness of the  
18 treatments, the side effects, the cost, the  
19 inconvenience, and his overall health status that  
20 influenced his decision.

21           That said, if there were treatments that were  
22 likely to save his life, he probably would go through

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

101

1 the treatment, but knowing what he has in front of him,  
2 he's made this choice, and after contemplation and  
3 discussion with his doctor. But the truth is it wasn't  
4 a terribly difficult decision for him. He is a man who  
5 knows what he wants and this is what he wants. So it's  
6 not the right choice for everyone, but it is the right  
7 choice for him.

8           Another example of a gentleman who worked  
9 with NCCS for several years after he was diagnosed with  
10 lung cancer in his twenties, and his name is Dan Wigger  
11 (ph), and I didn't have the pleasure of knowing him,  
12 but I've heard so much about him from my colleagues.  
13 He just had an insatiable appetite for life and was  
14 willing to try anything, and he went through five lines  
15 of treatment, very difficult treatment, especially at  
16 the end. He was engaged to be married. He wanted to  
17 do whatever he could to help cancer patients, and  
18 that's why he worked for NCCS through his entire  
19 treatment.

20           So while we can never know what we would do  
21 until we are faced with that decision, I think that I  
22 would probably take the route that Dan did. I have

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

102

1 three young children, and if I were diagnosed, I would  
2 do anything to try to be there for them. But I think  
3 that my father-in-law and Dan are probably extreme  
4 examples of where the decision is a little bit more  
5 clear-cut. It wasn't a hard decision for my father-in-  
6 law, and I don't think it was a hard decision for Dan  
7 to do whatever he could. But for other patients, the  
8 decision may not be so straightforward, and I think  
9 that's where the tradeoffs that are discussed in this  
10 panel and that have been discussed earlier become so  
11 important.

12 All patients that are diagnosed with lung  
13 cancer need to clearly understand the short- and long-  
14 term goals of treatment and whether the treatment is  
15 curative or palliative. If the goal is not curative  
16 because of the disease burden and limited treatment  
17 options, patients need to understand the risks and  
18 benefits of whatever choice they make.

19 The treatments chosen by lung cancer patients  
20 should follow an episode of clear communication and  
21 shared decision making with their physicians. That  
22 should result in a clearly communicated written

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

103

1 treatment plan that addresses the following questions:  
2 If cure is possible, what are the late and long-term  
3 effects of treatment? And we've heard a lot about some  
4 of those effects of treatment today. If cure is not  
5 likely, is there a clinical trial that might offer an  
6 increased benefit over a currently available treatment?  
7 If cure is not likely, will chemotherapy or other  
8 modalities help delay tumor progression and relieve  
9 symptoms? And then, does the physician understand what  
10 quality of life means to the patient? And which of the  
11 possible treatment options might best preserve those  
12 qualities of life?

13           And I think that last question is really  
14 important. It's often suggested that cancer patients  
15 have an exceptionally high tolerance for treatment side  
16 effects, but they have to be considered with respect to  
17 that individual's preferences. And this may sound  
18 obvious, but it's really not obvious. We hear  
19 countless stories of people, like the piano teacher,  
20 who despite talking to his physician about his  
21 profession, went through a treatment regimen that  
22 resulted in peripheral neuropathy and compromised his

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

104

1 ability to do what he loved and what his profession  
2 was, which was teaching piano.

3           So as the range of treatment options  
4 increases as new drugs are being developed, the  
5 comparison of different treatment options and the  
6 potential for benefit and the risks are critical for  
7 patients to understand. And we know that the FDA is  
8 working to develop a benefit- risk framework that will  
9 help patients be able to see the different treatment  
10 options compared against each other. And we think this  
11 is helpful and important for patients because patients  
12 need to understand and be able to make what's the best  
13 treatment choice for them.

14           So thank you.

15           DR. EGGERS: Thank you very much, Shelley.

16           And, finally, we have Stephanie.

17           MS. HANEY: Thank you. My name is Stephanie  
18 Haney, as I said. My life since lung cancer has been  
19 relatively easy in comparison to many lung cancer  
20 patients. I'm about five and a half years into this  
21 journey, and except for some pain in my right side that  
22 led to this two-year search for a source, I've been

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

105

1 symptom-free. I was diagnosed at Stage IV, so common  
2 practice dictated that my only option was drug  
3 therapies, no surgery, no radiation. And I'm clearly  
4 blessed that those drug therapies have had a positive  
5 impact in my case. I live and have lived since the  
6 start with essentially stable disease and no symptoms.

7           That all being said, those therapies did not  
8 come without a price. I had traditional chemo, which I  
9 thought might kill me all on its own, and that was  
10 without nausea or vomiting, that was all the other  
11 things, bone pain and that kind of thing. It was the  
12 most difficult time in my life, and I thought the end  
13 was near. Tarceva came with the expected side effects:  
14 red and rashy face and diarrhea for 3 years. Now I'm  
15 on Xalkori because I have the ALK mutation, so it was  
16 interesting that both of those drugs worked for me.  
17 Interestingly, it doesn't appear that I really have  
18 side effects at all. I'm so grateful that I happen to  
19 be chemo-responsive and will just have to string  
20 therapy upon therapy together as one wears out its  
21 usefulness.

22           I've dealt with issues such as frequent

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

106

1 traveling to appointments. For instance, I almost  
2 missed "Trick-or-treating" with my then 2- and 4-year-  
3 old daughters early in this process, and it was so  
4 devastating because then I assumed my time would be so  
5 short, I wasn't sure I would be there for the next  
6 Halloween. Lots of miles on the car and lost work  
7 hours, research, blood work that has transformed my  
8 beautiful firm veins into illusive, invisible rolling  
9 strings that require steps of prep with every stick,  
10 and piles of paperwork rivaled only by the IRS are  
11 nothing if they will keep me going. But I'm willing to  
12 pay any price to stay alive. It's easy for me because  
13 I'm young and otherwise healthy, and I have two little  
14 girls. There are so many more like me than most might  
15 know. I would love to have more aggressive treatments  
16 that would really whack this cancer back. I would  
17 endure any amount of bone pain and utter exhaustion,  
18 painful acne, or three more years of diarrhea,  
19 surgeries, hospitalizations, whatever it would take.  
20 I'm a single mother with two young daughters, and I  
21 will do what I must to fulfill that responsibility.

22                   The reality is this: there were few

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

107

1 decisions to be made in regard to treatment. In fact,  
2 I'm not sure I made any really. There are few  
3 tradeoffs for me because there are so few treatments  
4 available, maybe four to six options. I mean, some are  
5 similar to others, so once you use one, you kind of  
6 rule another one out, and that's if you can live that  
7 long. So, again, I've been fortunate that so far  
8 stringing together these therapies is working.

9           And don't think that I'm one to just blindly  
10 accept what my doctor says because I did do a lot of  
11 research, but when it came down to it, only having drug  
12 therapy options, I wasn't choosing between apples and  
13 oranges but apples and apples, so I took my trusted  
14 doctor's advice without much question.

15           Risks associated with the medication are  
16 irrelevant because they all have very serious side  
17 effects. We are monitored closely and will die without  
18 it anyway. I'm on my third therapy to try to hold the  
19 inevitable off, and I know what two drugs will follow  
20 this. Beyond that, I'm not sure if there will be more  
21 options. That's my only concern: what happens when I  
22 use everything up? We'll string together what is out

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

108

1 there. If the next big thing comes out before I die,  
2 I'll string that one on, too. There aren't really  
3 choices for me. I just hope that there will be enough  
4 options that work to get more years of parenting in.  
5 If treatments were more reliable and had longer impact,  
6 there would be decisions to make, but with the  
7 exception of some of the newer targeted therapies that  
8 may fit one patient better than another, we're just  
9 trying to make it through.

10 I did also want to comment on something that  
11 was said earlier about drugs with small benefit, and  
12 I'm always sensitive to that idea because basically to  
13 me -- and I'm not a statistician or a scientist -- what  
14 that means, you know, if they say it's 2 months overall  
15 survival, that's still an average, and so for some,  
16 that drug may have worked wonderfully, and for others,  
17 of course, it didn't work at all, and then you go off  
18 it. So I'm sensitive to drugs that fall off quickly  
19 because their overall survival was minimal when, in  
20 fact, probably for some they might have been a very  
21 powerful drug.

22 And I think that's it. Thank you.

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

109

1 DR. EGGERS: Thank you, Stephanie.

2 And I want to thank all the panelists. I  
3 mean, as with the first panel, it takes a lot of  
4 courage. This is a tough subject, and I think we  
5 should applaud these panelists, too, for their courage.

6 So thank you.

7 Large-Group Facilitated Discussion: Topic 2

8 DR. EGGERS: And I'm going to start with the  
9 second question I asked to start the last facilitated  
10 discussion, which is, how many of you here in the  
11 audience saw your own experiences in at least one of  
12 the experiences shared here today?

13 (Show of hands.)

14 DR. EGGERS: Anyone who is going to have a  
15 completely different experience?

16 (Show of hands.)

17 DR. EGGERS: Okay. So there were a lot of  
18 common themes that were talked about, and a lot of --  
19 we talked about the "obvious" decisions -- I'll put the  
20 "obvious" in quotes -- we talked about the very hard  
21 decisions, may not do it again, the decisions that why  
22 you might, despite everything, why you might decide

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

110

1 that the end is near and you want to continue as best  
2 you can knowing that. We talked about the lack of  
3 options and the limited options and the not having  
4 much, many, choices, and so I think we're going to  
5 follow up on all of those.

6           But to put it in context, I would like to ask  
7 one polling question, so if you can get your clickers  
8 out, and on the web if you can answer this polling  
9 question, too, and that is: Have you ever undergone  
10 any of the following cancer treatments to help reduce  
11 or control the spread of your lung cancer? And include  
12 your current treatments. So chemotherapy, radiation  
13 therapy, surgery to remove the tumor or any part of the  
14 lung; targeted drug therapies, something else; or if  
15 you have not undergone any cancer treatments; or if  
16 you're not sure. And choose all that apply. I think  
17 that button works. I think you can choose more than  
18 one.

19                           (Answering question.)

20           DR. EGGERS: Okay. It looks like folks are  
21 done. Okay, if we can move on. So it looks like we  
22 have a wide range of perspectives, a little bit of

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

111

1 everything except no one here has not undergone any  
2 treatments, and I think that that is important to  
3 acknowledge, that the discussion here today may not be  
4 fully representative of the whole population, so  
5 especially for those of you on the web or for the  
6 advocates or when you talk to your peers to submit to  
7 the docket those perspectives.

8           Okay. And on the web, can we just know what  
9 the common was? Or were they all generally mentioned?

10           MS. FURIA-HELMS: All very similar in  
11 response with the most being chemotherapy.

12           DR. EGGERS: Okay. So we want to talk about  
13 some of those, and I'll turn to my colleagues at some  
14 point to make sure that we've covered sort of the major  
15 benefits you see and the downsides you see of these  
16 treatments. And I suppose we'll take each one in turn.

17           Let's start with chemotherapy, understanding  
18 that we talked a lot about this in the first  
19 discussion, so if there is something -- we don't need  
20 to elaborate on specific things from that, but maybe if  
21 you think about these treatments that you're on, what  
22 might be surprising to FDA to know about that you see

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

112

1 as a benefit of a particular treatment? And it can be  
2 not just how effective that treatment is, but other  
3 aspects of the treatment that you think are very  
4 beneficial, and similarly the downsides. So with  
5 chemotherapy, is there anything that anyone would like  
6 to highlight as the real -- a benefit or a good thing  
7 about the chemotherapy generally speaking?

8 Yes?

9 MS. SKAMBIS: Well, I mean, the obvious  
10 benefit of chemotherapy is it keeps the cancer from  
11 recurring or it shrinks the tumor, so you have to  
12 mention that.

13 DR. EGGERS: Point taken.

14 Let's move on to --

15 Yes, go ahead, Karen.

16 DR. ARSCOTT: I would just like to comment.  
17 So the chemotherapy -- and, again, I had a significant  
18 amount -- in my research and what I believed was  
19 drinking a lot of water -- and even though I was  
20 nauseous, so whenever I wasn't nauseous, which wasn't  
21 often, I would just drink as much water as I could, and  
22 so although I had two platin agents, I never bumped my

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

113

1 BUN and creatinine, and I think that that had a lot to  
2 do with the fact that I didn't maybe have as much  
3 trouble with -- even though I had very significant  
4 chemotherapy, I didn't have -- and it's impressed upon  
5 patients as much.

6 I talk to a lot of patients about making sure  
7 that they drink water whenever they're not sick, and I  
8 think that that's something that should be brought out,  
9 that I think that it's very, very important, and that  
10 tea and coffee and soda and such is not the same, and  
11 that we really should be asking our patients to drink a  
12 lot more water when they're getting these very toxic  
13 agents.

14 DR. EGGERS: Okay. Are there any downsides  
15 to the treatment that haven't been mentioned that you  
16 think might be surprising to FDA about chemo that you  
17 want to highlight here?

18 Yeah, Montessa?

19 MS. LEE: I know they probably know this, but  
20 cisplatin, the hearing loss, because I had terrible  
21 ringing in my ears, and they actually had to switch me  
22 to carboplatinum because of the -- and I still have

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

114

1 some ringing in my ears at times from the cisplatin.

2 DR. EGGERS: Is the ringing in the ears -- we  
3 didn't mention that as a symptom -- if you feel  
4 comfortable raising your hand, has anyone experienced  
5 that as well?

6 (Show of hands.)

7 DR. EGGERS: Okay. Oh, I'm sorry, Denise.

8 MS. HOGAN: I don't have the ringing in my  
9 ears, but I have lost hearing.

10 DR. EGGERS: Hearing, okay.

11 MS. HOGAN: Yeah. And I wasn't aware of it  
12 until just recently.

13 DR. EGGERS: Anything else about the  
14 downsides or about chemotherapy that you want to  
15 highlight?

16 (No audible response.)

17 DR. EGGERS: My colleagues, do you have any  
18 specific questions about that?

19 Yeah, Shakun.

20 DR. MALIK: No, I don't have a question, I  
21 just wanted to follow up a comment on Karen. She had  
22 raised the question that, you know, I don't know

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

115

1 whether I should have mentioned the targeted therapies  
2 or not, and that there has been nothing done about it,  
3 I just wanted to mention that there is going to be NCI-  
4 driven protocols where they are going to actually  
5 patients who have had resected lung cancer and will be  
6 checked with a targeted -- if they have targeted -- you  
7 know, abnormalities, then they will be given a  
8 maintenance therapy, so that is coming.

9           I also wanted to mention that, again on your  
10 comment, is that there had been a long delay in the  
11 research for lung cancer, and that delay has been  
12 because of the stigma that has been attached to it for  
13 many years. There was really decades nothing going on  
14 in the research, and we don't have survivors, so we did  
15 not have any going to the Hill and asking for research  
16 money.

17           And then I started working for lung cancer  
18 patients. I remember that a few years ago that even my  
19 colleagues would say, "Well, we don't feel sorry for  
20 your patients because they did it to themselves," but  
21 it really took a while for people to realize that there  
22 are 20 percent of the patients who have never smoked,

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

116

1 and as you mentioned, more than 60 percent have quit  
2 smoking and they develop lung cancer.

3           So, again, I am very happy and we are all  
4 from FDA very happy that now that we do have research  
5 going on and we do have a lot of focus on lung cancer,  
6 so what your question is that it will be hopefully  
7 shortly answered.

8           DR. EGGERS: Yes, Lorren.

9           MS. SANDT: One perspective from one of the  
10 patients was that she had gone through two rounds of  
11 chemo before her mutation changed and she finally got  
12 that genetic test that made a difference, and now she's  
13 completely clear after Stage IV, so the genetic testing  
14 is really important, that it maybe happens before  
15 people go through all those rounds of chemo and make  
16 that happen, although the cost of that is for future  
17 discussion.

18           DR. EGGERS: The cost will be outside the  
19 scope of our discussion today.

20           Let's talk about the targeted therapies and  
21 see if you want to comment on your thoughts, your  
22 experiences, perspectives, on those for those of you

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

117

1 who have tried those. We heard some from the panel,  
2 but I know others out here have done that. Do you want  
3 to raise any what you've seen as maybe less obvious of  
4 the benefits of those targeted therapies for you?

5 MS. WARMERDAM: I would say probably the  
6 biggest benefit is that the side effects probably  
7 aren't as bad as traditional chemo except that there is  
8 no end date. We're on targeted chemotherapy every day  
9 basically for the remainder of our lives or until we  
10 stop responding to that drug. So it's not where  
11 chemotherapy ends and then our energy comes back and we  
12 don't have diarrhea anymore, you know. So I just  
13 wanted to point that out. I don't know how many people  
14 realize that it's an ongoing treatment.

15 DR. EGGERS: Thank you. Thank you, Susan.

16 Anyone else want to make any comments about  
17 the targeted therapies?

18 (No audible response.)

19 DR. EGGERS: Okay. Any follow-up questions?

20 (No audible response.)

21 DR. EGGERS: Okay. Let's take anything about  
22 treatments because I want to make sure we get on to

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

118

1 other topics. Anything about treatments that you would  
2 like to say?

3 So we have Kathleen and then over there.

4 MS. SKAMBIS: Myself and the people that I  
5 represent, several of them have said that they would --  
6 decisions about what kind of treatments that you're  
7 going to make change depending on how the treatment  
8 affects you, depending on whether it's functional and  
9 whether it's shrinking the tumors, and that has  
10 happened not so much with these people who responded  
11 but people who we have known who have lost their  
12 struggle. And various people, the side effects differ,  
13 even with the same chemotherapies. Some people will  
14 have horrible neuropathy, and some people won't have  
15 any neuropathy, and the fatigue, and that all varies.

16 And one of the things they wonder and one of  
17 the things we all think would be beneficial is in  
18 addition to typing the tumor, is it so that you know  
19 how the particular tumor is going to respond to the  
20 chemotherapy agent, is it possible to get other genetic  
21 information so that you have a better idea of what the  
22 side effects are going to be for these various

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

119

1   chemotherapies so that you can make a decision before  
2   you suffer some of these horrible side effects?   And  
3   that is a focus of research and a focus of medication  
4   that people would very much like to see.

5               DR. EGGERS:   Okay.   And can you state your  
6   name?

7               because I've forgotten it.

8               MS. ADKINS:   Thank you.   It's Donna.   And I  
9   would like to address the surgery to remove the tumors.  
10   In our case, our daughter that was 26, because doctors  
11   were not educated and because of her young age of being  
12   diagnosed, they were taking her lung.   Because I am  
13   adamant about getting second opinions and we got that  
14   from Mayo Clinic, her lung was saved, and they removed  
15   just the tumor.   Her outcome of life at age 26 is very  
16   different with them just removing the tumor, while she  
17   has chronic pain and other issues, versus what her  
18   outcome would have been if they would have taken her  
19   entire right lung.

20              And so I think the type of surgery and  
21   education and not again looking at the fact that  
22   because she was not a smoker and because she was so

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

120

1 young that this was not a possibility for her.

2 Education and just understanding that this disease is  
3 hitting more and more young people every day. She has  
4 met online through chats several other women who at the  
5 same age have this same diagnosis with no explanation.  
6 There is not a precursor for her having an atypical  
7 type of cancer. She didn't smoke, she wasn't around  
8 any chemicals, there is nothing there. And so I think  
9 doctor education and also patient education to  
10 understand what is right for the patient when it comes  
11 to the surgery and removal of the tumor.

12 DR. EGGERS: Thank you, Donna. We'll be  
13 getting into more of the considerations on decision  
14 making, so you'll have plenty of time to do that.

15 Andrea, do you have something about  
16 treatment?

17 MS. FERRIS: Andrea Ferris from Longevity  
18 Foundation. So I'm here both as a patient advocate but  
19 also as a caregiver. My mother passed away 5 years ago  
20 from lung cancer, and her treatment decisions were  
21 largely driven by the doctor, but she did participate  
22 in clinical trials. And I think John mentioned, and,

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

121

1 Stephanie, you did as well, many of our members that we  
2 represent similar to yourselves have very, very similar  
3 stories, where they're willing to undergo anything to  
4 make it to that next treatment.

5 I was having a dialogue during the break. I  
6 think that this has somewhat changed since crizotinib  
7 has been approved because you do see people who have  
8 been through multiple lines of therapy and then all of  
9 a sudden they were tested for a mutation and now their  
10 lives have transformed. So this has inspired people  
11 who are undergoing treatments and survivors to hang on  
12 until that next one because they, too, might have that  
13 mutation or that gene, and so I think that the tradeoff  
14 between what you're willing to endure in order to reach  
15 that silver bullet, that dynamic has changed in recent  
16 years, and so just take that into consideration as well  
17 when doing the whole risk-benefit tradeoffs of what  
18 really is a benefit and what really is a risk.

19 The other thing with what is the clinical  
20 trial paradigm. You know, many people talk about you  
21 can't enroll patients in clinical trials. Well, when  
22 85 percent of your patients are diagnosed Stage IV with

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

122

1 brain mets, you know, metastases, they don't qualify.  
2 So how can we change? because there is great medicine  
3 going on out there. I mean, we've seen now 12 known  
4 mutations have drugable targets if you have one of  
5 them, and if you don't have a mutation, there are  
6 immunotherapies coming out. There is a lot of great  
7 science out there for lung cancer that didn't exist 5  
8 years ago, but how can we get more patients to have  
9 access to that? And is there a way of changing the  
10 clinical trials -- and this might be a topic for  
11 different discussion -- such that you can enroll high-  
12 risk patients in a satellite trial that doesn't  
13 influence the registration trial so that industry is  
14 more apt to allow these patients onto the clinical  
15 trial as well?

16 DR. EGGERS: Pat, would you like to follow  
17 up?

18 DR. KEEGAN: So I do want to clarify. Often  
19 the very early trials try and get a homogenous  
20 population of patients just so they can do the right  
21 dose-finding studies and determine that, but beyond  
22 that, there really is no restriction other than that

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

123

1 which are necessary to be able to address the question.  
2 So we actually do have trials ongoing with patients  
3 with brain metastases, and I think that there is really  
4 no barrier to that other than the barrier of what the  
5 drug developer might want to do. So there is not any  
6 regulatory barrier to that.

7 MS. FERRIS: Then it's a practice because  
8 that's very different than many of our constituents are  
9 faced with, where they're told repeatedly they're not  
10 eligible. So I think it's a different --

11 DR. KEEGAN: No, no, they may not be eligible  
12 for a particular trial, but that is not because of a  
13 regulatory barrier, and it may be an educational effort  
14 that needs to be undertaken. There is no reason why  
15 those patients can't be studied. I think there is a  
16 lot more openness, particularly now as we get to some  
17 of the targeted therapies that we know -- cross blood-  
18 brain barrier and other places -- to do that. So  
19 that's not really an issue.

20 I also wanted to bring up -- and I don't know  
21 if he's -- oh, Diko is still here -- that the issue  
22 about differences in toxicity and side effects and

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

124

1 things like that, you know, that there is a focus on  
2 evaluating patients and how patients handle and  
3 metabolize drugs in order to determine whether or not  
4 there are optimal ways of dosing them to avoid side  
5 effects if possible. And there is also a lot of  
6 information on drug interactions, which are probably  
7 even a bigger issue for when patients are exposed to a  
8 higher dose than necessary. But one of the things is  
9 whether or not people are paying attention to those  
10 efforts as we try and describe that in product  
11 labeling.

12           So maybe one of the issues that could be  
13 brought in to the document -- to the docket, rather, on  
14 this is, to what extent do we need better educational  
15 efforts to talk to prescribers about looking at those  
16 aspects of product labeling to make sure that they're  
17 using drugs optimally? And is there a need to look  
18 into that to educate further on that so that optimum  
19 dosing is provided for patients? because I think that  
20 may be helpful as well.

21           DR. EGGERS: Thank you, Pat.

22           I can see that the conversation is going

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

125

1 quickly into the decision making aspects of it, and  
2 that is important. It's important for FDA, and I can  
3 see that it is very important for you. So I'm going to  
4 keep us going and move on so we can get to that topic  
5 because we have to do these polling questions in order,  
6 so I have to ask the next one. It's a very important  
7 question.

8           So save your comment, Susan, and we'll come  
9 back to it.

10           So we talked about treatments. I think we  
11 got a lot about the specific good and bad of the  
12 treatments.

13           One thing we wanted to know was -- if we can  
14 go to the next polling question -- besides your cancer  
15 treatments, we wanted to just get a sense for what  
16 other therapies you have taken or are currently taking  
17 to manage any symptoms that you experience because of  
18 your lung cancer or because of your lung cancer  
19 medications: pain medications, steroids, supplemental  
20 oxygen, breathing exercise or relaxation techniques,  
21 dietary supplements or other diet changes,  
22 complementary or alternative therapies, something else

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

126

1 that's not mentioned, or you're not doing anything to  
2 treat symptoms. And for those of you who had more  
3 symptoms in the past, think about what you did in the  
4 past.

5 (Answering question.)

6 DR. EGGERS: And while you're thinking about  
7 this, to foreshadow, we'll highlight just a few of the  
8 most important ones, but we would like to know  
9 generally, are these therapies helping your symptoms?  
10 Are they addressing the symptoms? And then we'll  
11 follow up with a question about what symptoms are still  
12 remaining that are most significant that you would like  
13 to see in your experience better managed for yourself.

14 So with that, we'll move on to the results of  
15 this. It looks like that there is again a wide range,  
16 lots of things being taken, particularly pain  
17 medications, steroids, breathing techniques, the  
18 dietary supplements, and the complementary medicines as  
19 well.

20 And on the web, do we have generally the  
21 same?

22 different?

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

127

1 MS. FURIA-HELMS: The two top that are neck-  
2 and- neck is breathing and relaxation and dietary  
3 supplements, and then following pain medications.

4 DR. EGGERS: Okay. So I think we're hearing  
5 about a lot of nondrug therapies being tried here.  
6 Would anyone like to highlight something that hasn't  
7 been yet mentioned that is really working for them?  
8 We've talked about water, we've talked about getting  
9 the rest. Anything else that's really working?

10 DR. ARSCOTT: I would just like to comment on  
11 after my surgery, my second surgery, at that point I  
12 had read about yoga, and I knew a yoga instructor, who  
13 -- it was a gentle yoga, not like hot serious yoga, but  
14 like a gentle yoga. And yoga improves pulmonary  
15 function, and so I did yoga -- I started yoga three  
16 weeks postop and did it until I was able to do it on my  
17 own, and I think that's a beneficial thing for people  
18 who are undergoing any kind of pulmonary issues. We  
19 know that yoga improves pulmonary function, but you  
20 have to be careful that you go to the right yoga  
21 instructor and that it's someone that you can trust.  
22 Maybe talk to a lot of different people, but it is

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

128

1 good.

2 DR. EGGERS: Thank you, Karen. Anyone else?

3 Lorren?

4 MS. SANDT: So one patient, the first time  
5 they went through chemo, they did acupuncture after  
6 their chemo, and then the next time around they did it  
7 before their chemo, and they noticed a huge difference  
8 in side effects and how they felt going through  
9 chemotherapy when they did their acupuncture right  
10 before their shot versus after.

11 DR. EGGERS: And that's for pain management.

12 MS. SANDT: All of her side effects were  
13 improved.

14 DR. EGGERS: Anyone else?

15 Yes, Denise.

16 MS. HOGAN: I think it's a mind-body  
17 connection. I think I may be in a "Pollyanna" state by  
18 saying I don't have cancer, I'm not going to have  
19 cancer. I think it helps. I also think just the  
20 basics, you know, getting rest, eating properly,  
21 exercise, and just not giving in -- I've learned to say  
22 no, which has been very hard for me. It's really

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

129

1 taking care of yourself. It's not being selfish,  
2 you're taking care of yourself, and people appreciate  
3 you more once you do that.

4 DR. EGGERS: Thank you, Denise.

5 Oh, yes, Marie.

6 MS. SMITH: I'm Karen's mother, and I see  
7 something that's missing: positive attitude in just  
8 being happy, as happy as you can be. We're living  
9 today, and we're going to get better because she had a  
10 positive attitude and worked hard. So I think that's  
11 one of the good things.

12 DR. EGGERS: Thank you, Marie.

13 So let's talk about then the symptoms that  
14 remain that aren't being addressed as well as you would  
15 like in your experience. And on the web, I'm going to  
16 put a call out for this, too, if you would like to  
17 answer this question, we'll try to summarize this after  
18 the public comment period. Is there anything that  
19 still remains that you wish you could, in your  
20 experience, have had better managed?

21 Karen.

22 DR. ARSCOTT: So, yeah, I have a symptom that

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

130

1 I still have now that's really a little frustrating to  
2 me, and I believe it's due to the radiation. I have  
3 excessive mucous, and it's produced predominantly if  
4 I'm exposed to cigarette smoke, so I have to hold my  
5 breath if I'm near smokers, but it's really -- so I was  
6 doing a medical mission in Haiti, and there were some  
7 other people there, and one of them was smoking outside  
8 the sleeping quarters, and in the middle of the night I  
9 woke up feeling like I was going to drown. And so I  
10 have spoken to my radiation oncologist and different  
11 people about treatment for this, and he said I could  
12 use a steroid inhaler, but it probably really -- and I  
13 tried it and it didn't help.

14           And so I'm five and a half years out, and I  
15 still have this, and people who are around me know that  
16 if I'm exposed to it, I feel like I can't breathe, I  
17 just like literally feel like I'm drowning in mucous,  
18 and there doesn't seem to be anything for that. So I'm  
19 kind of learning to live with that, but it is a problem  
20 that I've talked to other people and they have a  
21 similar symptom.

22           DR. EGGERS: Okay. Thank you. Anyone else?

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

131

1           Yes. Go ahead, Sheila.

2           MS. ROSS: Yeah, I just thought of this, and  
3 I had forgotten about it, but on the two surgeries I  
4 had, they were both on my right side, and they were the  
5 same incision, the same everything, the same doctor,  
6 the same hospital, it was really kind of bizarre, but  
7 on both occasions -- and with this surgery, you're like  
8 this -- (Indicating.) -- during the three- or four-hour  
9 surgery, and on both occasions no one thought to say,  
10 you know, your shoulder is going to hurt, and a steroid  
11 shot will really help. And it was just this old doctor  
12 who I happened to meet at a party, actually, and I told  
13 him I just couldn't get rid of this pain in my  
14 shoulder, he said, "All you need is a steroid shot,"  
15 and it was like a miracle. So anyone going out for  
16 surgery, please tell them to give you a steroid shot  
17 afterwards.

18           DR. EGGERS: I see a lot of laughs and head  
19 nods. Is this the experience shared by others?

20           (No audible response.)

21           DR. EGGERS: Okay. Anyone want to talk about  
22 something that's not being addressed?

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

132

1 (No audible response.)

2 DR. EGGERS: My colleagues, before we move on  
3 to the considerations on decision making, anything  
4 about these symptomatic treatments that you want to  
5 ask?

6 DR. BLUMENTHAL: I had a question about  
7 specifically the steroids. Do you ever feel like the  
8 dose of steroids is too high and you would like to  
9 titrate that dose down?

10 DR. EGGERS: Okay. Lorren, do you want to  
11 explain?

12 MS. SANDT: Well, it's not much of an  
13 explanation, but, to a T, it was I hate steroids.

14 DR. EGGERS: Kathleen.

15 MS. SKAMBIS: Well, and I'll have the  
16 counterpoint to that, which was I don't know if they  
17 could have been lower, and I did have side effects from  
18 them, but I know I, too, threw the kitchen sink with  
19 chemotherapy at my cancer, and they helped me  
20 tremendously with some of the other side effects.

21 DR. EGGERS: All right. Let's move on to  
22 talk about focusing on that decision making. We've

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

133

1 alluded to many points, and we'll be revisiting those.  
2 So we want to hear your perspective and experience with  
3 regard to your decisions, and we heard such courageous  
4 decisions explained up here. So I'm going to pose a  
5 general question about when thinking about your -- you  
6 know what? I'm going to stop there. I'm going to go to  
7 the polling question because I think we'll get to hear  
8 all the factors at once, and then we can address this  
9 tradeoffs question.

10           So on the web and in here, this is a very  
11 important question. There are many factors that go  
12 into the decision, and we put six up here that FDA is  
13 particularly interested in understanding how they  
14 factor into your decisions, so of the following  
15 factors, which two would you rank as most important to  
16 your decisions about using treatments to help reduce or  
17 control the spread of your lung cancer? And as you  
18 think about it, you've made many decisions and you will  
19 make future decisions, so you can think about this sort  
20 of generally as the two factors that would or have or  
21 are factoring most into your decisions: whether the  
22 treatment is expected to help relieve the symptoms that

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

134

1 you experience; whether there is a small but  
2 significant risk of serious side effects, such as blood  
3 clots or kidney failure that could lead to  
4 hospitalization or even death; how long the treatment  
5 would probably prolong my life, so there we're talking  
6 about what's expected to happen; how long a treatment  
7 could possibly prolong my life, so for longer than  
8 expected; what are the expected side effects of the  
9 treatment, such as nausea, loss of appetite, et cetera;  
10 and all sorts of things about how the treatment is  
11 administered, such as how long the treatment takes, if  
12 you have to take it for the rest of your life or  
13 whether it requires hospitalization, doctor visits, et  
14 cetera.

15 (Answering question.)

16 DR. EGGERS: I know this is a hard question  
17 to throw at you. There is no right or wrong answer,  
18 it's just for discussion purposes.

19 All right, so let's go on. How long the  
20 treatment would probably prolong my life is the most  
21 raised thing, although they were all mentioned except  
22 how the treatment is administered and the small but

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

135

1 significant risks of serious side effects.

2 Can I ask, Andrea, on the phone what the most  
3 common ones were?

4 MS. FURIA-HELMS: The two most common that  
5 were equal was how long the treatment would probably  
6 prolong my life and how long the treatment could  
7 possibly prolong my life for longer than expected.

8 DR. EGGERS: Okay. All right. And so we'll  
9 keep this in mind. I have a -- Chad, if we go to the  
10 next question, will we be able to come back to this one  
11 and look at the answers?

12 CHAD: (Off mic.)

13 DR. EGGERS: Okay, so we can go back and look  
14 at the answers.

15 So then let's ask the next question just so  
16 we have the full context. And of those same factors,  
17 which one would you rank as least important to your  
18 decision about using treatments to help reduce or  
19 control the spread of your cancer?

20 Yes, Kathleen.

21 MS. SKAMBIS: Since nobody picked 6, do you  
22 want to eliminate 6?

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

136

1 DR. EGGERS: To eliminate -- well, we have to  
2 leave it so you can just -- how the treatment is --

3 DR. MALIK: Can I reword this Number 6?

4 DR. EGGERS: Yes.

5 DR. MALIK: So instead of saying how long the  
6 treatment is, I would also ask the question whether  
7 it's oral or IV. Will that make a difference? Or  
8 going to the doctor every three weeks to get the IV  
9 treatment versus taking a pill and going home and  
10 coming and seeing the doctor once a month or something  
11 like that. Just keep that in mind when you are  
12 answering that question.

13 DR. EGGERS: Okay. So let's leave the  
14 question as is, but then we can come back and talk  
15 about what the next one would be for you if that one is  
16 your least important.

17 (Answering question.)

18 DR. EGGERS: Okay, we're still getting some  
19 responses. Okay, I think that's the same number we had  
20 last time.

21 So overwhelmingly Number 6, how the treatment  
22 is administered, although we do have some indication

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

137

1 that the other ones are taken into account, whether the  
2 treatment is expected to help relieve symptoms, the  
3 risk of side effects -- I'm sorry, the risk of serious  
4 side effects, and those expected side effects, the more  
5 common ones. Okay.

6 And on the web, Andrea?

7 MS. FURIA-HELMS: Very similar.

8 DR. EGGERS: Okay. All right.

9 So let's go back to those most important  
10 ones. We don't need to come back to this finding, but  
11 can we go back to the previous one? Okay, it doesn't  
12 give the findings. There we go. This is all new  
13 technology that we're trying out here.

14 So does anyone want to explain their  
15 response?

16 Yes.

17 MS. SKAMBIS: I'll just say on the forms that  
18 I got back, the questions that people answered, they  
19 did address that they would want to know what the very  
20 serious but small likelihood side effects would be, but  
21 overwhelmingly it had to do with prolonging life or  
22 shrinking the tumor, which were kind of equated.

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

138

1 DR. EGGERS: And was there anything specific  
2 about their situation that you would attribute that to,  
3 any factors that went most into that judgment?

4 MS. SKAMBIS: It was young people and older  
5 people, so, no, but you've mentioned that our  
6 experiences in this room are not necessarily reflective  
7 of all lung cancer patients, and I think that's true,  
8 but I think it's true in large part for the reasons  
9 that Marie said, which is most of the people who are  
10 participating here and who are in contact with us as  
11 survivors or as support personnel are people who do  
12 have a good attitude, you know, who do have hope, and  
13 so in that sense, it is a nonrepresentative sample.

14 DR. EGGERS: Okay. Then I'm not going to ask  
15 the question now, but I'm going to seed it in the minds  
16 of the advocates to think about as you think about the  
17 people who aren't here today, how their experiences  
18 might be different. So I'm going to call on the  
19 advocates in the room as we go through the remainder of  
20 this discussion, and if you can try to pull in and give  
21 that other perspective of voice as well, the other  
22 experiences.

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

139

1           What about the tradeoff, any more about the  
2 tradeoff, between the importance of prolonging life  
3 versus making it as comfortable as possible?

4           MS. SANDT: So with the patients that I  
5 talked to, two were very young, one had children, one  
6 didn't, and one was older, and really it was about the  
7 young lady with children, it was just, "Keep me alive  
8 to see my grandchildren," that was her whole goal. She  
9 didn't care about anything else, just, "Keep me alive."  
10 She could deal with all the side effects, she didn't  
11 care.

12           DR. EGGERS: Amy?

13           MS. COPELAND: Just to give the perspective  
14 of another advocate who we worked with for a long time  
15 who unfortunately passed away earlier this year, when  
16 she was dealing with her second recurrence, she had  
17 surgery her first case of lung cancer, surgery a second  
18 time, was going through chemotherapy, third time she  
19 was unable to go through surgery again because of  
20 invasion of the chest wall, but it was still fairly  
21 localized, it hadn't spread anywhere else in her body,  
22 but she got to the point where the chemotherapy drug

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

140

1 that she was taking was so debilitating that she  
2 couldn't get out of bed, she was in so much pain, she  
3 couldn't walk, and she and her husband had plans to go  
4 on a cruise about a month or two later. So she actually  
5 made the choice to go off treatment and go into hospice  
6 because her quality of life was so bad that she wasn't  
7 even going to be able to go on this cruise with her  
8 husband, and she came to us at Lung Cancer Alliance and  
9 she kind of said, "Is that a bad decision?" and she  
10 really questioned that decision because there is so  
11 much pressure to do whatever it takes, and she was  
12 making this choice because of quality of life, and we  
13 reassured her that it was she felt was best for her was  
14 the important thing.

15           And the good news is she and her husband --  
16 she was well enough to go on that cruise, and she and  
17 her husband had the most amazing time, and we got to  
18 hear about it, but it was really difficult for her to  
19 make that decision, she had gone through so much, but  
20 she literally could not get out of bed, and she wasn't  
21 living, so she had to make that choice.

22           DR. EGGERS: Thank you very much, Amy.

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

141

1           And I'm going to ask Denise also to think  
2 about this because there is a point that's being made  
3 about where maybe the factors were one way before the  
4 decision about treatment was made, and those factors  
5 shifted while you were on treatment or after you  
6 experienced treatment. And Denise raised it and now Amy  
7 is raising it. Would anyone else like to follow up on  
8 that and share an experience of themselves or someone  
9 else who had a similar experience where they discovered  
10 that their priorities might be shifting?

11           MS. SKAMBIS: There was another women in our  
12 group, and I think who was super optimistic, much like  
13 the person just described, and did a number of  
14 treatments and was determined to beat it, and at some  
15 point it wasn't really working, and even though she  
16 could have kept trying different treatments, she really  
17 lost hope, and I think at some point even the most  
18 optimistic among us have faced some sort of reality  
19 that tells you -- and when you know that ultimately  
20 you're not going to be cured, her decision was to  
21 forego treatment as well, and then she gathered her  
22 family and went to the beach, and she had a wonderful,

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

142

1 wonderful last month of life.

2           And so, yeah, I think that decisions do  
3 change. And most people who filled out this form and  
4 said, "Prolonging life is the most important said, but  
5 then again, I have symptoms I can manage; if I didn't,  
6 my choice might be different."

7           MS. WARMERDAM: Yeah, and I'll kind of  
8 piggyback on that a little bit, too, because being on  
9 Tarceva, I live a pretty comfortable life right now,  
10 but I would be willing to be more uncomfortable to  
11 prolong my life, but it's easy to say. I feel good.  
12 Until I don't feel good anymore, and then, yeah, maybe  
13 then my priorities would change, my decisions would  
14 change.

15           DR. EGGERS: Go ahead, Donna.

16           MS. ADKINS: I just wanted to bring a point  
17 that hasn't been said, and that's the patient's  
18 pressure from family members. I had a friend that died  
19 5 weeks after diagnosis at age 74. Her children all  
20 lived out of state, so I took care of her, they came.  
21 She knew that she was dying, that they didn't catch it  
22 in time, but yet she still undergone chemotherapy and

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

143

1 actually had a treatment two days prior to her death  
2 because she didn't want to disappoint the children, and  
3 the children wouldn't let her make that decision to  
4 stop treatment and have a quality of life, and this is  
5 a woman who volunteered for the American Cancer Society  
6 for over 15 years and was a hospice volunteer, so she  
7 understood quality versus quantity of life, and she so  
8 wanted to stop the treatments, but felt pressured from  
9 her family not to stop the treatments.

10 DR. EGGERS: Thank you, Donna.

11 Anyone else?

12 Yes, go ahead, Denise. And then we'll go to  
13 Shelley.

14 MS. HOGAN: It does depend on a lot of  
15 things. My children are in their forties; my  
16 grandchildren are teenagers. So quality of life, you  
17 know, I don't have to worry about taking care of  
18 children anymore. I had the chemo as precaution. They  
19 told me I had no more cancer, so I was having an  
20 extremely difficult time taking chemo when I didn't  
21 have cancer anymore. So it might be different if I had  
22 cancer and that was the only cure, but I still believe

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

144

1 in the quality of life and extending someone's life so  
2 they can lay in bed is not something I would choose.

3 DR. EGGERS: Shelley?

4 MS. FULD NASSO: I think a couple of the  
5 points that were raised go to the importance of having  
6 supportive care along with active treatment, you know,  
7 from the beginning, and the study by Jennifer Temel and  
8 others a couple of years ago that showed with Stage IV  
9 lung cancer patients that having the supportive care,  
10 while it doesn't mean deciding I'm giving up and I'm  
11 not going to try to beat this, it was offered alongside  
12 the active treatment, and it both extended life and  
13 reduced some of the symptoms and improved the quality  
14 of life.

15 I think, though, to your point, you may have  
16 this resolved, that I'm going to do whatever I can, but  
17 at a certain point that calculation may change and  
18 you've had enough, and I think it's tough when a  
19 patient doesn't feel comfortable saying to their  
20 family, "I've had enough and I'm okay, I know what's  
21 happening, and I'm okay with it," and I think that  
22 happens too often where patients are having toxic

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

145

1 treatments in the last few weeks of their life because  
2 they didn't have that supportive care and that help in  
3 the decision-making process to understand when to  
4 transition to more of just a palliative care. And that  
5 happened, my best friend died last year of kidney  
6 cancer, and 10 days before he died he said to his  
7 oncologist -- and he was a physician himself, so he  
8 understood -- he said to his oncologist, "I think it's  
9 time for hospice," and his oncologist said, "Well, I've  
10 never had a patient throw in the towel after just one  
11 line of therapy," and the man was obviously -- he was  
12 in the hospital very, very sick and obviously dying,  
13 and he didn't even get the support from his oncologist  
14 that it was okay. So he did go, he had a scan a couple  
15 days later that showed how extensive the cancer was,  
16 and he went home, and had about a week at home in  
17 hospice, but he could have had a much more comfortable  
18 last few months of his life if he had better supportive  
19 care.

20 DR. EGGERS: Thank you.

21 From my FDA colleagues, anything about these  
22 factors that you want to know more about their

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

146

1 thinking?

2 (No audible response.)

3 DR. EGGERS: Okay. Let's talk about the one  
4 -- so how treatment is administered was the least  
5 raised. Is there something else on this list of the 1  
6 through 6 that if you picked that one as the least,  
7 what would be your second least? Or for those of you  
8 who didn't pick the administration as your least and  
9 you want to explain why one of the other factors -- I  
10 don't think we get to go back to it now -- but why one  
11 of the other factors on this list was not as important  
12 to you?

13 MS. FULD NASSO: I would say that I think  
14 that how treatment is administered -- I mean, I think  
15 people are willing to do whatever it takes, but if we  
16 had treatments that were a little easier to administer,  
17 and especially I think in the case of my father-in-law,  
18 who I said lives in a rural area, and getting to  
19 treatment would be very challenging for him. If he had  
20 the option of an oral medicine that he could take from  
21 home, he might be more likely to consider it. So I do  
22 think it would be a factor for him, but I think because

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

147

1 there are a lot of factors at play, I think part of it  
2 is your proximity to a medical center where you can get  
3 the treatment that you need.

4 DR. EGGERS: What about the small but  
5 significant risk of serious side effects? Anyone want  
6 to comment on their thinking about that?

7 (No audible response.)

8 DR. EGGERS: What about the difference  
9 between probably prolong my life versus possibly  
10 prolong my life? Has anyone put -- was that a  
11 consideration to them, that difference between what's  
12 expected? I know we heard about it on a panel, between  
13 what's expected and what possibly could happen and how  
14 you thought about that?

15 (No audible response.)

16 DR. EGGERS: Okay. Then I think let's move  
17 on unless anyone has anything else to say about these  
18 factors in their decision making. We have a couple  
19 scenarios that we would like to put up and explore, and  
20 this is how FDA thinks about these types of things.

21 Can we go on to the next slide? One more  
22 slide.

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

148

1           There are a couple of scenarios, and we're  
2 just putting these up just to get your thoughts and  
3 your reactions to these types of scenarios. We're not  
4 looking for decisions to be made. But getting your  
5 thoughts will be helpful in getting your perspective as  
6 FDA thinks through these decisions.

7           And so the first scenario is that there is a  
8 Drug X. It's a chemotherapy drug being developed for  
9 patients with metastatic non-small cell lung cancer  
10 studied in a clinical trial comparing the standard of  
11 care chemo plus Drug X versus just standard of care  
12 alone. And the clinical trial showed that the addition  
13 of Drug X prolonged survival on average by 2 months.  
14 The median survival was 12 months for Drug X plus  
15 standard of care versus 10 months on standard of care  
16 alone. In addition to the toxicities related to the  
17 standard of care chemo, patients treated with Drug X  
18 had more diarrhea and rash and had more rare but  
19 serious toxicities such as liver injury and lung  
20 inflammation.

21           Is this a clear scenario? Are there any  
22 questions about the scenario?

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

149

1 (No audible response.)

2 DR. EGGERS: Any first reactions, just things  
3 that come to mind as you see this, as you hear it?  
4 Lorren, I see you shaking your head. So can  
5 we --

6 MS. SANDT: Yeah. Two months longer with  
7 potentially rare or serious side effects? It's not  
8 enough of a tradeoff.

9 DR. EGGERS: Anyone else want to follow on  
10 this?

11 Yes.

12 MS. PHANG: I just think that when my liver  
13 function went up on Tarceva, they dropped the dose  
14 down, so sometimes you can make a decision taking  
15 something and they can make an adjustment that you  
16 don't have to have it be so clear-cut.

17 DR. EGGERS: Thank you, Ruth.

18 Any other thoughts?

19 Stephanie?

20 MS. HANEY: Yes, but half the patients got  
21 more than that 2 months, so some of them might have  
22 gotten 3 years.

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

150

1 DR. EGGERS: Okay. Anyone want to follow up  
2 on anything else?

3 Kathleen?

4 MS. SKAMBIS: I'm with Stephanie.

5 DR. EGGERS: Yeah. Okay. Do you want to  
6 explain more about this? Any other thoughts about this  
7 to expand upon that?

8 We'll let Diko ask a follow-up question.

9 DR. KAZANDJIAN: I'm sorry. So I just want  
10 to add along with those patients that may have lived 3  
11 years longer, some of those patients actually died of  
12 liver failure and inflammatory lung disease, so  
13 something just to keep in mind. And, of course, if you  
14 don't have that, you're happy and you're glad that you  
15 took the medicine, but if you had that side effect --  
16 and this was brought up a bunch of times -- we can't  
17 predict that unfortunately.

18 DR. EGGERS: So what's your thinking about  
19 all of this, about how these tradeoffs?

20 Kathleen.

21 MS. SKAMBIS: Well, and I could get hit by a  
22 car crossing the street or I could choose to jump out

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

151

1 of an airplane because I think that's something that I  
2 want to experience before I die, and my chute might not  
3 open. I mean, there are those -- for me, if I'm  
4 needing that extra 2 months of life for the hope of  
5 another drug in the future or I'm thinking I'm going to  
6 be in the smaller sample that's going to be longer, I  
7 would look at the statistics, I would look at the  
8 studies, but I would probably make that tradeoff.

9 DR. EGGERS: Andrea?

10 MS. FERRIS: I'm just going to piggyback off  
11 of that. I think the thing, at least for a lot of our  
12 constituents, is you're already facing a fatal disease  
13 anyway, so you're going to die. It's not like you have  
14 the option of living a healthy life but then you may  
15 die of liver failure; your choice is dying of lung  
16 cancer or liver failure or perhaps being in the 3-year  
17 bucket.

18 DR. EGGERS: We have Karen. Well, first,  
19 Karen, let's let Pat ask a follow-up, please.

20 DR. KEEGAN: So actually, because the staff  
21 worked this up, this is actually sort of a typical  
22 situation for us, and one that usually would be thought

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

152

1 to be a positive scenario for Drug X, but I guess what  
2 might be helpful would be to know what would you want  
3 to know about the additional toxicity? I mean, that's  
4 the typical issue: you add another drug, you get a  
5 little bit more toxicity, but maybe you get a little  
6 bit more efficacy. But what things might you want to  
7 know about that toxicity? For instance, does it  
8 require you to be hospitalized? What about that might  
9 influence your decision? Because I think maybe, as  
10 presented, it isn't coming through. But are there  
11 certain things that we should be asking that are  
12 important to patients that might have changed, whether  
13 you said, "Yeah, this is okay," and what of those  
14 things should we be collecting?

15 DR. EGGERS: We'll let Karen go first.

16 DR. ARSCOTT: So I agree completely with  
17 Andrea. So the thing is that, are you going to die of  
18 lung cancer or are you going to die of one of these  
19 toxicities? You know, the thing is that you already  
20 have something very serious. The chemotherapies, the  
21 standard of care of chemotherapies, have very, very  
22 serious side effects also. You could die from any one

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

153

1 of those.

2           But here I was, I had a 14 percent 5-year  
3 survival, you know, 6 years ago, and so I looked at  
4 that and I just said, okay, I'm one of the 14 percent,  
5 you know, and that was my attitude. You know, I'm not  
6 one of the 86 percent, I'm going to be one of the 14  
7 percent. Now, I'm fortunate that I was. Maybe I  
8 wouldn't have been, but to me, I look at it, there is  
9 no question to me that I would go for it because,  
10 again, it's that positive attitude.

11           And, you know, you deal with what you're  
12 given in life, and that I agree none of us are  
13 guaranteed tomorrow in any way, whether you have lung  
14 cancer or not, and so, you know, now, if I was 93 years  
15 old or 100 years old, maybe I would have a completely  
16 different attitude, but where I am right now in my  
17 life, I would say, "You know what? Hit me, you know,  
18 give it to me, because maybe I'll be in that 1 percent  
19 that gets 3 years without any side effects."

20           DR. EGGERS: Okay. Anyone want to follow up?  
21 And thinking also of Pat's question.

22           Stephanie, were you going to say something?

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

154

1           MS. HANEY: I was just going to say one of  
2 the things I would want to know is, how will those  
3 risks be monitored? So if it's possible for liver  
4 injury, does that mean then I have blood tests for  
5 liver function, however? I mean, I'm sure some of  
6 those things you see coming, maybe some you don't,  
7 maybe some just occur and you're gone, but how is it  
8 monitored? How would you know if one of those things  
9 was developing?

10           DR. EGGERS: Sheila?

11           MS. ROSS: Thank you. This is a great  
12 question because so many patients face this. It shows  
13 the importance of having patient-friendly information  
14 on the range of possibilities from taking this drug or  
15 adding this drug to the regimen, and that information  
16 is very hard to come by. Just your comment there about  
17 the patients who had liver problems, as a side effect,  
18 they died, I didn't know that, and I try to keep up  
19 with all the information on these drugs. But it has to  
20 be clearly spelled out. And the other missing piece of  
21 information for late-stage lung cancer patients that's  
22 very important to them is, how much will it cost?

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

155

1 Because at this point they've drained their resources,  
2 their families' resources, they have to know. Who is  
3 going to tell them? Is that FDA's job to say how much  
4 it costs? I know you're going to say no.

5           Who is going to tell them? I mean, this is a  
6 difficult area.

7           DR. EGGERS: Andrea?

8           MS. FERRIS: Just to follow on to the  
9 question of, how will it be monitored? I guess another  
10 key question would be, is it irreversible or is it  
11 reversible if you stop treatment? And what does that  
12 look like? Is it permanent damage or otherwise?

13           MS. SKAMBIS: Well, and back to one of the  
14 points I made earlier, is there any way to know given  
15 my larger genetic makeup whether it's more likely to  
16 work for me?

17           DR. EGGERS: Did you have your hand up?

18           UNIDENTIFIED FEMALE SPEAKER: No.

19           DR. EGGERS: Anyone else on this scenario?

20           (No audible response.)

21           DR. EGGERS: I'm going to see if my  
22 colleagues have -- we want to get to our public

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

156

1 comment, and I want to see first, do you have any other  
2 follow-up questions about anything being asked today  
3 about the factors or anything else that you want to  
4 make sure gets asked?

5           And while they're seeing that, I'm going to  
6 make a point about the docket. The docket on our  
7 website will be open for the next month, and we are  
8 looking into a way that we can get it to stay open for  
9 a following month, so until the end of August. So you  
10 have some time to put your thoughts together, but we  
11 really encourage you to contribute to the docket,  
12 especially if you're on the web and there are things,  
13 or you are advocates and there are perspectives that  
14 are really important to share that we haven't heard  
15 today.

16           Pat.

17           DR. KEEGAN: That's what I was going to ask,  
18 that if there is anything after you leave the meeting  
19 and then you say, "Oh, I really wish I brought this  
20 up," if you could put it in the docket, then it will be  
21 available for us to review as you maybe think further.

22           DR. EGGERS: Especially on the things that

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

157

1 you think might be surprising or gray areas, things  
2 that FDA might not know about.

3 Kathleen.

4 MS. SKAMBIS: I know there are people  
5 listening to this who have no idea what a docket is.

6 DR. EGGERS: What a docket. Okay, let me  
7 explain.

8 Let's see if I can do it. Very fair point.  
9 The docket is, if you go on our website, there is going  
10 to be a link, and that will take you to the docket, and  
11 what the docket is, it's a vehicle, it's a bucket that  
12 you can submit -- anyone in the public can submit a  
13 comment, a Word document, you can upload a Word  
14 document, when you do that, it will be submitted to the  
15 docket, as we call it, and it will come to FDA. It  
16 might also, depending on some factors about personal  
17 information being conveyed, it might also be available  
18 on the website for others to see.

19 So it's your chance to make a public  
20 statement that FDA looks at and that others might also  
21 be able to look at, and we will take all of those  
22 comments when the public docket closes, when that

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

158

1 comment period closes, and we will incorporate those  
2 into our summary report here.

3 MS. SKAMBIS: Question, which is, this  
4 meeting has spurred a lot of interesting thought and  
5 discussion. Is the recording of this meeting going to  
6 be available for other people maybe to listen to before  
7 they make their comments in the docket?

8 DR. EGGERS: The slides will be up and the  
9 webcast recording will be up. The slides will up, it  
10 takes maybe a day or two. The webcast recording will  
11 take a little bit longer. Don't quote me, but it may  
12 be a week or more for that webcast recording to be up.  
13 And eventually the transcript of this meeting will be  
14 up. That takes a little bit longer, too.

15 We have Kim in the back.

16 Any other thoughts? Anything that is really  
17 relevant to the topics that we're discussing about the  
18 decision making that you would like to raise?

19 Susan?

20 KIM: Sara?

21 DR. EGGERS: Oh. I'm sorry.

22 KIM: Could I just ask a question about the

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

159

1 docket? Can people submit links to video testimony if  
2 they put a video on YouTube, can that URL be submitted  
3 for people who have a hard time putting things on  
4 paper?

5 DR. EGGERS: Yes, I believe they can. If you  
6 embed that link into your comments, either into the  
7 Word document that you can upload or if you don't have  
8 very much to say, you just maybe have a link, you don't  
9 even have to upload a document, you can go right to the  
10 webpage, and in the little comment box, I believe  
11 that's there, you can make your comment and perhaps  
12 upload your document. Thanks, Kim.

13 Susan.

14 MS. WARMERDAM: I don't know if this is an  
15 appropriate time, I think it is, to bring up about  
16 clinical trials that I didn't get to talk about on the  
17 panel, but I entered into a clinical trial the same  
18 time I started Tarceva, which was the only option for  
19 me to enter into that trial, and, of course, I was  
20 expecting it to be the miracle drug; unfortunately, it  
21 was not. And I also found it interesting, too, my  
22 doctor just told me last week that only 3 percent of

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

160

1 cancer patients are in clinical trials. Is that a  
2 pretty accurate number?

3 (No audible response.)

4 MS. WARMERDAM: Yeah? I was fortunate that  
5 the hospital where I'm being treated is just a short  
6 cab ride away from where I work, but I often wondered  
7 how I would have managed it if I needed to travel  
8 further than that during a full-time workweek because  
9 each appointment was several hours long and a lot of  
10 times more than once a week. So besides the time  
11 commitment, my biggest concern was the exposure, the  
12 unnecessary extensive exposure, to radiation during  
13 that trial, radiation that my doctor would not have  
14 exposed me to had I not been on the trial.

15 So I guess it's more of a question maybe.  
16 Can the trials be more, quote/unquote, "personalized"  
17 where maybe not everybody needs -- I was getting a CT  
18 of the chest and a CT of the abdomen and pelvis every 6  
19 weeks, and my doctor said that she didn't or wouldn't  
20 have ordered the CT of the abdomen and pelvis, that it  
21 was not necessary, and the CT of the abdomen and pelvis  
22 is -- I don't know how many of you know this, I did

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

161

1 this in my research, it's like 20,000 millisieverts,  
2 which is like getting 200 chest x-rays in a row every 6  
3 weeks in addition to the radiation from the chest x-  
4 ray. That put me at a calculation I found on the web,  
5 I don't know if this is that accurate, but at a 94  
6 percent chance of developing an additional cancer just  
7 from that radiation from the clinical trial.

8           So a little bit of input even from my doctor  
9 was about trials needing to be or having fewer  
10 roadblocks, you know, for time commitment, maybe having  
11 blood draws where they can get them closer to their  
12 homes or having the follow-up appointments on the phone  
13 rather than having to travel into the office.

14           And then also removing the blanket or the  
15 restrictions that prevent every hospital to be able to  
16 enter in any trial that they have qualified patients  
17 for.

18           But just going back a little bit, is that  
19 possible to have a clinical trial that is more  
20 personalized where your doctor maybe would have more  
21 input if there was something that could be done  
22 differently? Because not everybody is the same.

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

162

1 DR. KEEGAN: That's true that not everyone is  
2 the same, and I think that there can be flexibility in  
3 discussions about a clinical trial, but the clinical  
4 trial is, not to be too crass about it, but essentially  
5 an experiment, and so in order to do it right, there  
6 has to be some level of standardization. So I think  
7 probably what really needs to be done is a discussion  
8 of what's essential and what's not essential and  
9 working that through. So some things will be essential  
10 that it be standardized in order to be able to draw  
11 some valid conclusions at the end. A lot of that is  
12 driven by what the expectations and goals of the trial  
13 are, and other things are not as essential.

14 So I think we're constantly striving towards  
15 what is nonessential, what could be addressed in a  
16 different way, and I think that each trial, each set of  
17 drugs, each condition, is going to be different in that  
18 regard, and so it almost has to be done on a case-by-  
19 case basis looking at what the trial and the drugs are  
20 -- what questions they're asking, what are the  
21 essential things that need to be done?

22 So I think there is flexibility. I think

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

163

1 there is certainly flexibility on the Agency's part.

2 There can be flexibility on the part of commercial drug  
3 manufacturers, although to some extent there is also a  
4 little bit of rigidity because once they have a well-  
5 established system, they kind of like to continue it  
6 on, you know, it decreases errors and things like that  
7 if they continue it forward.

8           So we have to work through those tensions,  
9 but certainly our goal, and I think even everybody's  
10 goal, is that you only do what is necessary to answer  
11 the questions, the important questions, and so I think  
12 that's part of what we're asking, is always, what are  
13 those important questions? You know, there are people  
14 who would say in a large simple trial, all you really  
15 need to know is who died and when they die, and then  
16 you would have to do no studies, you know. But  
17 oftentimes people don't think that's enough  
18 information, and a lot of times in cancer people really  
19 do want to know what's happening to their tumors as  
20 well as how long they're living.

21           So it's that kind of tension, but there are  
22 likely some issues of flexibility that can always be

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

164

1 discussed in any clinical trial.

2 DR. EGGERS: Thank you, Pat.

3 MS. WARMERDAM: Thank you.

4 DR. EGGERS: Oh, go ahead, Shakun.

5 DR. MALIK: I just wanted to make a follow-up  
6 comment, is that with the targeted therapies, so more  
7 and more clinical trials in a way will be personalized,  
8 so people who have that specific target, so the trials  
9 are being done for that population. I mean, the CAT  
10 scan thing Pat already discussed.

11 But the other thing is that your point that,  
12 can these trials be done in all the hospitals? So I  
13 think not from all over the places including NCI has  
14 apportioned community-based clinical trials, so I think  
15 that we will be seeing more and more of the community-  
16 based, not just the academic-based, clinical trials.

17 DR. EGGERS: So with that, I think we're  
18 going to have to close the facilitated discussion. Is  
19 it something -- do we have one really quick thing?

20 MS. SANDT: Just really quickly, if a  
21 clinical trial is going to do testing for mutations,  
22 then the patients deserve that information. To hide

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

165

1 that from the patients, which has happened several  
2 times, is completely unacceptable, to not tell them  
3 what their mutation is.

4 DR. MALIK: Yeah, I agree. I agree.

5 MS. SANDT: Thank you. Open Public Comment

6 DR. EGGERS: So I want to thank -- my portion  
7 is almost done of the meeting. We're going to go into  
8 an Open Public Comment in a minute, but I want to  
9 sincerely thank, on behalf of my colleagues, your  
10 discussion today and your continuing discussion in the  
11 docket. After the public comment, we will see if there  
12 are any comments on the web that haven't been raised.  
13 So I thank you also on the web.

14 And with that, we're going to move into the  
15 Open Public Comment period, and we're not going to use  
16 timers or anything, and I think we'll just stay where  
17 you are. So there are five people. If your comment has  
18 already been made, you can decline to do the comment.  
19 We just ask that you really stick to 3 minutes, and  
20 I'll nudge you along if you go over 3 minutes, we don't  
21 have to have any timers, and if you can, state if you  
22 have any affiliation and you want to state that, please

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

166

1 do so as part of your comment.

2           So we have in this order: Susan Warmerdam,  
3 James Phang, Kim McCleary, Raymond Powers, and Donna  
4 Adkins.

5           So we'll start with Susan. Do you still have  
6 a comment to make?

7           (No audible response.)

8           DR. EGGERS: Okay.

9           MS. WARMERDAM: Because there aren't a lot of  
10 treatments out there for me, I've kind of taken it upon  
11 myself to do some other things within my control that I  
12 feel -- and I guess that's the main thing, is I feel  
13 that they're helping, whether that be helping my  
14 cancer, helping my immune system, helping my attitude.  
15 I mean, I've done everything from renewed my faith to  
16 holistic practices, putting water filters on every sink  
17 and shower head in my home, and air filters, and air  
18 filtering plants, and electromagnetic field protectors,  
19 I could go on and on, but I think most drastically what  
20 I've changed that I feel has made the biggest  
21 difference is my diet. I've moved to a primarily plant-  
22 based diet with an occasional fish protein, and while I

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

167

1 realize you're not the part of the FDA, I just had a  
2 question, if any research you know of is being done in  
3 relationship to cancer and food, for example, like the  
4 safety and labeling of foods?

5 DR. EGGERS: I'm not sure if my colleagues  
6 will be able to answer that now, but it's on the public  
7 record, and if information can come out, if we can  
8 address that, we will follow up with you directly. But  
9 your question is out there on the public record.

10 Is there any other part of your comment?

11 MS. WARMERDAM: That's it.

12 DR. EGGERS: Thank you, Susan.

13 We have James. James is here.

14 DR. PHANG: Thank you. I'm James Phang. I'm  
15 actually with the NCI and basic research, so it's been  
16 a rather different perspective, and I think that -- and  
17 also Ruth's situation was somewhat different because  
18 the initial diagnosis was thyroid cancer, and in fact  
19 it was only after the thyroidectomy that the tissue  
20 reports, histology and special stains and so forth came  
21 back to say that this was a metastatic lesion from a  
22 primary in the lung. And so you can see that we really

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

168

1 went through some rollercoaster responses in terms of  
2 the options that were open to us from a follicular  
3 initial diagnosis of follicular thyroid cancer, which  
4 would be cured by thyroidectomy and then ablated  
5 radioiodine therapy, to one of non-small cell lung  
6 cancer. So it was quite a change.

7           And so our physician at the NCI, when she --  
8 you know, very excitedly, both of us having a little  
9 insomnia, e-mailed us at 4:00 a.m. to tell us that we  
10 actually had the exon 19 deletion mutation, EGF  
11 receptor. I mean, so we then knew that there was a  
12 targeted therapy that worked.

13           And so that's why we're going through what  
14 you mentioned, wondering when the next drug will be  
15 available and whether or not she will have the mutation  
16 which will be responsive that conveys resistance to  
17 erlotinib. And so we're just very delighted that  
18 basically we're at this phase after having had the  
19 rollercoaster of sort of emotional responses to what  
20 was going on.

21           DR. EGGERS: Thank you, James.

22           Kim, Kim McCleary, in the back.

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

169

1 MS. McCLEARY: Thank you. My name is Kim  
2 McCleary. I'm an independent advocate who has worked  
3 in the patient-focused health policy and research area  
4 for 22 years, and I would like to thank the FDA, and  
5 particularly Dr. Mullin, Admiral Kweder, Dr. Woodcock,  
6 Sara, Andrea, Graham, and the whole team for this  
7 series of patient-focused drug development workshops  
8 and their efforts to understand the real-world context  
9 of conditions selected for these workshops by creating  
10 a multilayer dialog with patients and their advocates.

11 I've been part of the process consultation  
12 meetings to shape the format for these workshops and  
13 also participated in planning meetings for the ME/CFS  
14 workshop that opened the series and served on a panel  
15 at that meeting providing data from a survey conducted  
16 of 1,400 ME/CFS patients. I also viewed the webcast of  
17 the HIV workshop 2 weeks ago, so today is my third  
18 workshop. And I would like to offer a couple of  
19 observations of themes that are emerging across the  
20 three that have been conducted so far.

21 First is just to commend the FDA for their  
22 consistent respect and compassion for the patients

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

170

1 sharing their experiences and for drawing out the  
2 patient experiences through the questioning and the  
3 format. It's just been really great over the three  
4 conducted so far. Also for providing ways for patients  
5 to participate in person, live on the web, with the  
6 recorded archived recordings of the webcast, and then  
7 through the docket, even though most people don't know  
8 what a docket is. And the transcript of the meeting,  
9 the workshop report; it's just almost every format that  
10 you could hope for, the FDA has made that available.

11           Second is striking to me, the prominence of  
12 disabling fatigue is a life-impacting symptom, whether  
13 it's primary to the condition or a consequence of  
14 treatment or both. That was certainly a feature at the  
15 chronic fatigue syndrome meeting and at the HIV  
16 meeting, and we heard a lot about it this morning, and  
17 I expect you'll hear about fatigue from the narcolepsy  
18 patients who will be here in September. This strikes  
19 me because having spent 22 years in chronic fatigue  
20 syndrome ME/CFS research, I know how poor the  
21 measurement tools are for measuring fatigue, and it  
22 seems that maybe there is a way through C-Path or some

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

171

1 of the other FDA partnerships to help better measure  
2 fatigue like we do with fever and blood sugar, and  
3 maybe mobile health apps or wearable technologies like  
4 a PPT (ph) will give us new tools to be able to do that  
5 more sensitively since this dimension seems to cross so  
6 many diagnostic categories.

7           Another common theme across the three patient  
8 groups is the prevalence of comorbidities in the face  
9 of serious disease. The aging process, immediate  
10 treatment effects, long-term treatment consequences,  
11 and chronicity of disease all create new health  
12 conditions that complicate care and create new burdens  
13 for the individual patient and their caregivers. It  
14 also creates challenges for treatment sponsors in  
15 studying the safety and efficacy of new therapies.

16           And, finally, in each of the three conditions  
17 highlighted so far the patients are taking a number of  
18 medications with some using multiple medications at one  
19 time and others who go serially through different  
20 medications. Drug interactions, serial treatment  
21 effects, and treatment resistance all need to be better  
22 understood in these conditions as regulatory decisions

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

172

1 are being made.

2           Again, thank you for this important series  
3 and the enhancements you've made with each of the three  
4 workshops so far. That's impressive on its own, but as  
5 somebody who has been to dozens of federal meetings  
6 over two decades, it's particularly impressive.

7           So thank you very much.

8           DR. EGGERS: Thank you, Kim.

9           We have Raymond Powers? Raymond Powers,  
10 second chance?

11           (No audible response.)

12           DR. EGGERS: Okay. Then we will go on to  
13 Donna Adkins.

14 Donna, if you can just raise your hand so we 15 --

16           MS. ADKINS: And I'll be brief. Most of that  
17 I wanted to say has already been said, but I greatly  
18 appreciate what the FDA is doing and want to say thank  
19 you on behalf of our family and all of the patients  
20 that are out there that you are looking at this and to  
21 bring some awareness, that in 1984, when my father died  
22 of lung cancer and we were in the hospital, cancer was

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

173

1 such a hush word at that time that the nurse would not  
2 tell me my father's lung cancer had come back. I knew  
3 it had. He had his lung removed 2 years ago, prior to  
4 that, so we knew what he was dying of, the doctor had  
5 told me what was happening with him.

6           So I'm very appreciative that in 2013 we have  
7 come this far, that the very cancer that killed my  
8 father, my mother-in-law is now a 7-year survivor, so I  
9 thank you for all of your efforts that you have done in  
10 making that happen and just ask as we move forward that  
11 you continue to look at drug therapies that help the  
12 patient based on their own diagnosis and more  
13 personalized.

14           In the case of our daughter at age 26, there  
15 is not a drug out there that will address her pain.  
16 Flexeril is not the drug that she needs. Cymbalta is  
17 not the drug that she needs. But yet every day she has  
18 pain, she cannot sleep because of the pain from the  
19 thoracotomy. So at age 26, they're looking at her as  
20 though she is age 50 and trying to give her drugs that  
21 are not addressing it. So look at drugs that are more  
22 personalized, more personalized medicine, for the

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

174

1 patient because everyone is different, everyone's body  
2 is different, and how that they're going to respond.

3           And just the other thought would be more  
4 transparency. We know that they have her tumor, that  
5 they're doing research on her tumor in three different  
6 universities, but we will never know those outcomes,  
7 and as a mother and as my daughter, we would both -- as  
8 a nurse, her being a nurse, would like to know the  
9 outcomes. What did they find out from her tumor? Is  
10 it going to help a patient down the road? Is there  
11 something that gives us the answer as to why she  
12 received this type of cancer? The not knowing I think  
13 for patients is very hard when you can't put your  
14 finger and say, "Well, this is why I was diagnosed with  
15 this disease." You know, was it something that  
16 somebody else is going to be able to change later so  
17 that they don't have the diagnosis?

18           And again I thank you for the opportunity to  
19 be here today and for all that you are doing on behalf  
20 of patients.

21           DR. EGGERS: Thank you, Donna.

22           That's it for the Open Public Comment.

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

175

1           Pujita, do you want to give some of the web  
2 comments that are maybe not what we've heard so far or  
3 reiterate other points that we have heard?

4           MS. VAIDYA: Thank you. We have actually  
5 received a lot of comments on the web and will not be  
6 able to summarize them all. However, when thinking  
7 about decision making, web participants feel that  
8 quality of life is very important, and this includes  
9 the quality of support from a well-informed medical  
10 team.

11           We also have someone on the web comment that  
12 he would never forego effective treatment due to fear  
13 of side effects.

14           For Scenario 1, a web participant comments  
15 that she would pass on treatment with Drug X because 2  
16 versus 10 months is not enough time. She would  
17 consider the drug if life was prolonged by at least 3  
18 years.

19           Another web participant says he would try  
20 Drug X since not all patients have the same side  
21 effects.

22           DR. EGGERS: Thank you, Pujita.

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

176

1           I'll put a reminder out that there are  
2 evaluation forms so we can get your feedback if you  
3 would like to share that. And so if you haven't gotten  
4 one, I think they're still at the registration table,  
5 and if you have and you want to fill it out, just put  
6 it at the registration table as you leave.

7           With that, I am going to turn it over to  
8 Theresa Mullin to give some final remarks.

9           Thank you, Theresa. Closing Remarks

10           DR. MULLIN: Thank you, Sara. And I want to  
11 really begin the closing by thanking you all so much  
12 and to the patients and advocates who have come and  
13 come up here in our panel and to all the others of you  
14 who have contributed and just come today. I want to  
15 thank you, first of all, for your courage, which is  
16 very evident in what you've told us about what you've  
17 gone through yourselves and in describing the  
18 experiences of others and your generosity both in  
19 sharing that with us and giving us your time to come  
20 here today. What you have told us about has really  
21 provided us with a lot of insight, a lot of very  
22 helpful information, and far too much for me to kind of

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

177

1 fully recap, but I will just go over some of the things  
2 that I took away from this and heard.

3           And to begin with, when we were talking about  
4 symptoms, and has been pointed out by many, including,  
5 I guess, Kim McCleary, that fatigue is one of the  
6 central things you were telling us about, but that also  
7 getting diagnosed in many cases sounds like it was  
8 really kind of a fortunate coincidence, that you had  
9 symptoms that were really not very -- didn't point to  
10 lung cancer and that you kind of accidentally almost  
11 but happily discovered and were able to start getting  
12 treatment.

13           We also heard that lung cancer is somewhat  
14 unique in that there is a stigma, that people question  
15 your lifestyle, that that's a sort of unique aspect of  
16 lung cancer that's not something that happens when  
17 other people talk about other cancers and what your  
18 role your lifestyle may have played, and that it sounds  
19 that that's just sort of insult and hurt on top of the  
20 injury and kind of what you're already going through,  
21 that even that smoking is a highly addictive condition  
22 or disease itself, and that that can lead to and

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

178

1 increase the risk of getting lung cancer.

2           There was then a lot of discussion about  
3 treatments. Effectiveness sounds like it just varies a  
4 great deal, the side effects vary a lot, but some  
5 experience relatively minor, others, it's fairly  
6 terrible. Fatigue sounds like the most debilitating  
7 impact of therapy, it sounds like the biggest sort of  
8 concern. And that circumstances vary in terms of  
9 people's willingness to actually tolerate that and how  
10 you weigh the benefits and the risks that you may be  
11 exposed to. We've heard that certainly people with  
12 young children, dependent children, have more  
13 willingness and they feel that it's worth it that  
14 they'll just need to tolerate whatever risks if it can  
15 extend your life to take care of your children and take  
16 care of your family.

17           And in terms of that survey that we did,  
18 probably prolonging life and possibly prolonging life  
19 were just very consistently the most important factors  
20 that you mentioned, relieving symptoms coming in a bit  
21 much less than that. You weren't as concerned, from  
22 what we heard from those who responded today, about the

**Capital Reporting Company**  
**Patient-Focused Drug Development 06-28-2013**

179

1 administration, form of administration. And side  
2 effects were again not as important if there was a real  
3 benefit.

4           And related to that, when we asked about how  
5 much benefit, there was interest among many of you who  
6 responded to that sort of 2 months, but it sounds like  
7 the other point that you have made to us is that with  
8 new treatments you really want a clear understanding of  
9 what the added benefit might be, and particularly if  
10 that can be translated into your individual  
11 circumstances, into looking at perhaps your genetic  
12 makeup and what your particular risks may be, what side  
13 effects you may be particularly at risk for so that the  
14 more clear and the better our information along those  
15 lines, the more useful it would be to you in making  
16 decisions, and many other things.

17           We look forward to getting the comments from  
18 our docket and a further analysis of all that you've  
19 told us today. And I just want to thank you again.  
20 And I hope you have safe travels back to home and have  
21 a wonderful weekend.

22           Thanks.

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

180

1 DR. EGGERS: Since we don't have people  
2 jumping up, I will then officially say that this  
3 meeting is closed, and you are free to go and get your  
4 lunch and head out on your weekend. Thank you again so  
5 much.

6 (Whereupon, at 12:28 p.m., the Lung Cancer  
7 Public Meeting on Patient-Focused Drug  
8 Development was adjourned.)

9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

181

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22

CERTIFICATE OF NOTARY PUBLIC

I, NATALIA THOMAS, the officer before whom the foregoing meeting was taken, do hereby certify that the testimony appearing in the foregoing pages was recorded by me and thereafter reduced to typewriting under my direction; that said transcription is a true record of the testimony given by said parties; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this hearing was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

\_\_\_\_\_  
NATALIA THOMAS  
Notary Public in and for the  
State of Maryland

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

182

1 CERTIFICATE OF TRANSCRIBER

2 I, INSERT NAME HERE, do hereby certify that this  
3 transcript was prepared from audio to the best of my  
4 ability.

5 I am neither counsel for, nor party to this  
6 action nor am I interested in the outcome of this  
7 action.

8

9

10

11

12

-----  
DEBORAH ARBOGAST

13

14

15

16

17

18

19

20

21

22

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

Page 1

<u>          </u> \$	<b>19</b> 168:10	<b>28</b> 1:8 65:12	<b>50</b> 17:21 173:20
<b>\$5,000</b> 89:13	<b>1984</b> 172:21	<b>2-hour</b> 44:5	<b>5-1/2</b> 86:2
<u>          </u> 1	<b>1998</b> 52:13	<u>          </u> 3	<b>5-year</b> 14:10 153:2
<b>1</b> 4:14,15 6:7 27:13	<b>1999</b> 51:2 54:22	<b>3</b> 14:8 50:4 82:16	<u>          </u> 6
35:4,17 38:5	<u>          </u> 2	83:1 86:5 105:14	<b>6</b> 4:3 24:17 52:7
39:8 42:19 56:2	<b>24:17,18 6:7</b>	149:22 150:10	85:10 91:16
62:15 94:11	14:10,21 35:5,17	153:19 159:22	135:21,22
146:5 153:18	38:5 41:10	165:19,20	136:3,21 146:6
175:14	43:15,16 66:17	175:17	153:3 160:18
<b>1,400</b> 169:16	67:13,17 74:11	<b>30</b> 42:17 44:22	161:2
<b>10</b> 4:6 24:13 35:21	82:4 83:5 84:4,6	95:16 97:21	<b>6:00</b> 58:19
66:7 145:6	91:3 106:2	<b>30-year-olds</b> 94:3	<b>60</b> 96:1 116:1
148:15 175:16	108:14 109:7	<b>3-1/2</b> 50:6	<b>62</b> 4:15
<b>10:00</b> 43:4	148:13 149:21	<b>39</b> 4:14 13:17	<u>          </u> 7
<b>100</b> 153:15	151:4 169:17	<b>3A</b> 91:6	<b>7</b> 46:7 52:7 90:5
<b>100-mile</b> 55:22	173:3 175:15	<b>3-year</b> 151:16	<b>7-1/2</b> 92:5
<b>109</b> 4:18	179:6	<u>          </u> 4	<b>74</b> 142:19
<b>10903</b> 1:12	<b>20</b> 12:15,19 13:10	<b>4</b> 49:12 86:5 91:2	<b>79</b> 100:1
<b>11</b> 88:13 92:10	14:7 95:13,17	<b>4,500</b> 13:19	<b>7-year</b> 173:8
<b>11th</b> 14:19	115:22	<b>4:00</b> 168:9	<u>          </u> 8
<b>12</b> 24:13 67:13	<b>20,000</b> 161:1	<b>40</b> 42:1 46:21	<b>8</b> 24:17
91:1 92:3 98:2	<b>200</b> 55:20 161:2	<b>40-year-olds</b> 94:3	<b>8:00</b> 42:9 58:18
122:3 148:14	<b>200,000</b> 17:17	<b>41</b> 51:2	<b>8:23</b> 1:9
<b>12:28</b> 180:6	<b>2005</b> 53:2	<b>47</b> 45:10	<b>80th</b> 100:2
<b>13</b> 58:22 77:10	<b>2010</b> 53:13	<b>48</b> 91:9	<b>82</b> 4:16
<b>14</b> 153:2,4,6	<b>2011</b> 41:11 55:1	<b>49</b> 57:13	<b>84</b> 4:17 46:4
<b>15</b> 22:22 74:1 79:9	<b>2012</b> 54:1	<b>4-year</b> 106:2	<b>85</b> 18:1 121:22
95:8 143:6	<b>2013</b> 1:8 173:6	<u>          </u> 5	<b>86</b> 153:6
<b>15-minute</b> 81:22	<b>20993</b> 1:13	<b>5</b> 12:15 22:22	<b>8-block</b> 44:18
<b>16</b> 14:7 74:3 95:8	<b>20-year-olds</b> 94:3	38:6,9 46:7 50:5	<u>          </u> 9
<b>160,000</b> 17:18	<b>22</b> 36:8 169:4	51:11 66:5,17	<b>9</b> 96:18
<b>165</b> 4:19	170:19	120:19 122:7	<b>90</b> 13:19 66:6
<b>17</b> 4:9	<b>24</b> 77:8	142:19	
<b>176</b> 4:20	<b>25</b> 36:8		
<b>18</b> 95:12	<b>26</b> 4:12 70:7		
	119:10,15		
	173:14,19		

(866) 448 - DEPO

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

<p><b>93</b> 153:14 <b>94</b> 161:5 <b>99</b> 52:2</p> <hr/> <p style="text-align: center;">A</p> <hr/> <p><b>a.m</b> 1:9 42:9 43:4 168:9</p> <p><b>abdomen</b> 43:6 45:12 160:18,20,21</p> <p><b>ability</b> 12:12 26:4 59:5 72:10 74:7 104:1 182:4</p> <p><b>ablated</b> 168:4</p> <p><b>able</b> 22:3 29:13 39:6 41:7 43:7 44:4 49:11 55:13 58:10 60:15 72:6,13 78:12 82:21 91:22 92:22 104:9,12 123:1 127:16 135:10 140:7 157:21 161:15 162:10 167:6 171:4 174:16 175:6 177:11</p> <p><b>abnormalities</b> 21:21 22:4,6 115:7</p> <p><b>abnormality</b> 25:8</p> <p><b>abnormally</b> 43:12</p> <p><b>absolutely</b> 65:20</p> <p><b>academic-based</b> 164:16</p> <p><b>Academy</b> 58:16,17</p> <p><b>Accelerated</b> 24:22</p> <p><b>accept</b> 88:1 107:10</p> <p><b>access</b> 99:3 122:9</p>	<p><b>accidentally</b> 177:10</p> <p><b>accommodate</b> 33:9</p> <p><b>according</b> 50:5</p> <p><b>account</b> 86:20,21 97:13 137:1</p> <p><b>accurate</b> 160:2 161:5</p> <p><b>accurately</b> 24:1</p> <p><b>ache</b> 71:4</p> <p><b>acid</b> 53:16 98:1</p> <p><b>acknowledge</b> 37:3,7 111:3</p> <p><b>acne</b> 106:18</p> <p><b>across</b> 169:19 171:7</p> <p><b>act</b> 50:6</p> <p><b>action</b> 181:10,14 182:6,7</p> <p><b>active</b> 52:21 55:16 65:12 67:14,16 71:21 144:6,12</p> <p><b>activities</b> 13:4 40:9 48:5 55:12 69:8</p> <p><b>activity</b> 24:21 56:5</p> <p><b>actually</b> 9:6 26:3 43:15 50:1 57:4,5,16 73:7 76:11 81:5,6 113:21 115:4 123:2 131:12 140:4 143:1 150:11 151:20,21 167:15 168:10 175:4 178:9</p> <p><b>acupuncture</b></p>	<p>128:5,9</p> <p><b>acutely</b> 40:17</p> <p><b>adamant</b> 119:13</p> <p><b>add</b> 43:2 150:10 152:4</p> <p><b>added</b> 48:15 179:9</p> <p><b>addicted</b> 95:11,19</p> <p><b>addiction</b> 89:2 95:20</p> <p><b>addictive</b> 177:21</p> <p><b>adding</b> 154:15</p> <p><b>addition</b> 16:13 19:13 118:18 148:12,16 161:3</p> <p><b>additional</b> 16:8 152:3 161:6</p> <p><b>address</b> 21:1 79:17 83:22 100:12 119:9 123:1 133:8 137:19 167:8 173:15</p> <p><b>addressed</b> 84:1 129:14 131:22 162:15</p> <p><b>addresses</b> 103:1</p> <p><b>addressing</b> 126:10 173:21</p> <p><b>adenocarcinoma</b> 18:6</p> <p><b>adequate</b> 23:16 96:10</p> <p><b>adjourned</b> 180:8</p> <p><b>adjustment</b> 149:15</p> <p><b>adjuvant</b> 90:13</p> <p><b>Adkins</b> 3:10 70:4,19 119:8 142:16 166:4</p>	<p>172:13,16</p> <p><b>administer</b> 146:16</p> <p><b>administered</b> 134:11,22 136:22 146:4,14</p> <p><b>administration</b> 1:1,10 146:8 179:1</p> <p><b>Admiral</b> 169:5</p> <p><b>adrenal</b> 45:11 81:12</p> <p><b>advance</b> 8:3 34:13,14 35:9</p> <p><b>advanced</b> 10:8 18:19 19:22 21:3 46:5 100:3</p> <p><b>advances</b> 24:15 97:16</p> <p><b>advice</b> 96:4 107:14</p> <p><b>advisory</b> 11:16</p> <p><b>advocacy</b> 9:7 16:5 56:17 57:6</p> <p><b>advocate</b> 30:9 59:3 70:5 85:12,20 120:18 139:14 169:2</p> <p><b>advocates</b> 7:8 27:4,20 36:3 79:18 84:16 99:10,16 111:6 138:16,19 156:13 169:10 176:12</p> <p><b>affect</b> 8:11 13:4,5</p> <p><b>affected</b> 13:12,13 87:22</p> <p><b>affects</b> 51:1 65:2 118:8</p> <p><b>affiliation</b> 84:20</p>
--	--	---	--

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

Page 3

<p>165:22 <b>afternoon</b> 44:2 <b>afterwards</b> 16:10 131:17 <b>against</b> 85:1 104:10 <b>age</b> 37:12 42:1 70:7 119:11,15 120:5 142:19 173:14,19,20 <b>Agency's</b> 163:1 <b>agenda</b> 5:11,14,15 28:9 86:9 <b>agent</b> 118:20 <b>agents</b> 112:22 113:13 <b>aggressive</b> 19:6 94:2,4 106:15 <b>aging</b> 76:16,21 171:9 <b>ago</b> 25:14 38:5,6,9 41:10 45:9 57:7 59:1 66:17 73:4 77:10 85:15 86:2 90:5 91:16 96:18 97:21 115:18 120:19 122:8 144:8 153:3 169:17 173:3 <b>agreed</b> 90:15 <b>ahead</b> 5:2 74:21 81:4 112:15 131:1 142:15 143:12 164:4 <b>AIDS</b> 49:4 <b>aim</b> 25:19 <b>aimed</b> 18:20 <b>air</b> 166:17</p>	<p><b>airplane</b> 151:1 <b>ALA</b> 85:1 <b>aligned</b> 70:20 <b>alive</b> 106:12 139:7,9 <b>ALK</b> 98:9 105:15 <b>ALK-</b> <b>rearrangement</b> 25:8 <b>allergies</b> 73:16 <b>allergy</b> 46:2 <b>alleviate</b> 100:15 <b>Alliance</b> 39:22 56:17 71:16 85:12 92:16 140:8 <b>allow</b> 49:3 56:6 63:16 122:14 <b>alluded</b> 133:1 <b>alone</b> 148:12,16 <b>alongside</b> 144:11 <b>already</b> 14:4 20:6 44:14 46:4 49:21 93:18 96:2 151:12 152:19 164:10 165:18 172:17 177:20 <b>alternative</b> 125:22 <b>altitude</b> 51:21 <b>alumni</b> 58:18 <b>am</b> 5:6,11 7:2 31:3 32:5,9 41:3,5 45:1 47:8 48:3 55:13,16,21 58:12 59:1 60:19 62:16 67:12 85:10,11,22 90:5 91:20 93:10 98:9</p>	<p>116:3 119:12 153:16 176:7 181:9,11 182:5,6 <b>amazing</b> 140:17 <b>Ambassadors</b> 39:15 41:3 <b>American</b> 39:17,19 87:8 143:5 <b>among</b> 141:18 179:5 <b>amount</b> 6:11 100:3 106:17 112:18 <b>AM's</b> 42:14 <b>Amy</b> 3:11 71:14,15 72:17 139:12 140:22 141:6 <b>analysis</b> 2:6 4:13 179:18 <b>Andrea</b> 2:7 3:11 120:15,17 135:2 137:6 151:9 152:17 155:7 169:6 <b>announcement</b> 82:12 <b>annoying</b> 45:22 <b>answer</b> 36:19,20 37:9 40:3 110:8 129:17 134:17 163:10 167:6 174:11 <b>answered</b> 116:7 137:18 <b>answering</b> 34:22 35:7,19 36:14 37:13,19 38:8,21 63:20 64:3 110:19 126:5 134:15</p>	<p>136:12,17 <b>answers</b> 50:17 135:11,14 <b>Anti</b> 44:22 <b>antibodies</b> 25:10 <b>antidepressant</b> 44:22 <b>anti-nausea</b> 42:17 <b>anxiety</b> 63:14 <b>anybody</b> 65:20 74:15 91:18 93:2 <b>anymore</b> 47:10 70:20 88:10 92:12 117:12 142:12 143:18,21 <b>anyone</b> 6:5 64:22 65:22 67:9 68:6 69:21 71:12 72:18 74:20 75:12 76:7 78:11 80:22 109:14 112:5 114:4 117:16 127:6 128:2,14 130:22 131:15,21 137:14 141:7 143:11 147:5,10,17 149:9 150:1 153:20 155:19 157:12 <b>anything</b> 6:17,18 64:10 66:10 80:22 85:15 95:15 101:14 102:2 112:5 114:13 117:21 118:1 121:3 126:1 127:9 129:18 130:18</p>
---	--	--	---

(866) 448 - DEPO

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

<p>132:3 138:1 139:9 145:21 147:17 150:2 156:2,3,18 158:16 165:16</p> <p><b>anytime</b> 34:9</p> <p><b>anyway</b> 75:19 95:4 107:18 151:13</p> <p><b>anyways</b> 49:6</p> <p><b>anywhere</b> 74:4 87:11 139:21</p> <p><b>apartment</b> 65:15,16</p> <p><b>appear</b> 105:17</p> <p><b>appearing</b> 181:5</p> <p><b>appetite</b> 20:4 63:12 101:13 134:9</p> <p><b>applaud</b> 109:5</p> <p><b>applause</b> 61:10</p> <p><b>apples</b> 107:12,13</p> <p><b>applications</b> 9:8,9 24:14</p> <p><b>apply</b> 110:16</p> <p><b>appointment</b> 41:19,21 160:9</p> <p><b>appointments</b> 106:1 161:12</p> <p><b>apportioned</b> 164:14</p> <p><b>appreciate</b> 35:12,13 99:12 129:2 172:18</p> <p><b>appreciative</b> 173:6</p> <p><b>approach</b> 10:13 11:7 78:4</p> <p><b>approaches</b> 27:11</p>	<p>84:7</p> <p><b>appropriate</b> 33:14 159:15</p> <p><b>approval</b> 24:22 99:12</p> <p><b>approved</b> 22:8 25:2 121:7</p> <p><b>approving</b> 23:15</p> <p><b>approximately</b> 55:20</p> <p><b>apps</b> 171:3</p> <p><b>April</b> 14:19</p> <p><b>apt</b> 122:14</p> <p><b>ARBOGAST</b> 182:12</p> <p><b>archived</b> 170:6</p> <p><b>area</b> 12:10 23:2 35:4,6,11 146:18 155:6 169:3</p> <p><b>areas</b> 13:17,18,20,21 157:1</p> <p><b>aren't</b> 49:7 108:2 117:7 129:14 138:17 166:9</p> <p><b>arm</b> 53:2</p> <p><b>arrive</b> 43:4</p> <p><b>Arscott</b> 3:10 72:22 85:8,9 90:4 112:16 127:10 129:22 152:16</p> <p><b>artery</b> 52:7</p> <p><b>aside</b> 67:19</p> <p><b>asleep</b> 81:9</p> <p><b>aspect</b> 177:15</p> <p><b>aspects</b> 8:10 13:5 33:2 112:3</p>	<p>124:16 125:1</p> <p><b>assessment</b> 10:14,16</p> <p><b>assistance</b> 98:17</p> <p><b>associate</b> 84:20</p> <p><b>associated</b> 74:6 90:9 107:15</p> <p><b>Association</b> 39:17,19 87:8</p> <p><b>assumed</b> 106:4</p> <p><b>ate</b> 43:22</p> <p><b>attached</b> 94:17 115:12</p> <p><b>attacking</b> 88:3</p> <p><b>attempts</b> 21:20</p> <p><b>attendance</b> 7:7</p> <p><b>attended</b> 26:21</p> <p><b>attending</b> 9:19</p> <p><b>attention</b> 59:6 124:9</p> <p><b>attitude</b> 129:7,10 138:12 153:5,10,16 166:14</p> <p><b>attorney</b> 181:12</p> <p><b>attribute</b> 76:15 138:2</p> <p><b>attributed</b> 79:21 80:16</p> <p><b>atypical</b> 120:6</p> <p><b>audible</b> 69:17 114:16 117:18,20 131:20 132:1 146:2 147:7,15 149:1 155:20 160:3 166:7</p>	<p>172:11</p> <p><b>audience</b> 7:6 9:4 28:2 30:17 109:11</p> <p><b>audio</b> 182:3</p> <p><b>augment</b> 98:17</p> <p><b>August</b> 53:1 55:1 156:9</p> <p><b>Austin</b> 100:8</p> <p><b>available</b> 6:11 15:17 24:20 34:10 49:6 54:19 99:3 103:6 107:4 156:21 157:17 158:6 168:15 170:10</p> <p><b>Avenue</b> 1:12</p> <p><b>average</b> 108:15 148:13</p> <p><b>avoid</b> 97:21 124:4</p> <p><b>aware</b> 14:3 114:11</p> <p><b>awareness</b> 53:12 172:21</p> <p><b>away</b> 6:14 56:6 59:22 80:3 87:10 120:19 139:15 160:6 177:2</p> <hr/> <p style="text-align: center;"><b>B</b></p> <hr/> <p><b>B-12</b> 97:22</p> <p><b>babysitting</b> 58:2</p> <p><b>background</b> 4:9 5:16 9:21 10:10 17:6,8,11 26:15,16,17</p> <p><b>backside</b> 28:9</p> <p><b>bad</b> 39:6 53:14 57:15 87:16 117:7 125:11</p>
--	--	--	---

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

Page 5

<p>140:6,9 <b>balancing</b> 23:18 47:13 <b>ball</b> 52:4 <b>barrier</b> 123:4,6,13,18 <b>based</b> 18:3 21:11 22:1,5 164:16 166:22 173:12 <b>bases</b> 21:13 <b>basic</b> 6:16 10:13 167:15 <b>basically</b> 20:13 56:19 86:9 108:12 117:9 168:18 <b>basics</b> 128:20 <b>basis</b> 41:18 70:10 162:19 <b>bay</b> 48:12 <b>beach</b> 141:22 <b>beat</b> 141:14 144:11 <b>beautiful</b> 106:8 <b>became</b> 73:7 95:18 <b>become</b> 73:6 95:11,20 102:10 <b>becomes</b> 54:8 <b>becoming</b> 59:3 76:17 <b>bed</b> 42:2,16 44:19 45:2 66:9 69:5 140:2,20 144:2 <b>begin</b> 42:20 44:4 48:14 87:2 95:1,7 176:11 177:3</p>	<p><b>beginning</b> 144:7 <b>behalf</b> 41:4 71:17 85:20 165:9 172:19 174:19 <b>behind</b> 74:16 81:12 <b>believe</b> 6:8 35:22 98:4 130:2 143:22 159:5,10 <b>believed</b> 112:18 <b>believes</b> 53:18,20 <b>beneficial</b> 112:4 118:17 127:17 <b>benefit</b> 9:15 11:5 15:5 23:20 24:3,7,10 25:18 26:8 33:22 53:11 103:6 104:6,8 108:11 112:1,6,10 117:6 121:18 179:3,5,9 <b>benefit-risk</b> 9:18 10:14 <b>benefits</b> 8:19 11:2 102:18 111:15 117:4 178:10 <b>besides</b> 89:16 125:14 160:10 <b>best</b> 34:6 38:15 67:19 99:4 100:5 103:11 104:12 110:1 140:13 145:5 182:3 <b>Bethesda</b> 98:6,14 <b>better</b> 7:14 22:15 24:1,2 41:18 45:4 67:15 68:3 77:1,12 80:4 92:20 108:8 118:21 124:14</p>	<p>126:13 129:9,20 145:18 171:1,21 179:14 <b>bevacizumab</b> 25:13 <b>beyond</b> 19:2,16 45:14 98:18 107:20 122:21 <b>bicycles</b> 55:19 <b>bigger</b> 124:7 <b>biggest</b> 70:12 117:6 160:11 166:20 178:7 <b>bike</b> 55:20,22 <b>bilateral</b> 55:2 <b>bill</b> 52:2 89:12 <b>bind</b> 25:11 <b>Biologics</b> 32:11 <b>biomarkers</b> 91:19 <b>biopsied</b> 52:15 53:3 <b>bit</b> 12:1,8 26:17,20 28:12 50:19 51:22 64:8 65:19 69:19 70:10 74:11 75:4,6 82:20,22 90:19 102:4 110:22 142:8 152:5,6 158:11,14 161:8,18 163:4 178:20 <b>bizarre</b> 131:6 <b>blanket</b> 161:14 <b>bleed</b> 80:21 <b>bleeding</b> 22:13 23:8,13 <b>blessed</b> 105:4</p>	<p><b>blindly</b> 107:9 <b>blocked</b> 58:6 <b>blood</b> 23:13 42:21 43:1,7,18 44:14 57:19 63:11 79:12 88:4 96:20 106:7 123:17 134:2 154:4 161:11 171:2 <b>Blumenthal</b> 2:3 32:2 132:6 <b>blur</b> 63:4 <b>body</b> 8:16 22:16,18 38:19 46:7 56:8 139:21 174:1 <b>bone</b> 23:10 70:14 71:1 97:18,19 105:11 106:17 <b>bones</b> 72:4 88:3 <b>boost</b> 44:6 <b>bottles</b> 42:16 <b>bound</b> 69:5 <b>box</b> 29:17 78:14 159:10 <b>brachial</b> 73:21 74:4 <b>brain</b> 22:22 46:11 75:9,13,15 76:6 122:1 123:3,18 <b>brave</b> 58:10 <b>break</b> 4:16 6:2,9 33:9 80:14,18 81:3 82:1,3 121:5 <b>breaks</b> 95:11 <b>Breakthrough</b> 24:19</p>
---	---	---	--

(866) 448 - DEPO

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

<p><b>breast</b> 17:15</p> <p><b>breath</b> 20:3 22:13 23:3 52:18 54:12,14 63:10 64:13,19 65:18 68:12 69:19 70:1 71:13 73:2 83:16 92:13 100:6 130:5</p> <p><b>breathe</b> 79:11 130:16</p> <p><b>breathing</b> 63:11 64:13 69:20 87:17 125:20 126:17 127:2</p> <p><b>brief</b> 5:5 17:11 82:10 172:16</p> <p><b>briefly</b> 44:7 59:12 74:22</p> <p><b>brigade</b> 97:21</p> <p><b>bring</b> 27:15 77:16 81:1 123:20 142:16 159:15 172:21</p> <p><b>brings</b> 62:11</p> <p><b>brittle</b> 72:4</p> <p><b>broad</b> 7:6 17:20 24:11</p> <p><b>broaden</b> 27:22</p> <p><b>broke</b> 70:21</p> <p><b>bronchioloalveolar</b> r 51:10</p> <p><b>bronchus</b> 58:6,7,11</p> <p><b>brought</b> 72:14 113:8 124:13 150:16 156:19</p> <p><b>bucket</b> 97:21 151:17 157:11</p>	<p><b>build</b> 28:4 48:13</p> <p><b>building</b> 6:14 48:19 83:2</p> <p><b>bullet</b> 121:15</p> <p><b>bumped</b> 112:22</p> <p><b>BUN</b> 113:1</p> <p><b>bunch</b> 150:16</p> <p><b>burden</b> 17:19 89:10 100:11 102:16</p> <p><b>burdens</b> 171:12</p> <p><b>buttock</b> 53:3</p> <p><b>button</b> 31:11 110:17</p> <hr style="width: 100%;"/> <p style="text-align: center;">C</p> <hr style="width: 100%;"/> <p><b>cab</b> 160:6</p> <p><b>cachexia</b> 59:17 60:2</p> <p><b>calculation</b> 144:17 161:4</p> <p><b>Campus</b> 1:11</p> <p><b>cancer</b> 1:5 2:3 4:9 5:9,19 6:1,3 7:1,18,20 8:2,4,7,9,14,15 9:3 17:7,8,11,13,14, 15,16,21 18:1,4,8 19:2,5,9,12,15,1 6,19 20:7,14,16 21:19 22:5 24:5,16 25:3,5 26:16 27:3,9,21 29:9 32:3 35:17 36:1 37:3 38:16,17,20 39:20,21 40:7,11 41:5,6,8,12,13</p>	<p>42:6 45:10 46:4,6,10 47:4,18,20 48:12,14,17,22 50:2,3,13,14,22 51:3,6,14 52:16 53:4,11,16,17,20 ,21 54:8,10,22 55:5,9 56:6,10,17 57:7,10,13 59:7,9,11 60:6,8 63:2,7,15 65:11,19 69:1 70:7 71:16,18 72:7 73:17 74:2,16 77:12 78:1 79:1,21 80:17 81:2,12 82:19 84:7 85:2,10,11,14,19 ,20 86:1,10,13 87:6 88:2,6,7,10,11,1 4,17 89:1,4,6 90:6,20 92:16 93:21 94:1,2,6,16,17,1 9 96:2 97:11 98:11 99:15,17,20 100:11 101:10,17 102:13,19 103:14 104:18,19 106:16 110:10,11,15 112:10 115:5,11,17 116:2,5 120:7,20 122:7 125:14,18 128:18,19 132:19 133:17 135:19 138:7</p>	<p>139:17 140:8 143:5,19,21,22 144:9 145:6,15 148:9 151:16 152:18 153:14 154:21 160:1 161:6 163:18 166:14 167:3,18 168:3,6 172:22 173:2,7 174:12 177:10,13,16 178:1 180:6</p> <p><b>cancer-free</b> 66:4 70:8</p> <p><b>cancers</b> 77:5 177:17</p> <p><b>candidate</b> 20:19</p> <p><b>capable</b> 97:4</p> <p><b>Capital</b> 1:19</p> <p><b>capture</b> 8:9 12:4 14:4 26:7</p> <p><b>captured</b> 13:6 16:22</p> <p><b>capturing</b> 26:2</p> <p><b>car</b> 106:6 150:22</p> <p><b>carboplatin</b> 92:4</p> <p><b>carboplatinum</b> 113:22</p> <p><b>carcinoma</b> 18:5 51:10</p> <p><b>cards</b> 27:16 82:5</p> <p><b>care</b> 43:16 46:17 47:10 69:1,2,7 85:21 86:14 94:5 99:17 100:15 129:1,2 139:9,11 142:20 143:17 144:6,9 145:2,4,19 148:11,15,17</p>
---	---	---	---

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

Page 7

<p>152:21 171:12 178:15,16 <b>careful</b> 127:20 <b>carefully</b> 9:10 <b>caregiver</b> 30:9 70:6 71:17 120:19 <b>caregivers</b> 30:6 71:17 171:13 <b>caretakers</b> 16:5 27:4 30:12 36:3 <b>Caring</b> 39:15 41:3 <b>carried</b> 55:18 <b>case</b> 78:2 89:7 94:20 97:8 105:5 119:10 139:17 146:17 162:19 173:14 <b>case-by</b> 162:18 <b>cases</b> 19:10 20:12,19,21 24:9 60:6 177:7 <b>cat</b> 44:2 58:4 90:17 91:2 93:16 164:9 <b>catch</b> 19:7 44:5 142:21 <b>categories</b> 17:20 18:6 21:17 24:11 171:6 <b>category</b> 25:10 <b>catnap</b> 46:19 <b>cause</b> 7:20 17:16 48:17 <b>caused</b> 72:2 88:21 <b>causes</b> 23:5 <b>causing</b> 21:6 <b>cavity</b> 54:3</p>	<p><b>CBER</b> 2:18 <b>CDER</b> 1:2 2:4,6,8,11,13,16, 21 3:5,7,8 4:5,8,11,13,21 <b>celebrate</b> 44:9 <b>cell</b> 17:21,22 18:4,5,8,9 19:5,9,12,15 20:10,16 21:15,16 65:19 87:6 99:20 148:9 168:5 <b>cells</b> 20:14 88:2 <b>Cellular</b> 2:18 32:12 <b>center</b> 1:2 5:6 7:3 10:13 32:11 43:16 72:7 98:11 147:2 <b>centimeter</b> 91:3 <b>centimeters</b> 79:10 87:7 <b>central</b> 100:6 177:6 <b>certain</b> 24:4 25:9 144:17 152:11 <b>certainly</b> 11:5 26:6 60:9 100:11 163:1,9 170:14 178:11 <b>CERTIFICATE</b> 181:2 182:1 <b>certify</b> 181:4 182:2 <b>cessation</b> 95:1 <b>cetera</b> 134:9,14 <b>Chad</b> 29:1 135:9,12 <b>challenges</b> 25:20</p>	<p>41:15 46:13 171:14 <b>challenging</b> 146:19 <b>chance</b> 50:4 51:11 157:19 161:6 172:10 <b>change</b> 56:20 60:15 118:7 122:2 142:3,13,14 144:17 168:6 174:16 <b>changed</b> 93:22 116:11 121:6,15 152:12 166:20 <b>changes</b> 8:18 18:18 23:14 48:3 49:8 125:21 <b>changing</b> 122:9 <b>charged</b> 20:12 <b>chart</b> 21:17 <b>chat</b> 44:7 <b>chats</b> 120:4 <b>check</b> 91:18 <b>checked</b> 42:7 115:6 <b>check-in</b> 43:4 <b>checks</b> 96:21 <b>chemicals</b> 120:8 <b>chemo</b> 42:18 45:1,18 46:10 60:11 66:17 67:2,13 75:9,13,15 76:6,20 87:8 89:19 92:9 93:8 105:8 113:16 116:11,15 117:7</p>	<p>128:5,6,7 143:18,20 148:11,17 <b>chemo-responsive</b> 105:19 <b>chemotherapeutic</b> s 25:4 <b>chemotherapies</b> 118:13 119:1 152:20,21 <b>chemotherapy</b> 18:15,22 19:11,13,18 21:2,9,13 23:4,9,12 51:16 52:7,8,17 53:6,17 66:6 71:22 79:4,6 85:16 87:12,14,21 90:13 97:9,10,14 103:7 110:12 111:11,17 112:5,7,10,17 113:4 114:14 117:8,11 118:20 128:9 132:19 139:18,22 142:22 148:8 <b>chest</b> 23:1 45:12,16 51:6 52:15 53:14 54:3 57:20 58:1 63:9 139:20 160:18 161:2,3 <b>children</b> 68:22 69:7 102:1 139:5,7 142:19 143:2,3,15,18 178:12,15 <b>choice</b> 101:2,6,7 102:18 104:13</p>
--	--	---	--

(866) 448 - DEPO

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

Page 8

<p>140:5,12,21 142:6 151:15 <b>choices</b> 48:11 108:3 110:4 <b>choose</b> 48:8 63:8 110:16,17 144:2 150:22 <b>choosing</b> 107:12 <b>chores</b> 47:15 <b>chose</b> 93:16 <b>chosen</b> 102:19 <b>chronic</b> 13:4 15:13 49:1 70:8,13 119:17 170:15,19 <b>chronicity</b> 171:11 <b>chute</b> 151:2 <b>cigarette</b> 130:4 <b>circumstances</b> 178:8 179:11 <b>cisplatin</b> 25:5 92:6 113:20 114:1 <b>City</b> 87:9 <b>clarify</b> 78:2 122:18 <b>class</b> 91:10 <b>classifications</b> 21:15 <b>claw-like</b> 73:7 <b>clean</b> 91:2 <b>clear</b> 58:1 102:20 116:13 148:21 179:8,14 <b>clear-cut</b> 102:5 149:16 <b>clearly</b> 102:13,22 105:3 154:20 <b>Clermont</b> 56:1</p>	<p><b>click</b> 62:7 <b>clicker</b> 16:17 34:17 <b>clickers</b> 28:20,21 29:2,21 34:15 110:7 <b>climb</b> 52:21 87:18 <b>clinic</b> 32:8 51:9 119:14 <b>clinical</b> 9:6 10:20 13:6 23:17,20 24:3,7,10 25:21,22 26:8 45:19 49:10 98:22 103:5 120:22 121:19,21 122:10,14 148:10,12 159:16,17 160:1 161:7,19 162:3 164:1,7,14,16,21 <b>clinician</b> 32:9 <b>clocking</b> 43:9 <b>close</b> 49:12 80:20 82:21 85:2 164:18 <b>closed</b> 180:3 <b>closely</b> 107:17 <b>closer</b> 161:11 <b>closes</b> 157:22 158:1 <b>closing</b> 4:20 176:9,11 <b>clothes</b> 44:19 <b>clots</b> 134:3 <b>Coalition</b> 85:19 <b>coffee</b> 6:16 42:10</p>	<p>113:10 <b>cognitive</b> 22:21 75:10,13 76:8 80:1 <b>coincidence</b> 177:8 <b>colitis</b> 52:14 <b>colleagues</b> 31:6 38:10 60:22 69:14 101:12 111:13 114:17 115:19 132:2 145:21 155:22 165:9 167:5 <b>collect</b> 29:15 <b>collecting</b> 152:14 <b>combination</b> 18:22 100:17 <b>combined</b> 92:9 <b>comes</b> 17:4,15 82:21 89:3 108:1 117:11 120:10 <b>comfortable</b> 81:15 100:16 114:4 139:3 142:9 144:19 145:17 <b>coming</b> 64:19 65:5 115:8 122:6 136:10 152:10 154:6 178:20 <b>commend</b> 67:20 169:21 <b>comment</b> 4:19 6:4,8,12 13:18 29:17 33:6 41:16 49:11 78:9,14 79:22 80:8 82:8,13 93:1,13,14 94:18 108:10 112:16 114:21 115:10</p>	<p>116:21 125:8 127:10 129:18 147:6 154:16 156:1 157:13 158:1 159:10,11 164:6 165:5,8,11,15,17 ,18 166:1,6 167:10 174:22 175:11 <b>comments</b> 4:14,17 13:19,20 29:15 32:21 39:8 50:20 62:7,9,10,13 64:21 78:3 82:16 83:1,6 84:4 117:16 157:22 158:7 159:6 165:12 175:2,5,14 179:17 <b>commercial</b> 163:2 <b>commitment</b> 35:12,13 160:11 161:10 <b>committed</b> 12:14 57:1 <b>committees</b> 11:17 <b>common</b> 7:20 17:14 22:9,11 23:5,7 25:3 33:12 45:17 59:16 105:1 109:18 111:9 135:3,4 137:5 171:7 <b>communicated</b> 102:22 <b>communication</b> 102:20 <b>community</b> 30:18</p>
--	--	---	---

(866) 448 - DEPO

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

Page 9

<p>94:13 164:15</p> <p><b>community-based</b> 164:14</p> <p><b>comorbidities</b> 171:8</p> <p><b>companies</b> 60:1</p> <p><b>company</b> 1:19 94:21</p> <p><b>compared</b> 87:14 104:10</p> <p><b>comparing</b> 148:10</p> <p><b>comparison</b> 104:5,19</p> <p><b>compassion</b> 169:22</p> <p><b>complementary</b> 125:22 126:18</p> <p><b>complete</b> 43:10</p> <p><b>completely</b> 33:21 34:22 45:14 53:15 58:5,21 89:19 91:2 109:15 116:13 152:16 153:15 165:2</p> <p><b>complicate</b> 171:12</p> <p><b>complicated</b> 31:5</p> <p><b>complications</b> 22:11</p> <p><b>components</b> 10:16</p> <p><b>comprised</b> 21:8</p> <p><b>comprises</b> 10:19</p> <p><b>compromised</b> 103:22</p> <p><b>computer</b> 42:16</p> <p><b>concentration</b> 83:16</p>	<p><b>concept</b> 23:20</p> <p><b>concepts</b> 26:8</p> <p><b>concern</b> 11:20,21 77:21 98:3 107:21 160:11 178:8</p> <p><b>concerned</b> 178:21</p> <p><b>concluded</b> 92:11 98:8</p> <p><b>conclusions</b> 162:11</p> <p><b>concurrently</b> 21:2</p> <p><b>condition</b> 10:17 11:3 15:16 29:10 33:2 38:13,16 40:15 162:17 170:13 177:21</p> <p><b>conditions</b> 13:12 24:16 169:9 171:12,16,22</p> <p><b>conduct</b> 9:6</p> <p><b>conducted</b> 169:15,20 170:4</p> <p><b>confirmation</b> 80:19</p> <p><b>connection</b> 128:17</p> <p><b>consequence</b> 170:13</p> <p><b>consequences</b> 171:10</p> <p><b>consider</b> 10:16 49:9 81:10 94:9 146:21 175:17</p> <p><b>consideration</b> 121:16 147:11</p> <p><b>considerations</b> 14:6 84:13 120:13 132:3</p>	<p><b>considered</b> 103:16</p> <p><b>consistent</b> 42:11 169:22</p> <p><b>consistently</b> 178:19</p> <p><b>constantly</b> 162:14</p> <p><b>constituency</b> 79:19</p> <p><b>constituents</b> 123:8 151:12</p> <p><b>constitutional</b> 20:1,3</p> <p><b>consultation</b> 169:11</p> <p><b>consumed</b> 88:7</p> <p><b>contact</b> 138:10</p> <p><b>container</b> 43:18</p> <p><b>cont'd</b> 3:1</p> <p><b>contemplation</b> 101:2</p> <p><b>CONTENTS</b> 4:1</p> <p><b>context</b> 5:16 10:20 11:14,22 15:2 110:6 135:16 169:8</p> <p><b>continue</b> 28:17 32:8 34:3 46:12 55:15,16 94:4 110:1 163:5,7 173:11</p> <p><b>continued</b> 3:2 72:12 93:11</p> <p><b>continuing</b> 165:10</p> <p><b>contribute</b> 26:5 30:7,10 32:18,20 156:11</p> <p><b>contributed</b> 176:14</p> <p><b>control</b> 45:14 48:8</p>	<p>49:9 86:12 110:11 133:17 135:19 166:11</p> <p><b>controlled</b> 53:9</p> <p><b>convene</b> 12:14</p> <p><b>conversation</b> 28:12 30:10 44:18 82:2,20 124:22</p> <p><b>conversations</b> 33:9 34:7</p> <p><b>conveyed</b> 157:17</p> <p><b>conveys</b> 168:16</p> <p><b>convinced</b> 88:6</p> <p><b>Coordinator</b> 2:8</p> <p><b>copay</b> 89:12</p> <p><b>copays</b> 89:13</p> <p><b>COPD</b> 52:18</p> <p><b>Copeland</b> 3:11 71:15 139:13</p> <p><b>copied</b> 56:2</p> <p><b>correct</b> 35:22</p> <p><b>cost</b> 100:18 116:16,18 154:22</p> <p><b>costs</b> 155:4</p> <p><b>cotton</b> 42:21</p> <p><b>couch</b> 66:9</p> <p><b>cough</b> 20:2 23:3 45:17 46:1 52:3,10 53:14,15 73:2,12</p> <p><b>coughing</b> 57:22 63:11 96:20</p> <p><b>council</b> 56:16</p> <p><b>counsel</b> 181:9,12 182:5</p>
---	--	---	---

(866) 448 - DEPO

Capital Reporting Company  
 Patient-Focused Drug Development 06-28-2013  
 Page 10

<p><b>counterpoint</b> 132:16  <b>countless</b> 103:19  <b>country</b> 7:19  <b>counts</b> 44:16  <b>couple</b> 38:3 93:3      144:4,8 145:14      147:18 148:1      169:18  <b>courage</b> 61:7      109:4,5 176:15  <b>courageous</b> 133:3  <b>courageously</b> 83:4  <b>course</b> 57:21 59:9      87:13 108:17      150:13 159:19  <b>courtesy</b> 34:4  <b>cover</b> 11:12      13:10,11 14:15  <b>covered</b> 111:14  <b>covering</b> 13:10,19      14:12,21  <b>coworkers</b> 95:10  <b>C-Path</b> 170:22  <b>crass</b> 162:4  <b>crawling</b> 73:1  <b>create</b> 171:11,12  <b>created</b> 95:20  <b>creates</b> 171:14  <b>creating</b> 169:9  <b>creatinine</b> 113:1  <b>Crest</b> 53:11  <b>criteria</b> 12:21 13:1  <b>critical</b> 16:10      104:6  <b>crizotinib</b> 25:7</p>	<p>121:6  <b>cross</b> 123:17 171:5  <b>crossing</b> 150:22  <b>crossover</b> 66:15  <b>cruise</b> 140:4,7,16  <b>CT</b> 43:5 59:6      160:17,18,20,21  <b>cup</b> 42:10  <b>curative</b> 102:15  <b>cure</b> 15:21,22 16:2      18:18 20:20      90:16 97:5 98:4      103:2,4,7 143:22  <b>cured</b> 18:12 20:8      47:9 141:20      168:4  <b>current</b> 8:8 11:4      13:9 15:2,19      17:7,12 24:19      38:16 84:7      110:12  <b>currently</b> 38:20      40:13 49:5 53:10      86:11 93:4 103:6      125:16  <b>CVs</b> 73:9  <b>cycle</b> 67:14 68:4  <b>cycling</b> 55:17,18  <b>Cymbalta</b> 173:16  <hr style="width: 20%; margin-left: 0;"/> <b>D.C</b> 35:4,5 56:19  <b>daily</b> 6:1 15:14      27:9 42:18,21      43:18 45:18      47:1,15 63:8      67:20 70:1,10  <b>Dallas</b> 100:8</p>	<p><b>damage</b> 22:17      23:5 155:12  <b>damaging</b> 20:15  <b>Dan</b> 101:10,22      102:3,6  <b>dark</b> 97:2 99:1  <b>data</b> 169:15  <b>date</b> 117:8  <b>daughter</b> 66:17,18      70:6 77:3 119:10      173:14 174:7  <b>daughters</b>      106:3,20  <b>day</b> 40:16      41:6,17,19,20,21      ,22 42:4,6,20      46:18 48:21      55:15,17 56:2      58:2,15 66:7      67:13 68:1,14,15      71:8 72:2 77:8      89:12 98:2 117:8      120:3 158:10      173:17  <b>daypack</b> 42:22  <b>days</b> 45:4 57:17      66:5,7 81:9      143:1 145:6,15  <b>dead</b> 50:6 89:16  <b>deal</b> 48:22 50:22      139:10 153:11      178:4  <b>dealing</b> 15:17 68:4      81:8 139:16  <b>deals</b> 70:8  <b>dealt</b> 105:22  <b>death</b> 7:20 134:4      143:1</p>	<p><b>deaths</b> 17:16,18  <b>debilitating</b> 29:9      66:11 69:6 140:1      178:6  <b>DEBORAH</b>      182:12  <b>decades</b> 115:13      172:6  <b>decide</b> 44:8 98:1      109:22  <b>decided</b> 51:12  <b>deciding</b> 144:10  <b>decipher</b> 41:14  <b>decision</b> 11:15      99:18,20      100:1,20      101:4,21      102:4,5,6,8,21      119:1 120:13      125:1 132:3,22      133:12 135:18      140:9,10,19      141:4,20 143:3      147:18 149:14      152:9 158:18      175:7  <b>decision-making</b>      145:3  <b>decisions</b> 21:13      82:19 84:12      86:22 107:1      108:6 109:19,21      118:6 120:20      133:3,4,14,16,18      ,19,21 142:2,13      148:4,6 171:22      179:16  <b>decline</b> 165:18  <b>decreases</b> 163:6  <b>define</b> 24:7 56:8</p>
---	---	--	--

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

<p><b>defined</b> 23:21 26:7 60:8</p> <p><b>definitely</b> 60:16 72:9 76:19 79:4</p> <p><b>definition</b> 75:1</p> <p><b>degree</b> 10:17,18 11:4</p> <p><b>Delaney</b> 57:4</p> <p><b>delay</b> 103:8 115:10,11</p> <p><b>deletion</b> 168:10</p> <p><b>delighted</b> 168:17</p> <p><b>delivered</b> 20:13</p> <p><b>demonstrated</b> 24:3</p> <p><b>Denise</b> 3:13 66:2,3 84:22 85:4 87:2,3 90:2 114:7 128:15 129:4 141:1,6 143:12</p> <p><b>depend</b> 143:14</p> <p><b>dependent</b> 178:12</p> <p><b>depending</b> 6:10 18:15 77:5 97:6 118:7,8 157:16</p> <p><b>depressed</b> 60:13</p> <p><b>depression</b> 60:7,10,16 63:14</p> <p><b>describe</b> 78:13,15 80:10 124:10</p> <p><b>described</b> 27:7 86:13 141:13</p> <p><b>describes</b> 38:15</p> <p><b>describing</b> 176:17</p> <p><b>deserve</b> 164:22</p> <p><b>deserves</b> 83:12</p>	<p>96:10</p> <p><b>deserving</b> 83:13</p> <p><b>designer</b> 55:15 71:20</p> <p><b>despite</b> 100:5 103:20 109:22</p> <p><b>detail</b> 7:17 62:3</p> <p><b>detailed</b> 97:13</p> <p><b>detect</b> 19:20</p> <p><b>detection</b> 46:3</p> <p><b>determine</b> 6:11 122:21 124:3</p> <p><b>determined</b> 52:16 56:11 141:14</p> <p><b>devastating</b> 8:3 106:4</p> <p><b>develop</b> 9:6 13:2 19:22 78:4 94:6 104:8 116:2</p> <p><b>developed</b> 12:21 77:2 104:4 148:8</p> <p><b>developer</b> 123:5</p> <p><b>developers</b> 7:9 9:7</p> <p><b>developing</b> 12:3 154:9 161:6</p> <p><b>development</b> 1:6 3:4 4:6 5:10,17 7:1,13 8:3 9:2,5 10:1 15:3 22:7 25:16 26:5,6 169:7 180:8</p> <p><b>diabetes</b> 49:4</p> <p><b>diagnosed</b> 8:14 35:17 36:8 41:10 45:10 46:1,6 50:3 51:2 52:2 53:1,13,22 55:1 57:12,16 59:5</p>	<p>65:12 70:7 79:7 80:4 81:8 86:1 87:5 90:4 99:19 101:9 102:1,12 105:1 119:12 121:22 174:14 177:7</p> <p><b>diagnoses</b> 17:18,22 18:2</p> <p><b>diagnosis</b> 18:2 38:5 50:2,9 52:1 56:4 73:4 90:6 96:10 120:5 142:19 167:18 168:3 173:12 174:17</p> <p><b>diagnostic</b> 171:6</p> <p><b>dialog</b> 169:10</p> <p><b>dialogue</b> 27:1 30:8 82:2 89:4 121:5</p> <p><b>diaphragm</b> 70:19</p> <p><b>diarrhea</b> 23:12 105:14 106:18 117:12 148:18</p> <p><b>Dickran</b> 2:12</p> <p><b>dictated</b> 105:2</p> <p><b>die</b> 89:5,6 107:17 108:1 151:2,13,15 152:17,18,22 163:15</p> <p><b>died</b> 57:7 142:18 145:5,6 150:11 154:18 163:15 172:21</p> <p><b>diet</b> 42:12 125:21 166:21,22</p> <p><b>dietary</b> 125:21 126:18 127:2</p>	<p><b>differ</b> 8:19 118:12</p> <p><b>difference</b> 54:9 67:5 75:21 76:14 78:12 116:12 128:7 136:7 147:8,11 166:21</p> <p><b>differences</b> 123:22</p> <p><b>different</b> 8:15,17 13:20 16:16 19:9 21:10,11 22:3,4 23:11 28:6 32:19 50:18,22 54:3 61:5,19 65:19 78:5 83:17 84:13 99:18 104:5,9 109:15 119:16 122:11 123:8,10 126:22 127:22 130:10 138:18 141:16 142:6 143:21 153:16 162:16,17 167:16,17 171:19 174:1,2,5</p> <p><b>differently</b> 26:20 48:9 161:22</p> <p><b>difficult</b> 8:17 19:20 29:11 41:14 45:3 47:12 51:13 68:21 71:5,19 72:11 78:17 101:4,15 105:12 140:18 143:20 155:6</p> <p><b>difficulties</b> 63:11 64:14 69:20</p> <p><b>difficulty</b> 8:16 22:20 63:13</p> <p><b>Diko</b> 31:12 123:21 150:8</p> <p><b>dimension</b> 171:5</p>
---	---	--	---

Capital Reporting Company  
 Patient-Focused Drug Development 06-28-2013  
 Page 12

<p><b>diminished</b> 55:5</p> <p><b>dinner</b> 44:8,11</p> <p><b>direct</b> 25:17</p> <p><b>directed</b> 87:8 97:8 98:12</p> <p><b>direction</b> 96:19 181:7</p> <p><b>directly</b> 7:22 11:1 36:17,22 167:8</p> <p><b>director</b> 2:10 3:6 4:4,7,21 7:2 31:18 32:1 41:2 59:14 85:18</p> <p><b>disabled</b> 87:15</p> <p><b>disabling</b> 170:12</p> <p><b>disappoint</b> 143:2</p> <p><b>disappointing</b> 67:7</p> <p><b>disclaimer</b> 31:3</p> <p><b>discovered</b> 141:9 177:11</p> <p><b>discuss</b> 11:12</p> <p><b>discussed</b> 102:9,10 164:1,10</p> <p><b>discussing</b> 12:18 33:11 158:17</p> <p><b>discussion</b> 4:12,15,18 5:4,8,20 6:2 7:11 9:1,12 11:19 12:1 26:11,18 27:6,18,22 28:3,11 30:2 32:16,18 40:4 50:16 61:2 62:11,15,17,18 63:18 77:20 80:21,22 82:17,18 83:2</p>	<p>84:6,14 86:6,8 95:22 101:3 109:7,10 111:3,19 116:17,19 122:11 134:18 138:20 158:5 162:7 164:18 165:10 178:2</p> <p><b>discussions</b> 5:21 27:17 33:5 60:21 98:19 162:3</p> <p><b>disease</b> 7:15 8:10 12:10,13 13:6,18,20,21 15:2,3 17:19 18:11,16 19:4,11 20:18 21:1,4 40:13 41:17 47:20 66:16 80:11 100:14 102:16 105:6 120:2 150:12 151:12 171:9,11 174:15 177:22</p> <p><b>disease-directed</b> 99:21</p> <p><b>diseases</b> 12:18,20 13:3 14:1,9,12,20</p> <p><b>distinctly</b> 78:12</p> <p><b>distinguished</b> 76:17</p> <p><b>dividing</b> 21:22 22:1</p> <p><b>division</b> 2:4,10,13,15,21 4:4,10 7:3 15:4,11 17:10 31:13 32:1,3,7</p> <p><b>divisions</b> 11:21</p>	<p>12:22 14:1</p> <p><b>DNA</b> 20:15</p> <p><b>docket</b> 62:4,9 79:16,17 80:15 111:7 124:13 156:6,11,20 157:5,6,9,10,11, 15,22 158:7 159:1 165:11 170:7,8 179:18</p> <p><b>doctor</b> 41:19,21 46:1,6 67:14 75:16 87:9 91:8 93:16 101:3 107:10 120:9,21 131:5,11 134:13 136:8,10 159:22 160:13,19 161:8,20 173:4</p> <p><b>doctors</b> 87:7 89:8 119:10</p> <p><b>doctor's</b> 96:19 107:14</p> <p><b>document</b> 124:13 157:13,14 159:7,9,12</p> <p><b>dominant</b> 8:13</p> <p><b>done</b> 22:17 25:22 29:5 39:9 55:14 56:1 71:9 72:3 74:12 110:21 115:2 117:2 161:21 162:7,18,21 164:9,12 165:7 166:15 167:2 173:9</p> <p><b>Donna</b> 3:10 70:4 119:8 120:12 142:15 143:10 166:3 172:13,14</p>	<p>174:21</p> <p><b>DOP</b> 32:7</p> <p><b>dose</b> 124:8 132:8,9 149:13</p> <p><b>dose-finding</b> 122:21</p> <p><b>doses</b> 44:20</p> <p><b>dosing</b> 124:4,19</p> <p><b>double</b> 98:5</p> <p><b>downsides</b> 75:5 111:15 112:4 113:14 114:14</p> <p><b>dozens</b> 172:5</p> <p><b>Dr</b> 5:2 6:21 10:2 17:9,13 26:13 31:12,15,18,22 32:2,5,10,14 35:8,20 36:10 37:14,20 38:1,9,22 39:9 40:1,22 45:6 49:19 50:10 56:13 60:18 61:9,18,22 62:16 63:21 64:4,20 65:22 66:12 67:8 68:6 69:4,12,18 70:16 71:11 72:17,22 74:19 75:3,22 76:5,7,13,17 77:14,18 78:9,22 79:15 80:6,8,13 81:15,20 82:11 84:3,5 85:4,8 86:3 90:2,4 96:14 98:7 99:6 104:15 109:1,8,14,17 110:20 111:12 112:13,16 113:14</p>
---	--	---	---

Capital Reporting Company  
 Patient-Focused Drug Development 06-28-2013  
 Page 13

114:2,7,10,13,17 ,20 116:8,18 117:15,19,21 119:5 120:12 122:16,18 123:11 124:21 126:6 127:4,10 128:2,11,14 129:4,12,22 130:22 131:18,21 132:2,6,10,14,21 134:16 135:8,13 136:1,3,4,5,13,1 8 137:8 138:1,14 139:12 140:22 142:15 143:10 144:3 145:20 146:3 147:4,8,16 149:2,9,17 150:1,5,9,18 151:9,18,20 152:15,16 153:20 154:10 155:7,17,19,21 156:17,22 157:6 158:8,21 159:5 162:1 164:2,4,5,17 165:4,6 166:8 167:5,12,14 168:21 169:5 172:8,12 174:21 175:22 176:10 180:1 <b>drained</b> 155:1 <b>drank</b> 44:1 <b>drastic</b> 48:3 49:8 <b>drastically</b> 166:19 <b>draw</b> 162:10 <b>drawing</b> 170:1 <b>drawn</b> 43:7	<b>draws</b> 161:11 <b>dress</b> 42:20 44:19 <b>drink</b> 34:10 73:14 112:21 113:7,11 <b>drinking</b> 112:19 <b>drip</b> 52:10 <b>driven</b> 115:4 120:21 162:12 <b>driving</b> 57:3 <b>drop</b> 44:10 83:19 <b>dropped</b> 58:18 149:13 <b>drown</b> 130:9 <b>drowning</b> 130:17 <b>drug</b> 1:1,2,6,10 4:6 5:6,10,17 7:1,3,8,13 8:3 9:2,5,22 11:8,15,22 23:18,19,22 24:8,13 25:16 26:3,5 31:5 44:20 48:13,22 49:2 53:7 60:1 83:18 99:11 105:2,4 107:11 108:16,21 110:14 117:10 123:5 124:6 139:22 148:8,11,13,14,1 7 151:5 152:1,4 154:14,15 159:20 163:2 168:14 169:7 171:20 173:11,15,16,17 175:15,17,20 180:7 <b>drugable</b> 122:4	<b>drugs</b> 3:4 9:6 10:14 22:7 23:15 24:20 25:1 31:17 104:4 105:16 107:19 108:11,18 124:3,17 154:19 162:17,19 173:20,21 <b>dry</b> 52:3,10 <b>due</b> 23:9 79:8,14 96:19 130:2 175:12 <b>duration</b> 24:8 <b>during</b> 121:5 131:8 160:8,12 <b>dusky</b> 73:6 <b>dwelt</b> 56:7 <b>dying</b> 42:1 47:12 142:21 145:12 151:15 173:4 <b>dynamic</b> 121:15 <hr style="width: 20%; margin-left: 0;"/> <b>earlier</b> 21:15 27:8 44:15 55:21 78:18 86:16 96:17 102:10 108:11 139:15 155:14 <b>early</b> 19:7,19 20:18 24:21 45:19 46:3,15 59:5,6 82:22 93:6 96:9,10 106:3 122:19 <b>ears</b> 113:21 114:1,2,9 <b>easier</b> 146:16 <b>easily</b> 100:6	<b>easy</b> 35:2 41:13 44:18 92:18 104:19 106:12 142:11 <b>eat</b> 42:11 43:22 <b>eating</b> 128:20 <b>educate</b> 124:18 <b>educated</b> 119:11 <b>education</b> 119:21 120:2,9 <b>educational</b> 123:13 124:14 <b>effect</b> 150:15 154:17 <b>effective</b> 8:4 30:2 112:2 175:12 <b>effectiveness</b> 9:10 100:17 178:3 <b>effects</b> 8:8 22:9,12 23:9,11 43:13 46:9,20 51:17 53:8 54:5,10,13,16,17 ,19 55:6,9 63:3,14 64:9 65:14 75:7 83:18,21,22 87:17 93:7,9 97:12,13 100:18 103:3,4,16 105:13,18 107:17 117:6 118:12,22 119:2 123:22 124:5 128:8,12 132:17,20 134:2,8 135:1 137:3,4,20 139:10 147:5 149:7 152:22 153:19
---	--	--	--

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

Page 14

<p>171:10,21 175:13,21 178:4 179:2,13 <b>efficacy</b> 23:19 152:6 171:15 <b>effort</b> 10:12,21 11:18 12:20 123:13 <b>efforts</b> 17:4 100:5 124:10,15 169:8 173:9 <b>effusion</b> 54:2 <b>EGF</b> 168:10 <b>EGFR</b> 25:9 45:13 98:9 <b>Eggers</b> 2:5 4:12 5:2,5 26:13,19 32:14 35:8,20 36:10 37:14,20 38:1,9,22 39:9 40:1,22 45:6 49:19 50:10 56:13 60:18 61:9,18,22 62:16 63:21 64:4,20 65:22 66:12 67:8 68:6 69:4,12,18 70:16 71:11 72:17 74:19 75:3,22 76:5,7,13,17 77:14 78:9,22 79:15 80:6,13 81:15,20 82:11 84:3,5 85:4 86:3 90:2 96:14 99:6 104:15 109:1,8,14,17 110:20 111:12 112:13 113:14 114:2,7,10,13,17 116:8,18</p>	<p>117:15,19,21 119:5 120:12 122:16 124:21 126:6 127:4 128:2,11,14 129:4,12 130:22 131:18,21 132:2,10,14,21 134:16 135:8,13 136:1,4,13,18 137:8 138:1,14 139:12 140:22 142:15 143:10 144:3 145:20 146:3 147:4,8,16 149:2,9,17 150:1,5,18 151:9,18 152:15 153:20 154:10 155:7,17,19,21 156:22 157:6 158:8,21 159:5 164:2,4,17 165:6 166:8 167:5,12 168:21 172:8,12 174:21 175:22 180:1 <b>eight</b> 50:18 <b>either</b> 8:11 25:11 40:14 77:18 159:6 <b>EKG</b> 43:2,10,11 <b>elaborate</b> 78:6,19 111:20 <b>elderly</b> 13:15 <b>electromagnetic</b> 166:18 <b>eligible</b> 123:10,11 <b>eliminate</b> 42:12 135:22 136:1 <b>else</b> 47:13 56:7 67:9 71:12 72:18</p>	<p>74:20 75:12 76:7 88:2 110:14 114:13 117:16 125:22 127:9 128:2,14 130:22 139:9,21 141:7,9 143:11 146:5 147:17 149:9 150:2 155:19 156:3 174:16 <b>e-mailed</b> 168:9 <b>embed</b> 159:6 <b>emergency</b> 96:19,21 <b>emerging</b> 169:19 <b>EMGs</b> 73:8 <b>emotional</b> 47:11 83:22 168:19 <b>emphysema</b> 100:3,12 <b>employed</b> 181:9,12 <b>employee</b> 181:12 <b>empty</b> 43:19 <b>encourage</b> 6:7 28:3 30:6 60:16 156:11 <b>encouragement</b> 92:20 <b>encourages</b> 26:6 <b>Endpoints</b> 3:3,4 31:16 <b>endure</b> 106:17 121:14 <b>energized</b> 97:14 <b>energy</b> 44:10 63:14 64:12,18,21 65:2 66:10 69:1</p>	<p>117:11 <b>engage</b> 26:22 <b>engaged</b> 101:16 <b>enhance</b> 9:12 99:4 <b>enhancement</b> 97:19 <b>enhancements</b> 172:3 <b>enjoy</b> 100:13 <b>enroll</b> 121:21 122:11 <b>ensuing</b> 97:3 <b>ensure</b> 30:3 100:15 <b>enter</b> 159:19 161:16 <b>entered</b> 159:17 <b>entire</b> 38:11 66:6 101:18 119:19 <b>entirely</b> 52:20 <b>epidermal</b> 91:20 93:10 <b>epiphany</b> 67:3 <b>episode</b> 102:20 <b>equal</b> 35:10 135:5 <b>equally</b> 96:9 <b>equated</b> 137:22 <b>erlotinib</b> 25:9 48:2 168:17 <b>errors</b> 163:6 <b>escaping</b> 46:18 <b>esophagus</b> 22:20 <b>especially</b> 35:15 72:12 73:12 89:14 101:15 111:5 146:17</p>
--	--	---	---

(866) 448 - DEPO

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

Page 15

<p>156:12,22 <b>essence</b> 26:4 <b>essential</b> 162:8,9,13,21 <b>essentially</b> 18:3,10 19:8,14 20:11 22:10 25:18 105:6 162:4 <b>established</b> 163:5 <b>et</b> 134:9,13 <b>evaluate</b> 9:10,14 <b>evaluating</b> 124:2 <b>evaluation</b> 1:2 5:6 7:4 32:12 33:20 78:4 176:2 <b>evening</b> 44:20 71:8 98:10 <b>event</b> 57:9,16 <b>eventually</b> 89:3 91:20 158:13 <b>every-4-month</b> 90:17,22 <b>everybody</b> 96:10 160:17 161:22 <b>everybody's</b> 163:9 <b>everyday</b> 74:9 <b>every-four-month</b> 93:16 <b>everyone</b> 27:19 30:3 32:17 34:6 50:1 54:7 56:9 61:13 77:2 83:3,12 85:4,5 88:13 101:6 162:1 174:1 <b>everyone's</b> 35:13 174:1 <b>everything</b> 48:18</p>	<p>55:14 68:11 71:9 80:5 88:2 91:9,12,13 92:7 95:13,14 97:11,15,20 107:22 109:22 111:1 131:5 166:15 <b>evidence</b> 23:16,17 24:21 <b>evident</b> 176:16 <b>exact</b> 64:1 <b>exactly</b> 37:20 <b>example</b> 13:14 15:13 22:20 24:7 33:13 37:4 101:8 167:3 <b>examples</b> 70:18 102:4 <b>except</b> 45:22 104:21 111:1 117:7 134:21 <b>exception</b> 108:7 <b>exceptionally</b> 103:15 <b>excessive</b> 48:16 130:3 <b>exchange</b> 43:17 <b>excited</b> 7:5 30:17 <b>excitedly</b> 168:8 <b>exciting</b> 84:14 <b>excuse</b> 76:5 <b>Executive</b> 41:2 <b>exercise</b> 67:18 68:2 83:20 125:20 128:21 <b>exertion</b> 57:15 <b>exhaustion</b> 106:17</p>	<p><b>exist</b> 122:7 <b>existing</b> 8:1 9:1 <b>exon</b> 168:10 <b>expand</b> 28:5 84:9 150:7 <b>expect</b> 170:17 <b>expectancy</b> 49:3 <b>expectations</b> 162:12 <b>expected</b> 105:13 133:22 134:6,8 135:7 137:2,4 147:12,13 <b>expecting</b> 159:20 <b>expedited</b> 24:14,17,19 <b>experience</b> 8:1 15:15,18 23:2 40:12 63:6,19 65:1,3 67:10 69:22 70:16 72:16 78:20 79:19,20 109:15 125:17 126:13 129:15,20 131:19 133:2 134:1 141:8,9 151:2 178:5 <b>experienced</b> 40:6 46:21 69:16 81:2 114:4 141:6 <b>experiences</b> 27:20 28:4 37:1,2 61:3,15,19 62:2 83:4 109:11,12 116:22 138:6,17,22 170:1,2 176:18 <b>experiencing</b> 11:1 12:13 63:1,2</p>	<p><b>experiment</b> 28:16,17 162:5 <b>expert</b> 31:4,20 <b>experts</b> 28:13 <b>explain</b> 47:22 75:12 132:11 137:14 146:9 150:6 157:7 <b>explained</b> 133:4 <b>explanation</b> 120:5 132:13 <b>exploration</b> 12:7 <b>explore</b> 11:19 147:19 <b>exploring</b> 16:16 75:6 <b>exposed</b> 45:17 124:7 130:4,16 160:14 178:11 <b>exposure</b> 160:11,12 <b>ex-smoker</b> 88:12,19 <b>extend</b> 82:16,19 178:15 <b>extended</b> 144:12 <b>extending</b> 144:1 <b>extensive</b> 19:10,17 145:15 160:12 <b>extent</b> 18:15 124:14 163:3 <b>extra</b> 151:4 <b>extraordinarily</b> 54:18 <b>extreme</b> 79:12 102:3 <b>extremely</b> 62:21</p>
--	---	---	---

(866) 448 - DEPO

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

<p>143:20 <b>eye</b> 46:21</p> <hr style="width: 20%; margin: 0 auto;"/> <p style="text-align: center;">F</p> <hr style="width: 20%; margin: 0 auto;"/> <p><b>face</b> 105:14 154:12 171:8 <b>faced</b> 101:21 123:9 141:18 <b>facial</b> 46:22 <b>facilitate</b> 25:15 <b>facilitated</b> 4:15,18 28:11 32:16 61:2 62:15 86:8 109:7,9 164:18 <b>facilitator</b> 5:8 26:19 <b>facing</b> 151:12 <b>fact</b> 10:22 60:7 73:11 107:1 108:20 113:2 119:21 167:18 <b>factor</b> 91:21 93:10 100:16 133:14 146:22 <b>factoring</b> 76:20 133:21 <b>factors</b> 73:16 86:21 100:17 133:8,11,15,20 135:16 138:3 141:3,4 145:22 146:9,11 147:1,18 156:3 157:16 178:19 <b>facts</b> 94:13 <b>failure</b> 134:3 150:12 151:15,16 <b>fair</b> 157:8</p>	<p><b>fairest</b> 30:2 <b>fairly</b> 72:4 92:8 139:20 178:5 <b>fairness</b> 97:15 <b>faith</b> 166:15 <b>faithfully</b> 16:22 57:21 <b>fall</b> 72:2 81:9 93:5 108:18 <b>families</b> 155:2 <b>family</b> 50:7,8 89:9 98:4,7 141:22 142:18 143:9 144:20 172:19 178:16 <b>fancy</b> 53:7 <b>fast</b> 24:19 87:20 95:12 <b>fatal</b> 151:12 <b>father</b> 172:21 173:8 <b>father-in</b> 102:5 <b>father-in-law</b> 99:18 102:3 146:17 <b>father's</b> 173:2 <b>fatigue</b> 15:9,13 20:4 22:12 23:4,12 46:10 53:20 54:13 59:16 63:13 64:12,18,21 65:1,13,20 66:18 67:10,15,16,22 68:3,7,10,12 69:5,15 70:9 71:9 72:15 73:1 77:20,21,22 78:22 79:4,12,20</p>	<p>80:9 81:16 83:15 97:22 118:15 170:12,15,17,19, 21 171:2 177:5 178:6 <b>fatigued</b> 53:19 <b>fault</b> 95:18 <b>favor</b> 82:14 <b>FDA</b> 1:1 2:2,4,6,8,11,13,1 6,18,21 3:2,5,7,8 4:5,8,11,13,21 5:6 7:4 9:5,8,21 10:13 23:15 24:12 25:2,14 26:6 30:3 31:1 32:9,11 49:22 56:16,22 57:4 87:5 93:1 99:9 104:7 111:22 113:16 116:4 125:2 133:12 145:21 147:20 148:6 157:2,15,20 167:1 169:4,21 170:10 171:1 172:18 <b>FDA's</b> 4:6 9:22 24:18 155:3 <b>fear</b> 44:15 175:12 <b>feature</b> 170:14 <b>February</b> 45:16 <b>federal</b> 13:16 14:18 172:5 <b>feedback</b> 33:19,22 176:2 <b>feel</b> 8:11 29:16 34:8 40:17 41:17 42:18 47:21 56:3 59:19 74:20</p>	<p>81:15 83:21 84:21 87:16 88:20 92:16,20 94:15 95:6 100:12 114:3 115:19 130:16,17 132:7 142:11,12 144:19 166:12,20 175:7 178:13 <b>feeling</b> 20:5 57:21 63:17 68:2 130:9 <b>feels</b> 23:21 24:1 25:19 26:3 47:9 53:19 78:19 <b>feet</b> 72:1 <b>felt</b> 14:1 56:4 61:6 65:17 67:19 89:16,17 128:8 140:13 143:8 <b>female</b> 37:18 49:13,17 78:21 155:18 <b>Ferris</b> 3:11 120:17 123:7 151:10 155:8 <b>fever</b> 171:2 <b>fewer</b> 161:9 <b>field</b> 19:17 26:5 166:18 <b>fight</b> 91:7 92:8,10 <b>fighters</b> 56:11 <b>fighting</b> 59:4 <b>figure</b> 8:17 12:19 14:9 <b>fill</b> 176:5 <b>filled</b> 142:3 <b>filtering</b> 166:18</p>
--	--	---	--

Capital Reporting Company  
 Patient-Focused Drug Development 06-28-2013  
 Page 17

<p><b>filters</b> 166:16,17  <b>final</b> 176:8  <b>finally</b> 43:19 44:4      56:14 58:4 60:12      73:20,21 104:16      116:11 171:16  <b>financial</b> 89:10  <b>financially</b> 181:13  <b>finding</b> 90:8      137:10  <b>findings</b> 137:12  <b>fine</b> 57:18,20 66:5      79:13  <b>finger</b> 174:14  <b>fingers</b> 23:7  <b>finish</b> 99:4  <b>finished</b> 55:18      60:11  <b>finishing</b> 85:16  <b>firm</b> 106:8  <b>first</b> 5:21 14:8      27:6,8,11,17      31:3 35:2 39:4      42:17 43:5 57:12      67:1,13 85:16      88:13,16 90:4      92:11 93:3      94:21,22 95:2,9      97:9 109:3      111:18 128:4      139:17 148:7      149:2 151:18      152:15 156:1      169:21 176:15  <b>first-line</b> 98:18  <b>fiscal</b> 14:12,13,21  <b>fish</b> 166:22  <b>fit</b> 12:9 15:2 31:8</p>	<p>108:8  <b>five</b> 75:16,21,22      76:11 80:3      81:7,21 82:13,15      87:6 101:14      104:20 130:14      165:17  <b>Flexeril</b> 173:16  <b>flexibility</b> 162:2,22      163:1,2,22  <b>floats</b> 70:22  <b>floors</b> 43:10  <b>Florida</b> 56:1  <b>flu</b> 51:4,5  <b>focus</b> 12:20 33:11      59:8 116:5 119:3      124:1  <b>focused</b> 5:10,22      7:13 12:6      15:14,18  <b>focuses</b> 36:13  <b>focusing</b> 28:12      56:6 132:22  <b>folic</b> 98:1  <b>folks</b> 6:17 30:16      39:1 62:1 63:16      64:6 78:14      82:4,15 110:20  <b>follicular</b> 168:2,3  <b>follow-up</b> 28:14      31:7 32:19      60:19,21 77:17      86:7 90:19,22      93:15 94:5,9      117:19 150:8      151:19 156:2      161:12 164:5  <b>follow-ups</b> 94:10  <b>food</b> 1:1,10 6:16</p>	<p>44:21 167:3  <b>foods</b> 167:4  <b>forego</b> 141:21      175:12  <b>foregoing</b> 181:4,5  <b>foreshadow</b> 126:7  <b>forget</b> 47:7,8 75:19  <b>forgot</b> 62:3 70:11  <b>forgotten</b> 51:4      119:7 131:3  <b>form</b> 8:3 142:3      179:1  <b>format</b> 4:12 5:20      15:1,10 26:12,18      27:6 34:12      169:12 170:3,9  <b>former</b> 42:14  <b>forms</b> 33:20      137:17 176:2  <b>forth</b> 167:20  <b>forties</b> 143:15  <b>fortunate</b> 48:5      59:1 93:15 107:7      153:7 160:4      177:8  <b>Fortunately</b> 77:4  <b>forward</b> 7:10,22      9:20 10:5 163:7      173:10 179:17  <b>foundation</b> 27:18      70:5 98:13      120:18  <b>foundational</b>      10:15  <b>four-hour</b> 131:8  <b>fracture</b> 72:5  <b>framework</b> 104:8</p>	<p><b>free</b> 29:16 34:8      40:18 84:21      85:2,9 180:3  <b>frequent</b> 75:20      105:22  <b>frequently</b> 56:22      100:5  <b>fresh-brewed</b> 42:9  <b>Friday</b> 1:8  <b>friend</b> 52:2,13      53:1,13,22 54:21      77:6 142:18      145:5  <b>front</b> 29:2 64:22      85:14 101:1  <b>frustrated</b> 68:11  <b>frustrating</b> 130:1  <b>frustration</b> 43:20  <b>Fuld</b> 3:12 85:17,18      99:8 144:4      146:13  <b>fulfill</b> 106:21  <b>full</b> 5:3 37:2 43:18      62:3,7 65:7      135:16  <b>full-time</b> 46:13      71:6 160:8  <b>fully</b> 19:8 20:8      40:10 111:4      177:1  <b>function</b> 51:19      127:15,19      149:13 154:5  <b>functional</b> 118:8  <b>functions</b> 23:22      24:2 25:20  <b>Furia-Helms</b> 2:7      36:7 64:17</p>
---	---	--	--

Capital Reporting Company  
 Patient-Focused Drug Development 06-28-2013  
 Page 18

111:10 127:1 135:4 137:7 <b>future</b> 34:3 78:3 116:16 133:19 151:5 <hr/> <p style="text-align: center;">G</p> <hr/> <b>Gail</b> 53:13 <b>gamma</b> 20:11 <b>gathered</b> 141:21 <b>gear</b> 55:19 <b>gene</b> 2:18 32:13 45:13 121:13 <b>general</b> 10:10 17:20 20:4 33:17,18 59:18 94:14,15 133:5 <b>generally</b> 21:8 28:10 34:19 111:9 112:7 126:9,20 133:20 <b>generosity</b> 176:18 <b>genetic</b> 21:21 22:2,3,5 25:8 98:15 116:12,13 118:20 155:15 179:11 <b>genomes</b> 98:12 <b>gentle</b> 83:11 127:13,14 <b>gentleman</b> 37:4 101:8 <b>gets</b> 44:7 54:11,14 71:7 80:4 153:19 156:4 <b>getting</b> 7:14 11:11 12:4 38:1 44:3 46:15,16 48:16 49:12 51:5 65:6	68:16 94:10 97:20 113:12 119:13 120:13 127:8 128:20 136:18 146:18 148:4,5 160:17 161:2 177:7,11 178:1 179:17 <b>GI</b> 42:12 <b>Gideon</b> 2:3 32:2 <b>girls</b> 106:14 <b>given</b> 26:3 70:14 115:7 153:12 155:14 181:8 <b>gives</b> 36:16 44:5 92:21 174:11 <b>giving</b> 26:14,15 30:14 76:3 96:3 128:21 144:10 176:19 <b>glad</b> 10:3 92:22 150:14 <b>gland</b> 45:11 81:13 <b>glass</b> 44:15 <b>goal</b> 18:17,19 26:22 31:4 102:15 139:8 163:9,10 <b>goals</b> 86:17,21 102:14 162:12 <b>god</b> 68:3 <b>golf</b> 52:3 68:15 <b>gone</b> 58:20 116:10 140:19 154:7 176:17 <b>Gosh</b> 45:8 <b>gotten</b> 149:22 176:3 <b>government</b> 7:9	30:19 <b>graces</b> 58:9 <b>Graham</b> 169:6 <b>grandchildren</b> 58:3 69:8 139:8 143:16 <b>grandson</b> 58:16,20 <b>grappling</b> 15:5 <b>grasping</b> 42:2 <b>grateful</b> 35:15 54:18 58:12 91:1 105:18 <b>gray</b> 157:1 <b>great</b> 36:1,10 40:1,22 44:17 47:14 58:15 82:1 83:2 84:15 98:10 122:2,6 154:11 170:3 178:4 <b>greatest</b> 98:3 <b>greatly</b> 41:19 172:17 <b>gripping</b> 99:2 <b>ground</b> 30:1 33:12 34:12 <b>group</b> 50:15 141:12 <b>groups</b> 9:7 16:5,14 57:6 171:8 <b>growing</b> 42:8 <b>growth</b> 71:1 91:21 93:10 <b>guaranteed</b> 153:13 <b>guess</b> 152:1 155:9 160:15 166:12 177:5 <b>guidance</b> 25:14	<b>guys</b> 54:20 74:22 <b>gym</b> 68:13 <hr/> <b>hair</b> 23:7 46:21 58:20 <b>Haiti</b> 130:6 <b>half</b> 5:16 28:9 70:21 92:15 104:20 130:14 149:20 <b>hall</b> 58:18 <b>Halloween</b> 106:6 <b>Hampshire</b> 1:12 <b>hand</b> 28:15 29:1 32:20 34:5 73:5,6,10,20 74:3,8,9,10 81:16,20,21 114:4 155:17 172:14 <b>handed</b> 28:20 <b>handle</b> 124:2 <b>hands</b> 61:3,8,14,17,21 81:18,19 109:13,16 114:6 <b>Haney</b> 3:12 66:13 85:22 104:17,18 149:20 154:1 <b>hang</b> 121:11 <b>happen</b> 36:5 105:18 116:16 134:6 147:13 173:10 <b>happened</b> 91:7 118:10 131:12 145:5 165:1 <b>happens</b> 75:19
--	--	---	--

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

Page 19

<p>107:21 116:14 144:22 177:16</p> <p><b>happily</b> 177:11</p> <p><b>happy</b> 7:10 58:22 89:17 116:3,4 129:8 150:14</p> <p><b>hard</b> 44:20 58:13 63:3 92:9,18 93:8 102:5,6 109:20 128:22 129:10 134:16 154:16 159:3 174:13</p> <p><b>harder</b> 15:8</p> <p><b>hate</b> 132:13</p> <p><b>haven't</b> 83:7,8 113:15 156:14 165:12 176:3</p> <p><b>having</b> 15:7 16:13 35:17 48:22 52:12,19 54:18 55:8 69:1 87:5 107:11 110:3 120:6 121:5 143:19 144:5,9,22 154:13 161:9,10,12,13 168:8,18 170:19</p> <p><b>head</b> 42:20 69:12 131:18 149:4 166:17 180:4</p> <p><b>Heads</b> 69:11</p> <p><b>health</b> 2:8 7:18 100:19 169:3 171:3,11</p> <p><b>healthy</b> 47:7 91:9 106:13 151:14</p> <p><b>hear</b> 8:21 27:11 30:8 36:1,3 37:8</p>	<p>39:10 62:11,14 75:11 84:9 85:4,6,7 86:5 103:18 133:2,7 140:18 149:3 170:17</p> <p><b>heard</b> 16:7 28:6 29:20 61:15 64:21 69:22 80:9 83:7 99:19 101:12 103:3 117:1 133:3 147:12 156:14 170:16 175:2,3 177:2,13 178:11,22</p> <p><b>hearing</b> 7:22 9:16 10:5 69:4 80:12 85:5 113:20 114:9,10 127:4 181:10</p> <p><b>heart</b> 43:12</p> <p><b>heating</b> 42:3</p> <p><b>Hello</b> 17:9 32:5,10 85:8,17</p> <p><b>help</b> 8:2,22 9:17 11:6 16:14 31:7 34:2 38:18 44:3 60:2 86:12,15 95:7 99:1,11 100:11 101:17 103:8 104:9 110:10 130:13 131:11 133:16,22 135:18 137:2 145:2 171:1 173:11 174:10</p> <p><b>helped</b> 83:21 90:9 132:19</p> <p><b>helpful</b> 16:3,6,8,12 98:16 104:11</p>	<p>124:20 148:5 152:2 176:22</p> <p><b>helping</b> 126:9 166:13,14</p> <p><b>helps</b> 56:7 128:19</p> <p><b>hemorrhaging</b> 58:3</p> <p><b>herbal</b> 44:1</p> <p><b>hereby</b> 181:4 182:2</p> <p><b>hereto</b> 181:13</p> <p><b>herself</b> 52:19</p> <p><b>he's</b> 37:7 100:2 101:2 123:21</p> <p><b>Hi</b> 32:2 39:16 50:12 66:3 70:4</p> <p><b>hide</b> 164:22</p> <p><b>high</b> 17:19 23:13 51:20 103:15 122:11 132:8</p> <p><b>high-energy</b> 20:11</p> <p><b>higher</b> 124:8</p> <p><b>highlight</b> 26:4 112:6 113:17 114:15 126:7 127:6</p> <p><b>highlighted</b> 171:17</p> <p><b>highly</b> 177:21</p> <p><b>hiking</b> 53:10</p> <p><b>hill</b> 77:8 115:15</p> <p><b>hills</b> 56:1</p> <p><b>hindsight</b> 45:22 81:10</p> <p><b>hip</b> 72:3,5</p> <p><b>histological</b> 18:2 21:14,22</p>	<p><b>histology</b> 21:14 167:20</p> <p><b>histories</b> 83:12</p> <p><b>history</b> 95:18</p> <p><b>hit</b> 91:8,11,13 92:3,6 97:15 150:21 153:17</p> <p><b>hits</b> 95:16</p> <p><b>hitting</b> 94:3 120:3</p> <p><b>HIV</b> 15:18 169:17 170:15</p> <p><b>hoarseness</b> 54:12 63:13</p> <p><b>Hogan</b> 3:13 66:3 75:15 76:2,6 84:22 85:1,6 87:4 114:8,11 128:16 143:14</p> <p><b>hold</b> 63:22 66:22 107:18 130:4</p> <p><b>holding</b> 56:16</p> <p><b>hole</b> 58:11</p> <p><b>holistic</b> 166:16</p> <p><b>Holland</b> 55:18</p> <p><b>home</b> 43:20 44:7,17 66:8 71:7 89:18 136:9 145:16 146:21 166:17 179:20</p> <p><b>homes</b> 161:12</p> <p><b>homogenous</b> 122:19</p> <p><b>Honestly</b> 41:17</p> <p><b>honeymoon</b> 51:6</p> <p><b>honor</b> 41:7</p> <p><b>hope</b> 13:11 29:12 37:7 49:10 75:15 89:2,3 108:3</p>
---	--	---	--

(866) 448 - DEPO

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

<p>138:12 141:17 151:4 170:10 179:20</p> <p><b>hopefully</b> 39:5,6 116:6</p> <p><b>hopes</b> 42:12</p> <p><b>hoping</b> 8:21 11:18 48:20</p> <p><b>horrible</b> 55:22 65:21 118:14 119:2</p> <p><b>hospice</b> 71:6 140:5 143:6 145:9,17</p> <p><b>hospital</b> 77:7 131:6 145:12 160:5 161:15 172:22</p> <p><b>hospitalization</b> 134:4,13</p> <p><b>hospitalizations</b> 106:19</p> <p><b>hospitalized</b> 152:8</p> <p><b>hospitals</b> 164:12</p> <p><b>hosting</b> 99:9</p> <p><b>hot</b> 127:13</p> <p><b>hour</b> 5:16 42:19</p> <p><b>hours</b> 43:15,16 74:3 77:8 100:7 106:7 160:9</p> <p><b>housekeeping</b> 5:12</p> <p><b>huge</b> 128:7</p> <p><b>humbled</b> 41:5</p> <p><b>Hundred</b> 55:22</p> <p><b>hungry</b> 43:21</p> <p><b>hurt</b> 131:10 177:19</p> <p><b>hurts</b> 77:11</p>	<p><b>husband</b> 90:11 92:19 140:3,8,15,17</p> <p><b>hush</b> 173:1</p> <p><b>hydrated</b> 89:12</p> <hr/> <p style="text-align: center;"><b>I</b></p> <hr/> <p><b>IA</b> 74:2 90:7 94:11</p> <p><b>idea</b> 50:21 108:12 118:21 157:5</p> <p><b>identified</b> 14:7</p> <p><b>identify</b> 22:3</p> <p><b>identifying</b> 13:19</p> <p><b>ignorant</b> 94:13</p> <p><b>II</b> 2:4,10,13,15,21 4:4,10 7:3 18:12,14 31:14 32:1,4,7 45:19 87:6</p> <p><b>III</b> 18:17,20,22</p> <p><b>IIIA</b> 91:19 93:4</p> <p><b>IIIB</b> 93:5</p> <p><b>ill</b> 29:12 30:13 36:22 37:6 44:12</p> <p><b>I'll</b> 17:5 28:14 31:3,8 32:19 34:6 38:10 40:19 42:5 44:2 50:5,11 52:1 60:4 74:11 79:16 82:7 84:17 88:6 93:22 108:2 109:19 111:13 132:15 137:17 142:7 153:18 165:20 172:16 176:1</p> <p><b>illness</b> 49:1 88:21</p> <p><b>illusiv</b> 106:8</p>	<p><b>I'm</b> 5:4 14:16,17 17:9,11 27:1 28:19 31:1,13,16,19,20 ,22 32:2,3,5,10 34:13 35:20 39:9,10,18 40:1 41:2,9 43:1,2,19,21 44:4,12,19 45:7 46:12 47:7,9 48:5,16,17,20 49:11,22 50:6,12,13,14,19 ,20 51:7,18 56:16 58:12,13,14,21 61:4,22 65:12 69:4,14 70:4,5 71:15 72:22 73:5 74:10 75:6 76:2,3 80:19 81:5 82:12,14 85:1,9,13,15,18 88:5,9 91:1,6,9 92:9,20,22 93:7 95:5,6 97:19 99:15 104:20 105:3,14,18 106:11,13,20 107:2,9,18,20 108:12,13,18 109:8 114:7 120:18 125:3 128:18 129:6,15 130:4,5,14,16,17 ,18 133:4,6 137:3 138:14,15,18 141:1 144:10,16,20,21 150:4,9 151:3,5,10 153:4,5,6,7 154:5 155:21</p>	<p>156:5 158:21 160:5 167:5,14 169:2 173:6</p> <p><b>image</b> 43:8 47:5</p> <p><b>immediate</b> 17:3 22:14 171:9</p> <p><b>immediately</b> 89:5 92:1</p> <p><b>immobilized</b> 42:2</p> <p><b>immune</b> 166:14</p> <p><b>immunotherapies</b> 122:6</p> <p><b>impact</b> 6:1 7:19 27:9 40:8 46:9 47:1 63:8 67:6 69:9 70:1 72:19 105:5 108:5 178:7</p> <p><b>impairment</b> 22:21</p> <p><b>impairs</b> 70:9</p> <p><b>implicit</b> 47:19</p> <p><b>importance</b> 86:18 139:2 144:5 154:13</p> <p><b>important</b> 26:8 28:2,13 29:14 30:14,22 33:19 34:5 40:9 54:6,20 56:5 62:5,12,13 77:16 78:6 84:13 89:21 102:11 103:14 104:11 111:2 113:9 116:14 125:2,3,6 126:8 133:11,15 135:17 136:16 137:9 140:14 142:4 146:11 152:12 154:22</p>
--	--	---	--

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

<p>156:14 163:11,13 172:2 175:8 178:19 179:2</p> <p><b>impossible</b> 54:8</p> <p><b>impressed</b> 113:4</p> <p><b>impressive</b> 172:4,6</p> <p><b>improve</b> 86:15</p> <p><b>improved</b> 34:2 128:13 144:13</p> <p><b>improvement</b> 23:21</p> <p><b>improves</b> 127:14,19</p> <p><b>improving</b> 18:20 86:19</p> <p><b>inability</b> 46:14</p> <p><b>incidental</b> 90:8</p> <p><b>incision</b> 131:5</p> <p><b>include</b> 20:2 27:19,22 110:11</p> <p><b>included</b> 29:18</p> <p><b>includes</b> 25:10 83:18 175:8</p> <p><b>including</b> 7:7 22:12 74:15 83:15 91:13 164:13 177:4</p> <p><b>inconvenience</b> 48:10 100:19</p> <p><b>incorporate</b> 158:1</p> <p><b>increase</b> 178:1</p> <p><b>increased</b> 23:8,13 103:6</p> <p><b>increases</b> 104:4</p> <p><b>incredibly</b> 16:11</p> <p><b>independent</b> 169:2</p>	<p><b>Indicating</b> 131:8</p> <p><b>indication</b> 34:18 136:22</p> <p><b>individual</b> 171:13 179:10</p> <p><b>individual's</b> 103:17</p> <p><b>induced</b> 96:20</p> <p><b>inducted</b> 58:16</p> <p><b>indulgence</b> 44:16</p> <p><b>industry</b> 30:18 95:19 122:13</p> <p><b>inevitable</b> 107:19</p> <p><b>inevitably</b> 48:13</p> <p><b>inexcusable</b> 94:12 96:6</p> <p><b>infection</b> 22:13 23:8</p> <p><b>infections</b> 46:22</p> <p><b>inflammation</b> 23:2 148:20</p> <p><b>inflammatory</b> 150:12</p> <p><b>influence</b> 122:13 152:9</p> <p><b>influenced</b> 100:20</p> <p><b>inform</b> 9:1 11:3 99:11</p> <p><b>information</b> 15:11 16:8 118:21 124:6 154:13,15,19,21 157:17 163:18 164:22 167:7 176:22 179:14</p> <p><b>informed</b> 97:3</p> <p><b>inhaler</b> 130:12</p>	<p><b>initial</b> 10:15 12:20 13:2 90:6 167:18 168:3</p> <p><b>initially</b> 8:6</p> <p><b>initiative</b> 4:6 5:10,17 7:13,16 10:1,10 11:10</p> <p><b>initiatives</b> 9:22</p> <p><b>injection</b> 43:8 97:10</p> <p><b>injections</b> 97:18</p> <p><b>injury</b> 23:14 148:19 154:4 177:20</p> <p><b>inoperable</b> 55:3</p> <p><b>in-person</b> 28:21</p> <p><b>input</b> 9:20 11:6,11 12:4 13:22 14:5 15:6 16:4 161:8,21</p> <p><b>insatiable</b> 101:13</p> <p><b>INSERT</b> 182:2</p> <p><b>inside</b> 54:1</p> <p><b>insight</b> 11:7 17:1 176:21</p> <p><b>insights</b> 16:6</p> <p><b>insisted</b> 87:9</p> <p><b>insomnia</b> 46:2 81:8,17 168:9</p> <p><b>inspired</b> 10:22 61:6 121:10</p> <p><b>inspiring</b> 61:11</p> <p><b>instance</b> 106:1 152:7</p> <p><b>instead</b> 21:22 33:16 136:5</p> <p><b>Institute</b> 97:12</p>	<p><b>instructor</b> 127:12,21</p> <p><b>instruments</b> 25:18 26:7</p> <p><b>insult</b> 177:19</p> <p><b>insurance</b> 94:21</p> <p><b>intend</b> 16:21</p> <p><b>interactions</b> 124:6 171:20</p> <p><b>interactive</b> 16:17</p> <p><b>interest</b> 7:10 80:13 179:5</p> <p><b>interested</b> 80:12 133:13 181:14 182:6</p> <p><b>interesting</b> 57:10 64:9 73:4 74:17 105:16 158:4 159:21</p> <p><b>Interestingly</b> 105:17</p> <p><b>interior</b> 55:15</p> <p><b>interviewed</b> 68:10</p> <p><b>intricate</b> 72:9</p> <p><b>intro</b> 96:17</p> <p><b>introduce</b> 31:2,10 39:11 84:17</p> <p><b>invasion</b> 139:20</p> <p><b>invisible</b> 47:6 106:8</p> <p><b>invite</b> 28:18</p> <p><b>inviting</b> 28:14</p> <p><b>involved</b> 22:21 25:12</p> <p><b>involvement</b> 16:9</p> <p><b>irradiation</b> 22:22</p>
--	---	---	---

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

<p><b>irrelevant</b> 107:16  <b>irrespective</b> 83:11  <b>irreversible</b>  155:10  <b>IRS</b> 106:10  <b>isn't</b> 75:17 93:6,12  152:10  <b>issue</b> 67:16 81:17  123:19,21 124:7  152:4  <b>issued</b> 25:14  <b>issues</b> 8:22 9:17  11:21 14:2  15:4,6,8 42:12  70:13 75:14 76:8  93:3 105:22  119:17 124:12  127:18 163:22  <b>it's</b> 8:17 10:12  11:16 18:11  20:15 26:17  32:19 33:21 40:6  41:6,14,16 42:7  44:8 45:3 47:12  57:2 58:14 60:4  63:2 64:17  66:11,15  68:14,20  69:6,9,15 71:2  75:15,20 76:6,11  77:1,10,13,15  78:6,17 79:2  88:18 89:1 92:18  93:21  94:2,4,5,11  101:5 103:14,18  106:12 108:14  113:4,9  117:10,14  118:8,9 119:8  123:7,10 125:2,6  127:21</p>	<p>128:16,22 129:1  130:2,3,5 132:12  134:18 136:7  138:8 142:11  144:18 145:8  148:8 149:7  151:13 153:10  154:3 155:15  157:11,19  160:15 161:1  163:21 167:6,15  170:3,9,13 172:6  178:5,13  <b>IV</b> 18:10,17,20  19:1 21:4 41:4  45:10 47:4 50:4  86:1 91:19 93:6  94:7 97:4 105:1  116:13 121:22  136:7,8 144:8  <b>I've</b> 40:13 41:15  44:20 49:8 73:1  74:12 92:14  101:12 104:22  105:22 107:7  119:7 128:21  130:20 144:20  145:9  166:10,15,20,21  169:11</p> <hr/> <p style="text-align: center;"><b>J</b></p> <hr/> <p><b>James</b> 3:14 166:3  167:13,14  168:21  <b>January</b> 59:7  <b>Jennifer</b> 144:7  <b>job</b> 26:17 70:9  71:6,20,21 95:9  155:3  <b>John</b> 3:16 53:1  67:11,12 85:13</p>	<p>96:15,17 99:6  120:22  <b>journey</b> 104:21  <b>judgment</b> 47:19  138:3  <b>jump</b> 150:22  <b>jumping</b> 180:2  <b>June</b> 1:8</p> <hr/> <p style="text-align: center;"><b>K</b></p> <hr/> <p><b>Karen</b> 3:10  72:21,22 74:19  85:8 90:3 96:14  112:15 114:21  128:2 129:21  151:18,19  152:15  <b>Karen's</b> 129:6  <b>Kathleen</b> 3:17  27:14 39:18  50:11,12 56:13  78:16 118:3  132:14 135:20  150:3,20 157:3  <b>Kazandjian</b> 2:12  31:12 150:9  <b>Keegan</b> 2:9 4:3  5:13 6:19,21 7:2  17:13 31:22  77:18 122:18  123:11 151:20  156:17 162:1  <b>key</b> 9:5 155:10  <b>Khozin</b> 2:14 4:10  17:9  <b>kicks</b> 43:22  <b>kidney</b> 134:3  145:5  <b>kids</b> 68:19,21 69:3</p>	<p><b>kill</b> 20:14 97:5  105:9  <b>killed</b> 173:7  <b>killing</b> 88:1  <b>Kim</b> 3:14 41:10  158:15,20,22  159:12 166:3  168:22 169:1  172:8 177:5  <b>kiosk</b> 6:16  <b>kitchen</b> 91:13  132:18  <b>knew</b> 67:15 91:7  127:12 142:21  168:11 173:2,4  <b>known</b> 93:17  118:11 122:3  <b>Kweder</b> 169:5</p> <hr/> <p style="text-align: center;"><b>L</b></p> <hr/> <p><b>labeling</b> 3:4  124:11,16 167:4  <b>lack</b> 46:2,3 63:13  64:12,18,21 65:2  83:16 110:2  <b>ladies</b> 62:8 68:9  <b>lady</b> 41:9 68:19  139:7  <b>lady's</b> 46:18  <b>landscape</b> 71:20  <b>lap</b> 66:22  <b>laptop</b> 44:1  <b>large</b> 9:16 12:9  55:1,4 138:8  163:14  <b>large-group</b>  4:15,18 60:20  61:1 62:15 86:8</p>
--	---	--	---

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

Page 23

<p>109:7 <b>largely</b> 120:21 <b>larger</b> 155:15 <b>last</b> 13:16 14:9 37:5 45:16 60:4 67:17 97:10 100:1,4 103:13 109:9 136:20 142:1 145:1,5,18 159:22 <b>lastly</b> 49:5 <b>late</b> 93:4,5 103:2 <b>lately</b> 68:4 <b>later</b> 14:17 42:17 45:1,18 49:11 74:3 90:19 91:3 140:4 145:15 174:16 <b>late-stage</b> 154:21 <b>latte</b> 43:11 <b>laughs</b> 131:18 <b>law</b> 102:6 <b>lawyer</b> 51:7,8 <b>lay</b> 45:2 144:2 <b>Le</b> 2:17 32:10 <b>lead</b> 134:3 177:22 <b>Leader</b> 2:3 32:3 <b>leading</b> 7:20 17:16 <b>leads</b> 28:13 <b>learn</b> 12:12 30:21 33:17 <b>learned</b> 44:20 128:21 <b>learning</b> 12:7,16 130:19 <b>least</b> 12:15 39:1 42:19 61:15</p>	<p>109:11 135:17 136:16 146:4,6,7,8 151:11 175:17 <b>leave</b> 29:4 34:9 43:19 136:2,13 156:18 176:6 <b>leaves</b> 42:1 <b>led</b> 104:22 <b>Lee</b> 3:13 65:10 79:3 80:2 113:19 <b>leg</b> 54:16 <b>legislation</b> 59:7 <b>legs</b> 52:14 <b>length</b> 38:4 <b>lesion</b> 167:21 <b>less</b> 38:5 117:3 178:21 <b>let's</b> 40:20 63:16 64:4,6,20 77:14 111:17 112:14 116:20 117:21 129:13 132:21 134:19 135:15 136:13 137:9 146:3 147:16 151:19 157:8 <b>level</b> 83:19 162:6 <b>Liaison</b> 2:20 32:6 57:6 <b>life</b> 6:1 18:21 27:9 41:18 46:9,11 47:1 48:6 49:3 52:12 63:8 65:2 69:10 70:2 86:18 87:15 88:4,5,7 89:17,21 91:8 99:4 100:13,22 101:13 103:10,12</p>	<p>104:18 105:12 119:15 134:5,7,12,20 135:6,7 137:21 139:2 140:6,12 142:1,4,9,11 143:4,7,16 144:1,12,14 145:1,18 147:9,10 151:4,14 153:12,17 175:8,17 178:15,18 <b>life-impacting</b> 170:12 <b>lifestyle</b> 48:3,11 49:8 177:15,18 <b>lifting</b> 65:17 71:4 <b>ligands</b> 25:12 <b>light</b> 42:22 74:1 <b>likelihood</b> 137:20 <b>likely</b> 24:2 100:22 103:5,7 146:21 155:15 163:22 <b>limit</b> 12:1 48:4 <b>limitations</b> 48:7 52:11,12,20 <b>limited</b> 11:10 19:9,11,14,15 47:14 91:15 102:16 110:3 <b>line</b> 79:13 145:11 <b>lines</b> 101:14 121:8 179:15 <b>lingering</b> 46:1 53:18 <b>link</b> 62:6 157:10 159:6,8</p>	<p><b>links</b> 98:22 159:1 <b>Lisa</b> 54:21 55:20 <b>list</b> 13:1,2,17 14:19 25:1 64:10,11 146:5,11 <b>listed</b> 54:4 <b>listen</b> 31:1 158:6 <b>listening</b> 30:21 31:20 77:19 79:18 99:10,12 157:5 <b>literally</b> 58:3 81:10 130:17 140:20 <b>literature</b> 90:15 <b>little</b> 12:8 26:20 27:16 31:11 50:19 51:22 55:20 58:13,14 65:19 69:19 70:10 74:11 75:6 82:22 90:19 102:4 106:13 110:22 130:1 142:8 146:16 152:5 158:11,14 159:10 161:8,18 163:4 168:8 <b>live</b> 35:3,4,5 41:12,16 48:5 49:3 56:21 67:20 83:12,13 105:5 107:6 130:19 142:9 170:5 <b>lived</b> 71:20 105:5 142:20 150:10 <b>liver</b> 23:14 44:16 148:19 149:12 150:12 151:15,16</p>
---	--	--	---

(866) 448 - DEPO

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

<p>154:3,5,17</p> <p><b>lives</b> 13:5 15:14 51:1 100:6 117:9 121:10 146:18</p> <p><b>living</b> 13:4 15:19 27:2 35:22 36:14 41:4,5,8,13,17 47:12 48:4 49:1 68:22 129:8 140:21 151:14 163:20</p> <p><b>lobe</b> 73:22</p> <p><b>local</b> 35:10 87:7</p> <p><b>localized</b> 18:10,12 20:8 22:19 38:16 139:21</p> <p><b>located</b> 6:13</p> <p><b>long</b> 100:13 102:13 107:7 115:10 134:4,6,11,19 135:5,6 136:5 139:14 160:9 163:20</p> <p><b>longer</b> 58:20 76:11 90:5 108:5 134:7 135:7 149:6 150:11 151:6 158:11,14</p> <p><b>Longevity</b> 120:17</p> <p><b>long-term</b> 38:13 103:2 171:10</p> <p><b>Lorren</b> 3:16 27:14 39:14 40:20 41:2 45:6 74:21 116:8 128:3 132:10 149:4</p> <p><b>losing</b> 46:21 74:7</p> <p><b>loss</b> 20:3,4 23:7 63:12 113:20</p>	<p>134:9</p> <p><b>lost</b> 55:7 100:3 106:6 114:9 118:11 141:17</p> <p><b>lot</b> 16:6 22:14 37:22 43:21 45:9 54:15 56:10 62:21 69:12 72:1,11 77:20 84:8 89:9,15 90:12 92:21 98:21 103:3 107:10 109:3,17,18 111:18 112:19 113:1,6,12 116:5 122:6 123:16 124:5 125:11 127:5,22 131:18 143:14 147:1 151:11 158:4 160:9 162:11 163:18 166:9 170:16 175:5 176:21 178:2,4</p> <p><b>lots</b> 5:4 7:5 106:6 126:16</p> <p><b>love</b> 92:15 106:15</p> <p><b>loved</b> 27:4 30:12 36:2,18 37:9 63:1 71:21 104:1</p> <p><b>loves</b> 68:17</p> <p><b>low</b> 79:12</p> <p><b>lower</b> 132:17</p> <p><b>luckily</b> 72:5</p> <p><b>lucky</b> 50:13 52:11 59:1 87:10,16 97:6</p> <p><b>lumps</b> 53:4</p> <p><b>lunch</b> 82:22 180:4</p>	<p><b>lung</b> 1:5 2:3 4:9 5:9,19,22 6:3 7:1,18 8:2,7,9,14 9:3 17:7,8,11,13,21, 22 18:4,8 19:5,9,12,15,19 20:7,16 21:19 22:5 23:2,14 25:3,4 26:16 27:2,9,21 29:9 31:13 32:3 35:17 36:1 37:2 39:17,19,21 40:7,11 41:4,6,8,12,13 45:10,17 46:4 47:4,18,20 48:22 50:2,3,13,14,22 51:3,6,13,19 52:4,5,16 53:4,11,15,17,20 ,21 54:1,2,7,10,22 55:2,8 56:10,17 57:10,12 58:5,11 59:6,8,11 60:8 63:2,7 65:11,19 68:22 70:7 71:16,18 73:17 74:2 77:5,6,12,22 78:1 79:1,21 80:16 81:2 84:7 85:11 86:1,13 87:6,8,11 88:11,17 89:1,4,6 90:6,20 92:15,16 93:19,21 94:1,2,5,16,17,1 9 96:2 99:15,20 101:10 102:12,19 104:18,19</p>	<p>110:11,14 115:5,11,17 116:2,5 119:12,14,19 120:20 122:7 125:18 133:17 138:7 139:17 140:8 144:9 148:9,19 150:12 151:15 152:18 153:13 154:21 167:22 168:5 172:22 173:2,3 177:10,13,16 178:1 180:6</p> <p><b>lungs</b> 19:3 38:17 43:5 51:3,7,11,19 55:3</p> <p><b>lymph</b> 18:13 45:12 51:14,15 91:3</p> <hr/> <p style="text-align: center;"><b>M</b></p> <hr/> <p><b>main</b> 26:22 166:12</p> <p><b>maintenance</b> 115:8</p> <p><b>major</b> 24:15 72:14 97:18 111:14</p> <p><b>makeup</b> 22:2 155:15 179:12</p> <p><b>male</b> 37:17</p> <p><b>malignances</b> 24:16</p> <p><b>malignant</b> 25:12</p> <p><b>Malik</b> 2:19 32:5 114:20 136:3,5 164:5 165:4</p> <p><b>man</b> 101:4 145:11</p> <p><b>manage</b> 86:15 125:17 142:5</p> <p><b>managed</b> 126:13</p>
--	--	---	---

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

Page 25

<p>129:20 160:7 <b>management</b> 77:12 128:11 <b>manager</b> 94:21 <b>managing</b> 47:12,15 <b>manifestation</b> 77:22 <b>manufacturers</b> 163:3 <b>marathon</b> 92:12 <b>marathons</b> 92:14,15 <b>Marie</b> 3:17 129:5,12 138:9 <b>marker</b> 93:20 <b>marketing</b> 98:10 <b>married</b> 51:5,7 101:16 <b>marrow</b> 23:10 <b>Maryland</b> 181:18 <b>mass</b> 45:17 <b>matchable</b> 98:21 <b>math</b> 35:21,22 <b>matter</b> 47:21 63:5 <b>Maureen</b> 59:13,17 <b>maximize</b> 12:12 <b>may</b> 9:15 13:6,7,8 15:4 17:2 26:21 29:15 33:4,5,13 37:1,20 38:11 41:10 48:9 51:2 52:2,13 98:21 99:1 100:10 102:8 103:17 108:8,16 109:21 111:3 123:11,13 124:20 128:17</p>	<p>144:15,17 150:10 151:14 158:11 177:18 178:10 179:12,13 <b>maybe</b> 13:12,14 28:5 45:22 57:15 62:2 66:7 72:18 77:19 81:3,13 83:7 97:22 107:4 111:20 113:2 116:14 117:3 124:12 127:22 141:3 142:12 152:5,9 153:7,15,18 154:6,7 156:21 158:6,10 159:8 160:15,17 161:10,20 170:22 171:3 175:2 <b>Mayo</b> 51:9 119:14 <b>mccleary</b> 169:1 <b>McCleary</b> 3:14 166:3 168:22 169:2 177:5 <b>MD</b> 1:13 2:3,9,12,14,17,1 9 4:3,10 <b>ME/CFS</b> 169:13,16 170:20 <b>meal</b> 44:17 <b>meals</b> 44:13 68:2 <b>mean</b> 18:19 27:3 49:15 59:21 69:9 77:4,10 78:12 87:17 89:11,18 107:4 109:3 112:9 122:3 144:10 146:14</p>	<p>151:3 152:3 154:4,5 155:5 164:9 166:15 168:11 <b>meaning</b> 18:2 <b>meaningful</b> 44:17 <b>means</b> 75:2,13 103:10 108:14 <b>meantime</b> 73:19 <b>measure</b> 21:5 25:19 43:3 171:1 <b>measurement</b> 170:21 <b>measurements</b> 25:21 <b>measures</b> 9:2 25:17 26:1 <b>measuring</b> 8:8 170:21 <b>mechanisms</b> 11:11 <b>median</b> 148:14 <b>mediastinal</b> 91:4 92:5 <b>mediastinum</b> 91:4,6 <b>medical</b> 2:3,12,15,17,20 10:19 17:10 31:3,13,20 32:6,11 85:11 94:13 130:6 147:2 175:9 <b>medication</b> 53:9 77:2 97:19 107:15 119:3 <b>medications</b> 125:19 126:17 127:3 171:18,20 <b>medicine</b> 122:2</p>	<p>146:20 150:15 173:22 <b>medicines</b> 126:18 <b>meet</b> 11:4 131:12 <b>meeting</b> 1:5 2:1 3:1 5:8,9 6:22 7:12 10:4,6 14:14 15:1 16:21 26:20 33:20,22 34:1 62:6 65:8 99:9 156:18 158:4,5,13 165:7 169:15 170:8,15,16 180:3,7 181:4 <b>meetings</b> 7:13 8:7 10:11,12 12:5,6,9,15,18 14:4,22 16:4,9,14,15,19 26:21 34:3 46:16 169:12,13 172:5 <b>member</b> 50:8,14 85:11 <b>members</b> 27:19 121:1 142:18 <b>memory</b> 75:17 83:16 <b>men</b> 7:21 17:15 37:21 <b>mental</b> 41:15 75:9,13 <b>mentally</b> 88:1 92:7 <b>mention</b> 60:4 62:3 70:11 77:16 112:12 114:3 115:3,9 <b>mentioned</b> 17:13 21:15 24:6 36:21 59:17 62:5,19</p>
---	--	---	--

(866) 448 - DEPO

Capital Reporting Company  
 Patient-Focused Drug Development 06-28-2013  
 Page 26

63:16 69:21 71:13 72:19 73:3 81:6 83:8,18,20 111:9 113:15 115:1 116:1 120:22 126:1 127:7 134:21 138:5 168:14 178:20 <b>mess</b> 31:6 <b>met</b> 94:10,14 120:4 <b>metabolize</b> 124:3 <b>metastases</b> 72:3 122:1 123:3 <b>metastasis</b> 91:5,6 93:19 94:6 <b>metastasized</b> 21:4 38:19 <b>metastasizes</b> 8:15 <b>metastasizing</b> 19:6 <b>metastatic</b> 19:2 148:9 167:21 <b>methods</b> 16:16 <b>metrics</b> 24:6 <b>metro</b> 35:11 <b>Metropolitan</b> 35:4,6 <b>mets</b> 122:1 <b>mic</b> 49:19 79:3 135:12 <b>microphones</b> 65:6 <b>microscope</b> 18:4 <b>middle</b> 54:1 130:8 <b>miles</b> 55:20 106:6 <b>millimeters</b> 74:1 <b>millisieverts</b> 161:1	<b>mind</b> 47:5 89:14 135:9 136:11 149:3 150:13 <b>mind-body</b> 128:16 <b>minds</b> 138:15 <b>mine</b> 77:7 <b>minimal</b> 108:19 <b>minimum</b> 34:7 <b>minor</b> 178:5 <b>minus</b> 18:15 <b>minute</b> 29:1 31:2 32:15 37:6 165:8 <b>minutes</b> 5:15 7:17 10:9 40:3 42:17 43:9 44:22 49:12 64:1 82:16 83:1 86:5 165:19,20 <b>miracle</b> 131:15 159:20 <b>miraculously</b> 48:3 <b>mirror</b> 47:2 <b>misdiagnosed</b> 46:2 <b>Miskala</b> 3:3 31:15 80:8 <b>missed</b> 106:2 <b>missing</b> 51:18 129:7 154:20 <b>mission</b> 130:6 <b>mixed</b> 54:11 <b>mobile</b> 171:3 <b>mobility</b> 15:8 <b>modalities</b> 103:8 <b>modality</b> 18:14 20:7 <b>mode</b> 12:16 30:21 31:20	<b>molecular</b> 21:20 59:10 98:16 <b>Mommy</b> 66:19,20,22 67:3 <b>Monday</b> 97:10 <b>money</b> 89:14 100:9 115:16 <b>monitored</b> 107:17 154:3,8 155:9 <b>monstrous</b> 46:22 <b>Montessa</b> 3:13 65:4,10 78:10 79:22 81:6 113:18 <b>month</b> 45:18 100:1 136:10 140:4 142:1 156:7,9 <b>monthly</b> 41:18 <b>months</b> 24:13,17 45:9 60:10 67:13 87:12 91:1,2 92:11 94:7 108:14 145:18 148:13,14,15 149:6,21 151:4 175:16 179:6 <b>month's</b> 42:3 <b>morning</b> 5:3 6:22 39:14 42:8,10,14 46:16 58:19 84:22 87:4 96:16 170:16 <b>mornings</b> 46:15 <b>morning's</b> 5:14 40:4 <b>morph</b> 59:20 <b>mother</b> 70:6 71:18 106:20 120:19 129:6 174:7	<b>mother-in-law</b> 173:8 <b>mouth</b> 94:22 <b>move</b> 6:2 37:11 64:4 69:18 79:15 83:5 84:5,10 86:7 96:15 99:7 110:21 112:14 125:4 126:14 132:2,21 147:16 165:14 173:10 <b>moved</b> 166:21 <b>moving</b> 97:9 <b>MPH</b> 2:7,14 4:10 <b>MRI</b> 43:8 73:21 <b>MSPH</b> 3:3 <b>mucous</b> 130:3,17 <b>Mullin</b> 3:6 4:7,21 7:16 9:21 10:2 31:18 169:5 176:8,10 <b>multilayer</b> 169:10 <b>multiple</b> 34:14 55:2 73:9 121:8 171:18 <b>muscles</b> 59:18 71:3 <b>mutation</b> 105:15 116:11 121:9,13 122:5 165:3 168:10,15 <b>mutations</b> 25:10 97:7 122:4 164:21 <b>myself</b> 42:15,21 46:5,17 48:1 50:14,19 74:8,16 118:4 166:11
---	--	--	---

Capital Reporting Company  
 Patient-Focused Drug Development 06-28-2013  
 Page 27

<p style="text-align: center;"><u>N</u></p> <p><b>nagging</b> 73:12</p> <p><b>nap</b> 44:5 67:20</p> <p><b>naps</b> 67:17,21</p> <p><b>Naptime</b> 44:1</p> <p><b>narcolepsy</b> 14:15 170:17</p> <p><b>Nasso</b> 3:12 85:17,18 99:8 144:4 146:13</p> <p><b>Natalia</b> 1:18 181:3,17</p> <p><b>National</b> 65:11 70:5 85:19</p> <p><b>natural</b> 82:21</p> <p><b>nausea</b> 23:4 42:19 43:22 44:22 97:21 105:10 134:9</p> <p><b>nauseous</b> 112:20</p> <p><b>Naval</b> 58:16</p> <p><b>navigating</b> 43:21</p> <p><b>NCCS</b> 101:9,18</p> <p><b>NCI</b> 59:8 115:3 164:13 167:15 168:7</p> <p><b>nearby</b> 18:13</p> <p><b>nebulous</b> 57:12 59:15</p> <p><b>necessarily</b> 138:6</p> <p><b>necessary</b> 123:1 124:8 160:21 163:10</p> <p><b>neck</b> 127:1,2</p> <p><b>needle</b> 43:6</p> <p><b>negatively</b> 8:12</p>	<p>46:9</p> <p><b>neighbor's</b> 65:16</p> <p><b>neither</b> 181:9 182:5</p> <p><b>nerve</b> 23:5</p> <p><b>nervous</b> 38:18</p> <p><b>neuropathy</b> 23:6 51:18 71:22 83:17 103:22 118:14,15</p> <p><b>never-smokers</b> 96:8</p> <p><b>newer</b> 21:9,19 25:6 108:7</p> <p><b>newest</b> 24:20</p> <p><b>news</b> 98:10 140:15</p> <p><b>nice</b> 37:14 43:22 76:18</p> <p><b>night</b> 44:8,18 67:18 130:8</p> <p><b>Nine</b> 85:14</p> <p><b>nines</b> 97:14</p> <p><b>nobody</b> 135:21</p> <p><b>nodding</b> 69:11,13</p> <p><b>node</b> 91:3</p> <p><b>nodes</b> 18:13 45:12 51:14,15</p> <p><b>nods</b> 131:19</p> <p><b>nodule</b> 73:22 74:4 91:3</p> <p><b>nodules</b> 55:2</p> <p><b>nominated</b> 8:6</p> <p><b>nondrug</b> 127:5</p> <p><b>none</b> 19:20 49:6 153:12</p> <p><b>nonessential</b></p>	<p>162:15</p> <p><b>nonproductive</b> 52:3</p> <p><b>nonrepresentative</b> 138:13</p> <p><b>non-small</b> 17:22 18:4,8,9 20:10,16 21:16 87:6 148:9 168:5</p> <p><b>non-smokers</b> 96:11</p> <p><b>nor</b> 181:9,13 182:5,6</p> <p><b>normal</b> 22:18 49:3 67:20 96:21</p> <p><b>normalcy</b> 46:11</p> <p><b>normally</b> 56:4</p> <p><b>Notary</b> 181:2,18</p> <p><b>nothing</b> 87:19 96:22 106:11 115:2,13 120:8</p> <p><b>Notice</b> 13:17 14:18</p> <p><b>noticed</b> 67:2 76:14 128:7</p> <p><b>November</b> 53:22</p> <p><b>nudge</b> 165:20</p> <p><b>numbness</b> 23:6 72:1 87:15</p> <p><b>nurse</b> 70:9 71:4,6 94:20 173:1 174:8</p> <p><b>nurses</b> 94:15</p> <p><b>nutrition</b> 83:20</p> <p style="text-align: right;">O</p> <p><b>Oak</b> 1:11</p> <p><b>observations</b></p>	<p>169:19</p> <p><b>obvious</b> 103:18 109:19,20 112:9 117:3</p> <p><b>obviously</b> 145:11,12</p> <p><b>occasional</b> 166:22</p> <p><b>occasions</b> 131:7,9</p> <p><b>occur</b> 154:7</p> <p><b>occurred</b> 73:17 74:15</p> <p><b>odd</b> 72:5</p> <p><b>offer</b> 103:5 169:18</p> <p><b>offered</b> 144:11</p> <p><b>office</b> 2:6,18 3:4,6 4:8,13 5:7 31:10,16,19 32:12 57:5 66:8 89:11 161:13</p> <p><b>officer</b> 2:3,12,15,17,20 17:10 31:13 32:6,11 181:3</p> <p><b>officially</b> 45:1 180:2</p> <p><b>officials</b> 7:9</p> <p><b>offset</b> 97:22</p> <p><b>oftentimes</b> 163:17</p> <p><b>oh</b> 43:13 47:3 49:20 60:12 65:5 114:7 123:21 129:5 156:19 158:21 164:4</p> <p><b>okay</b> 5:2 34:13 35:8,9,16,20 36:10,11 37:11,14,17,20 38:3,4,15,22 39:4 40:1 49:20</p>
---	---	--	--

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

<p>60:14 61:18,22 63:4 64:5,20 65:10 66:12 69:12,13,18 71:11 75:22 78:9,20 79:2 81:15,20,21 82:11 85:5 87:4 90:4 109:17 110:20,21 111:8,12 113:14 114:7,10 117:19,21 119:5 127:4 130:22 131:21 132:10 135:8,13 136:13,18,19 137:5,8,11 138:14 144:20,21 145:14 146:3 147:16 150:1,5 152:13 153:4,20 157:6 166:8 172:12</p> <p><b>old</b> 51:3 57:13 65:12 66:18 106:3 131:11 153:15</p> <p><b>older</b> 55:21 138:4 139:6</p> <p><b>old-fashioned</b> 93:21 94:1,5</p> <p><b>oncologist</b> 130:10 145:7,8,9,13</p> <p><b>oncologists</b> 97:4</p> <p><b>oncology</b> 2:4,10,13,15,20, 21 4:4,10 7:3 17:10 31:14 32:1,3,7 66:8 89:11 98:14</p>	<p><b>ones</b> 11:1 13:5 14:20 27:4,13 30:12 36:3 37:9 40:7 63:18 64:16 126:8 135:3 137:1,5,10</p> <p><b>ongoing</b> 117:14 123:2</p> <p><b>online</b> 120:4</p> <p><b>on-staff</b> 56:21</p> <p><b>onto</b> 122:14</p> <p><b>open</b> 4:19 6:4,8 82:13 89:4 151:3 156:7,8 165:5,8,15 168:2 174:22</p> <p><b>opened</b> 62:4 169:14</p> <p><b>opening</b> 6:19</p> <p><b>openness</b> 123:16</p> <p><b>opinion</b> 88:8 98:6</p> <p><b>opinions</b> 90:14 119:13</p> <p><b>opportunity</b> 29:8,14 92:21 174:18</p> <p><b>opposed</b> 95:5,6</p> <p><b>optimal</b> 124:4</p> <p><b>optimally</b> 124:17</p> <p><b>optimistic</b> 141:12,18</p> <p><b>optimum</b> 124:18</p> <p><b>option</b> 94:8 105:2 146:20 151:14 159:18</p> <p><b>options</b> 4:9 5:19 6:3 17:7,8,12 49:7 56:11 91:14</p>	<p>93:3 98:5 102:17 103:11 104:3,5,10 107:4,12,21 108:4 110:3 168:2</p> <p><b>oral</b> 45:18 54:4 97:8 136:7 146:20</p> <p><b>oranges</b> 107:13</p> <p><b>order</b> 52:1 84:18 121:14 124:3 125:5 162:5,10 166:2</p> <p><b>ordered</b> 160:20</p> <p><b>organization</b> 56:17 99:16</p> <p><b>organs</b> 19:3</p> <p><b>orthopedist</b> 72:6</p> <p><b>OSP</b> 2:6 3:6 4:8,13,21</p> <p><b>others</b> 7:9 9:7 40:13 98:19 107:5 108:16 117:2 131:19 144:8 157:18,20 171:19 176:13,18 178:5</p> <p><b>otherwise</b> 106:13 155:12 181:13</p> <p><b>outbreak</b> 52:14</p> <p><b>outcome</b> 9:2 72:10 119:15,18 181:14 182:6</p> <p><b>outcomes</b> 25:15 45:3 174:6,9</p> <p><b>outside</b> 11:22 29:4 34:8,10 35:5,10,11 38:17 54:2 69:8 116:18</p>	<p>130:7</p> <p><b>overall</b> 86:17 100:19 108:14,19</p> <p><b>overarching</b> 68:1</p> <p><b>overkill</b> 97:20</p> <p><b>overlap</b> 23:11</p> <p><b>overview</b> 4:6,12 9:22 18:7 26:11</p> <p><b>overwhelming</b> 67:22</p> <p><b>overwhelmingly</b> 136:21 137:21</p> <p><b>oxygen</b> 52:19 125:20</p> <hr/> <p style="text-align: center;">P</p> <hr/> <p><b>p.m</b> 180:6</p> <p><b>Pacific</b> 53:10</p> <p><b>pack</b> 42:22</p> <p><b>paclitaxel</b> 25:5</p> <p><b>pad</b> 42:3</p> <p><b>PAGE</b> 4:2</p> <p><b>pages</b> 181:5</p> <p><b>pain</b> 21:7 22:12 57:14 63:9,10 70:13,15,17 71:2,3,13,19 72:10,15 76:22 77:1,3,12 78:13,15,21 79:8 80:9,10,16 104:21 105:11 106:17 119:17 125:19 126:16 127:3 128:11 131:13 140:2 173:15,18</p> <p><b>painful</b> 77:10</p>
--	--	--	---

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

Page 29

<p>106:18 <b>pairs</b> 98:21 <b>Paivi</b> 3:3 31:15 80:6 <b>palliation</b> 18:18 <b>palliative</b> 21:5 102:15 145:4 <b>panel</b> 4:14,17 27:11,13,17,19 28:5,6 37:5 39:8 40:2 60:20 65:20 68:6 74:11 75:11 77:19 82:4,5 84:4,15 86:6 91:14 102:10 109:3 117:1 147:12 159:17 169:14 176:13 <b>panelists</b> 32:15 39:10,12 82:2 86:4 109:2,5 <b>panels</b> 84:10 <b>panel's</b> 37:1 <b>paper</b> 159:4 <b>paperwork</b> 106:10 <b>paradigm</b> 121:20 <b>paraneoplastic</b> 74:5,14 90:9 <b>parenting</b> 108:4 <b>park</b> 87:14 <b>parking</b> 43:21 <b>partial</b> 25:1 <b>participant</b> 33:19 175:14,19 <b>participants</b> 3:9 28:18 29:6,9 36:6 40:2 83:14,21 84:15</p>	<p>175:7 <b>participate</b> 11:14,16 15:21 28:3 92:17 120:21 170:5 <b>participated</b> 49:10 169:13 <b>participating</b> 27:13 37:7 138:10 <b>participation</b> 25:16 29:13 <b>particles</b> 20:12 <b>particular</b> 7:15 11:8,15,17,20,21 ,22 12:10,17 15:3 33:15 42:6 77:5 112:1 118:19 123:12 179:12 <b>particularly</b> 13:13 30:12 60:1 123:16 126:16 133:13 169:5 172:6 179:9,13 <b>parties</b> 181:8,10,13 <b>partner</b> 39:16 <b>Partnership</b> 65:11 <b>partnerships</b> 171:1 <b>party</b> 131:12 182:5 <b>pass</b> 175:15 <b>passed</b> 59:7 120:19 139:15 <b>past</b> 26:21 86:12 126:3,4 <b>Pat</b> 5:12 6:19</p>	<p>10:2,10 53:22 54:12 77:17 122:16 124:21 151:19 156:16 164:2,10 <b>patch</b> 58:11 <b>pathology</b> 97:7 <b>patient</b> 5:9 7:8,12 8:19,20 11:13 12:4,6 13:12 15:6,11 16:5,14 20:18,20 22:15 23:21 24:1 25:19 26:2,22 27:3,4,10,12 28:1 29:22 30:4,7,8 39:12,13 54:9 56:20,21 57:6 59:13 70:5 84:16 85:12,14 98:3 99:2,10,15 103:10 108:8 120:9,10,18 128:4 144:19 145:10 170:2 171:7,13 173:12 174:1,10 <b>patient-focused</b> 1:6 4:6 5:17 7:1 9:22 10:11,21 11:18 169:3,7 180:7 <b>patient-friendly</b> 154:13 <b>patient-reported</b> 25:15 <b>patients</b> 6:2 7:8,14,22 8:11,13 9:13,15,16 10:5,22 11:6,22</p>	<p>12:12 13:5 15:14,20 16:5,22 17:1 18:21 19:21 23:1 25:7,9,16 26:9,22 27:1,12,19 28:1 29:22 30:4,6 33:18 36:14 39:20 46:10 50:3 57:6 60:3 71:4 77:13 80:10 84:16 85:20 96:4 99:10,13,16 101:17 102:7,12,17,19 103:14 104:7,9,11,20 113:5,6,11 115:5,18,20,22 116:10 121:21,22 122:8,12,14,20 123:2,15 124:2,7,19 138:7 139:4 144:9,22 148:9,17 149:20 150:10,11 152:12 154:12,17,21 160:1 161:16 164:22 165:1 169:10,16,22 170:4,18 171:17 172:19 174:13,20 175:20 176:12 <b>patient's</b> 26:4 30:11 142:17 <b>Patricia</b> 2:9 4:3 7:2 31:22 <b>Pat's</b> 78:11 153:21 <b>Patty</b> 57:4,8 <b>pay</b> 89:12 106:12</p>
--	--	--	---

(866) 448 - DEPO

Capital Reporting Company  
 Patient-Focused Drug Development 06-28-2013  
 Page 30

<p><b>paying</b> 68:3 124:9  <b>PDUFA</b> 12:14  <b>peace</b> 98:8 99:22  <b>peaceful</b> 100:13  <b>pediatric</b> 13:14  <b>peers</b> 40:16 79:20      111:6  <b>pelvis</b>      160:18,20,21  <b>people</b> 7:5,7 27:2      28:14 30:18      35:21 36:8,14      40:16 41:5,7      47:7,18      50:16,18,22 51:9      52:1 54:17 56:10      59:4 60:5,6 61:5      67:14 74:13      82:13      88:15,17,20 89:5      92:17 93:17      94:6,10 95:7      96:2,7 103:19      115:21 116:15      117:13      118:4,10,11,12,1      3,14 119:4 120:3      121:7,10,20      124:9 127:17,22      129:2      130:7,11,15,20      137:18      138:4,5,9,11,17      142:3 146:15      157:4 158:6      159:1,3      163:13,17,18      164:8 165:17      170:7 177:14,17      178:11 180:1  <b>people's</b> 47:21      178:9</p>	<p><b>perceived</b> 48:9  <b>percent</b> 17:22 18:1      22:22 46:4,21      50:4 51:11 96:1      115:22 116:1      121:22      153:2,4,6,7,18      159:22 161:6  <b>perceptions</b> 47:21  <b>perform</b> 42:22  <b>perhaps</b> 151:16      159:11 179:11  <b>period</b> 6:4 33:6      129:18 158:1      165:15  <b>periodic</b> 16:14  <b>periodically</b> 28:17  <b>peripheral</b> 71:22      103:22  <b>permanent</b> 51:17      155:12  <b>permitting</b> 86:6  <b>persistent</b> 52:3,10  <b>person</b> 28:18      29:12 42:14      47:3,6 64:7      90:20,21 141:13      170:5  <b>personal</b> 157:16  <b>personalized</b>      160:16 161:20      164:7 173:13,22  <b>personnel</b> 138:11  <b>perspective</b> 12:5      15:20 30:8,11,15      33:2 39:2 49:5      69:10 84:6 116:9      133:2 138:21      139:13 148:5</p>	<p>167:16  <b>perspectives</b> 6:3      7:15 17:1 27:10      33:18 34:19      99:11 110:22      111:7 116:22      156:13  <b>peskier</b> 43:9  <b>ph</b> 101:11 171:4  <b>Phang</b> 3:14,15      149:12 166:3      167:14  <b>pharmacy</b> 43:3,17  <b>phase</b> 45:19 85:16      168:18  <b>PhD</b> 2:5,17 3:3,6      4:7,12,21  <b>phlegm</b> 63:12      96:21  <b>phone</b> 34:8 135:2      161:12  <b>phrase</b> 47:13  <b>physical</b> 41:15      46:8 48:7 56:5      70:14 83:20  <b>physically</b>      55:7,11,16 87:22  <b>physician</b> 73:6      85:9 90:11,12      93:22 94:12 95:5      103:9,20 145:7      168:7  <b>physicians</b> 94:14      95:22 96:3      102:21  <b>piano</b> 103:19      104:2  <b>pick</b> 66:20 67:1,3      146:8</p>	<p><b>picked</b> 135:21      146:6  <b>picking</b> 68:21  <b>pie</b> 21:17  <b>piece</b> 154:20  <b>piggyback</b> 142:8      151:10  <b>piles</b> 106:10  <b>pill</b> 42:17,18,20      44:22 136:9  <b>-pills</b> 42:16  <b>places</b> 51:21      123:18 164:13  <b>plan</b> 103:1  <b>planning</b> 14:22      169:13  <b>plans</b> 140:3  <b>plant</b> 166:21  <b>plants</b> 166:18  <b>platin</b> 112:22  <b>play</b> 15:9 147:1  <b>played</b> 177:18  <b>plays</b> 9:5 68:14      89:13  <b>please</b> 27:16      29:4,22 37:9      50:6 62:10 83:1      96:15 131:16      151:19 165:22  <b>pleasure</b> 57:2      58:15 101:11  <b>plebe</b> 58:17  <b>plenty</b> 33:1 120:14  <b>pleural</b> 54:2  <b>plexus</b> 73:22 74:4  <b>plop</b> 42:15</p>
---	---	--	---

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

Page 31

<p><b>plug</b> 79:16 80:15  <b>plus</b> 18:14  148:11,14  <b>podium</b> 26:11  <b>point</b> 10:6 22:14  38:12 43:8 59:10  62:11 63:17  65:15 78:17,18  90:18  91:10,15,17  111:14 112:13  117:13 127:11  139:22  141:2,15,17  142:16  144:15,17 155:1  156:6 157:8  164:11 177:9  179:7  <b>pointed</b> 177:4  <b>points</b> 133:1 144:5  155:14 175:3  <b>policy</b> 56:20,21  85:18 169:3  <b>poll</b> 29:6 70:12  <b>polling</b> 29:21  34:16 36:13 39:5  110:7,8 125:5,14  133:7  <b>Pollyanna</b> 128:17  <b>poor</b> 170:20  <b>poorly</b> 44:16  <b>population</b> 15:7  38:11 94:14,15  111:4 122:20  164:9  <b>populations</b>  13:8,12 15:7  <b>port</b> 19:16</p>	<p><b>portion</b> 165:6  <b>pose</b> 46:12 133:4  <b>posed</b> 28:7  <b>position</b> 77:6  88:19  <b>positioned</b> 11:2  <b>positive</b> 45:13  91:21 93:20 97:7  98:9 105:4  129:7,10 152:1  153:10  <b>positively</b> 8:12  <b>possibilities</b>  154:14  <b>possibility</b> 98:22  120:1  <b>possible</b> 5:5 45:3  46:12 103:2,11  118:20 124:5  139:3 154:3  161:19  <b>possibly</b> 134:7  135:7 147:9,13  178:18  <b>postnasal</b> 52:10  <b>postop</b> 127:16  <b>post-treatment</b>  59:21  <b>potential</b> 8:2 9:13  13:17 18:18  98:17 104:6  <b>potentially</b> 18:11  20:8,20 26:2  149:7  <b>Powell</b> 98:7  <b>power</b> 55:17 85:1  <b>powerful</b> 108:21  <b>Powers</b> 166:3</p>	<p>172:9  <b>PPT</b> 171:4  <b>practice</b> 28:22  34:15 105:2  123:7  <b>practices</b> 166:16  <b>praying</b> 48:21  <b>precaution</b> 87:12  143:18  <b>precursor</b> 120:6  <b>prediagnosis</b>  45:21  <b>predict</b> 150:17  <b>predominantly</b>  130:3  <b>preferences</b>  103:17  <b>prep</b> 106:9  <b>preparation</b> 34:1  <b>prepare</b> 42:20  44:12,20 86:4  <b>prepared</b> 92:7  182:3  <b>prescribers</b> 124:15  <b>present</b> 19:21 23:2  29:13  <b>presented</b> 83:15  152:10  <b>preserve</b> 103:11  <b>press</b> 35:3,5  <b>pressing</b> 79:10  <b>pressure</b> 23:13  79:12 140:11  142:18  <b>pressured</b> 143:8  <b>pretty</b> 38:22 55:5</p>	<p>92:9 142:9 160:2  <b>prevalence</b> 171:8  <b>prevalent</b> 37:15  64:11  <b>prevent</b> 48:4  161:15  <b>previous</b> 137:11  <b>price</b> 105:8 106:12  <b>primarily</b> 37:15  166:21  <b>primary</b> 19:4 20:7  167:22 170:13  <b>principally</b> 51:20  <b>prior</b> 11:9 56:4  73:4 143:1 173:3  <b>priorities</b> 141:10  142:13  <b>Priority</b> 24:22  <b>PRO</b> 26:7  <b>probably</b> 49:11  58:8 74:5  79:10,14 81:7  90:8 100:22  101:22 102:3  108:20 113:19  117:5,6 124:6  130:12 134:5,20  135:5 147:9  151:8 162:7  178:18  <b>problem</b> 42:13  58:2 130:19  <b>problems</b> 81:17  154:17  <b>process</b> 16:15  25:12,17 46:14  97:15 99:12  106:3 145:3  169:11 171:9</p>
--	--	---	---

(866) 448 - DEPO

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

<p><b>produced</b> 130:3  <b>producing</b> 16:20  <b>product</b> 17:4  95:20 98:13,15  124:10,16  <b>products</b>  2:4,10,13,15,21  4:4,10 7:3 9:8,11  17:10 31:14  32:1,4  <b>profession</b> 103:21  104:1  <b>professor</b> 73:12  85:10  <b>profile</b> 22:5 23:11  98:16  <b>program</b> 2:6 4:13  11:13 24:20  26:15 39:15 41:3  95:1  <b>programs</b> 2:8 3:6  4:8 5:7  24:14,17,19  31:19  <b>progress</b> 48:14  <b>progresses</b> 100:14  <b>progression</b> 72:12  103:8  <b>prolong</b>  134:5,7,20  135:6,7 142:11  147:9,10  <b>prolongation</b>  23:22  <b>prolonged</b> 148:13  175:17  <b>prolonging</b> 18:21  86:18 137:21  139:2 142:4</p>	<p>178:18  <b>prolongs</b> 24:2  <b>prominence</b>  170:11  <b>promising</b> 24:21  <b>promote</b> 71:1  <b>proper</b> 26:1  <b>properly</b> 128:20  <b>PROs</b> 25:15,17,21  26:3  <b>prostate</b> 17:15  <b>protectors</b> 166:18  <b>protein</b> 42:10  166:22  <b>protocols</b> 115:4  <b>provide</b> 9:21 17:1  30:11 33:1 34:18  83:11  <b>provided</b> 16:6  124:19 176:21  <b>providing</b> 16:7  169:15 170:4  <b>proximity</b> 147:2  <b>psychological</b>  47:11  <b>public</b> 1:5 3:9 4:19  5:9 6:4,8,12 7:18  13:18,22 26:20  29:18 33:6 62:4  65:7,9 82:8,13  83:1 129:18  155:22  157:12,19,22  165:5,8,11,15  167:6,9 174:22  180:7 181:2,18  <b>published</b> 13:16  14:19</p>	<p><b>Pujita</b> 3:8 34:14  80:19 84:3  175:1,22  <b>pull</b> 138:20  <b>pulmonary</b> 52:6  127:14,18,19  <b>purpose</b> 27:17  28:4  <b>purposes</b> 34:21  134:18  <b>push</b> 31:11  <b>puts</b> 88:19  <b>putting</b> 76:18  148:2 159:3  166:16  <hr style="width: 20%; margin-left: 0;"/> <b>qualified</b> 161:16  <b>qualify</b> 122:1  <b>qualities</b> 103:12  <b>quality</b> 85:21  88:4,5 89:21  99:17 103:10  140:6,12  143:4,7,16  144:1,13 175:8,9  <b>quantity</b> 143:7  <b>quarters</b> 130:8  <b>question</b> 28:22  32:22 35:7,19  37:11,13,19  38:8,21 55:12  62:17,18,20  63:20 64:3 75:7  77:17 78:11 80:7  88:15,18 94:22  103:13 107:14  109:9 110:7,9,19  114:20,22 116:6  123:1 125:7,14</p>	<p>126:5,11 129:17  132:6  133:5,7,9,11  134:15,16  135:10,15  136:6,12,14,17  138:15 150:8  153:9,21 154:12  155:9,10  158:3,22 160:15  167:2,9 177:14  <b>questioned</b> 140:10  <b>questioning</b> 170:2  <b>questions</b> 11:20  12:10 15:1,4  28:7,8,10,14,19  31:7 32:19  34:16,18,20  36:13,15,20  37:10 39:5 40:3  50:16,17  60:19,21 69:15  86:7,9 103:1  114:18 117:19  125:5 137:18  148:22 156:2  162:20  163:11,13  <b>quick</b> 34:17 43:2,5  46:19 164:19  <b>quickie</b> 43:17  <b>quickly</b> 14:11 54:8  108:18 125:1  164:20  <b>quit</b> 96:2,4,7 116:1  <b>quite</b> 57:5,18 64:8  168:6  <b>quote</b> 158:11  <b>quote/unquote</b>  160:16</p>
---	--	---	--

Capital Reporting Company  
 Patient-Focused Drug Development 06-28-2013  
 Page 33

<p><b>quotes</b> 109:20</p> <hr/> <p style="text-align: center;"><b>R</b></p> <hr/> <p><b>radiate</b> 20:22</p> <p><b>radiation</b>          19:1,12,15,17          20:9,10,11,12,17          ,20 21:5 22:16          23:1 48:16          52:8,17 53:5          60:11,12 72:3          79:5,6 87:7          90:14 92:6,8          105:3 110:12          130:2,10          160:12,13          161:3,7</p> <p><b>radioiodine</b> 168:5</p> <p><b>radiologist</b> 97:1</p> <p><b>raise</b> 28:15 32:20          33:5 34:5 53:11          61:2,14 81:18          117:3 158:18          172:14</p> <p><b>raised</b> 33:13 40:4          64:16 81:3          114:22 134:21          141:6 144:5          146:5 165:12</p> <p><b>raises</b> 81:20,21</p> <p><b>raising</b> 81:16          114:4 141:7</p> <p><b>range</b> 7:7 13:10,11          27:20 29:10          50:21 64:8 104:3          110:22 126:15          154:14</p> <p><b>ranging</b> 11:19</p> <p><b>rank</b> 133:15          135:17</p>	<p><b>rare</b> 57:17 91:5          148:18 149:7</p> <p><b>rarely</b> 19:7</p> <p><b>rash</b> 23:12 46:22          148:18</p> <p><b>rashy</b> 105:14</p> <p><b>rate</b> 43:12</p> <p><b>rather</b> 44:12          100:13 124:13          161:13 167:16</p> <p><b>ray</b> 161:4</p> <p><b>Raymond</b> 166:3          172:9</p> <p><b>Raynaud's</b> 73:8</p> <p><b>reach</b> 121:14</p> <p><b>reaction</b> 22:19</p> <p><b>reactions</b> 148:3          149:2</p> <p><b>readable</b> 16:21</p> <p><b>reading</b> 97:11</p> <p><b>ready</b> 43:19          44:2,19 45:1,2          46:16 65:6 80:18          98:20</p> <p><b>real</b> 35:21 52:19          68:20 112:6          179:2</p> <p><b>reality</b> 106:22          141:18</p> <p><b>realize</b> 96:1          115:21 117:14          167:1</p> <p><b>really</b> 6:7 8:22          9:17 10:4,21          14:2 15:2,10          16:6,8,11 27:18          28:7 29:3 31:6          32:17 33:10,11</p>	<p>34:18 36:1,13          40:6 45:21          47:9,13 52:11          53:14 54:20          57:2,10 59:10,11          68:10,16          72:4,6,8,11,13,1          4,15 73:11,15          76:22 79:1,17          80:15 82:18          84:6,11 86:19          91:18 93:6 95:15          99:12 103:13,18          105:17 106:16          107:2 108:2          113:11          115:13,21          116:14 121:18          122:22 123:3,19          127:7,9 128:22          130:1,5,12          131:6,11 139:6          140:10,18          141:15,16          156:11,14,19          158:16 162:7          163:14,18          164:19,20          165:19 167:22          170:3 176:11,20          177:8,9 179:8</p> <p><b>real-world</b> 169:8</p> <p><b>reason</b> 8:12 34:17          123:14</p> <p><b>reasons</b> 8:6 19:21          138:8</p> <p><b>reassured</b> 140:13</p> <p><b>reauthorization</b>          14:10</p> <p><b>recap</b> 177:1</p> <p><b>receive</b> 90:13</p> <p><b>received</b> 13:18,22</p>	<p>50:8 94:20          174:12 175:5</p> <p><b>recent</b> 121:15</p> <p><b>recently</b> 95:22          99:19 114:12</p> <p><b>receptor</b> 91:21          168:11</p> <p><b>receptor-positive</b>          93:10</p> <p><b>receptors</b> 25:11</p> <p><b>recess</b> 82:10</p> <p><b>recognize</b> 10:22          29:11</p> <p><b>recommended</b>          13:21</p> <p><b>record</b> 29:18          65:8,9 167:7,9          181:8</p> <p><b>recorded</b> 170:6          181:6</p> <p><b>recording</b>          158:5,9,10,12</p> <p><b>recordings</b> 170:6</p> <p><b>recuperates</b> 22:16</p> <p><b>recurrence</b> 74:12          91:4 139:16</p> <p><b>recurring</b> 112:11</p> <p><b>recurs</b> 91:22</p> <p><b>red</b> 105:14</p> <p><b>reduce</b> 20:14 21:6          86:12 100:11          110:10 133:16          135:18</p> <p><b>reduced</b> 144:13          181:6</p> <p><b>reflect</b> 27:20 37:2          44:16 92:21</p>
---	--	---	---

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

<p><b>reflective</b> 38:11 138:6</p> <p><b>reflux</b> 53:16</p> <p><b>refuse</b> 56:8</p> <p><b>regard</b> 39:3 107:1 133:3 162:18</p> <p><b>regarding</b> 33:12 82:19</p> <p><b>regimen</b> 103:21 154:15</p> <p><b>register</b> 13:17 14:18 82:14</p> <p><b>registered</b> 70:9 82:15</p> <p><b>registrants</b> 6:9,10</p> <p><b>registration</b> 33:8,21 82:8 122:13 176:4,6</p> <p><b>regular</b> 76:16</p> <p><b>regularly</b> 91:10</p> <p><b>regulars</b> 77:9</p> <p><b>regulatory</b> 123:6,13 171:22</p> <p><b>reiterate</b> 49:22 175:3</p> <p><b>relate</b> 22:10 45:9 68:20</p> <p><b>related</b> 22:17 66:15,16 78:16 80:10 81:6 148:16 179:4 181:9</p> <p><b>relates</b> 80:9</p> <p><b>relationship</b> 167:3</p> <p><b>relative</b> 181:11</p> <p><b>relatively</b> 16:20 104:19 178:5</p>	<p><b>relaxation</b> 41:22 125:20 127:2</p> <p><b>relevant</b> 6:7 33:4 158:17</p> <p><b>reliable</b> 26:7 108:5</p> <p><b>relieve</b> 54:16 103:8 133:22 137:2</p> <p><b>relieved</b> 74:3</p> <p><b>relieving</b> 178:20</p> <p><b>rely</b> 8:14 31:6</p> <p><b>remain</b> 129:14</p> <p><b>remainder</b> 117:9 138:19</p> <p><b>remaining</b> 36:12 52:8 53:20 126:12</p> <p><b>remains</b> 129:19</p> <p><b>remarks</b> 4:20 5:5,13 6:20 40:3 86:5 176:8,9</p> <p><b>remember</b> 29:4 46:14 53:7 66:14,19 67:1 115:18</p> <p><b>reminder</b> 9:4 47:3 82:7 83:11 176:1</p> <p><b>remission</b> 38:20 88:9</p> <p><b>removal</b> 120:11</p> <p><b>remove</b> 58:10 110:13 119:9</p> <p><b>removed</b> 52:17 53:4,5 119:14 173:3</p> <p><b>removing</b> 119:16 161:14</p> <p><b>renewed</b> 166:15</p>	<p><b>repeatedly</b> 123:9</p> <p><b>replace</b> 20:18</p> <p><b>report</b> 16:21 158:2 170:9</p> <p><b>Reported</b> 1:18</p> <p><b>Reporting</b> 1:19</p> <p><b>reports</b> 167:20</p> <p><b>represent</b> 25:17 41:7 84:16 118:5 121:2</p> <p><b>representative</b> 11:13,14 37:21 111:4</p> <p><b>representatives</b> 27:1,3,12 28:1 29:22 30:4,7 36:2 39:13</p> <p><b>representing</b> 30:13 36:17,18 39:2</p> <p><b>require</b> 90:16 106:9 152:8</p> <p><b>required</b> 44:5</p> <p><b>requires</b> 23:15 134:13</p> <p><b>rescue</b> 48:22</p> <p><b>research</b> 1:2 5:6 7:4 15:21,22 16:2 30:18 32:12 51:8 74:13 93:6,12 98:12 106:7 107:11 112:18 115:11,14,15 116:4 119:3 161:1 167:2,15 169:3 170:20 174:5</p> <p><b>researchers</b> 7:8</p>	<p>9:7 22:1</p> <p><b>resect</b> 19:8</p> <p><b>resected</b> 20:9,21 115:5</p> <p><b>resection</b> 74:3 90:10 92:5</p> <p><b>residual</b> 20:22 21:1 53:21</p> <p><b>resistance</b> 48:13,19 49:2 168:16 171:21</p> <p><b>resolve</b> 22:15</p> <p><b>resolved</b> 144:16</p> <p><b>resonates</b> 40:19</p> <p><b>resources</b> 155:1,2</p> <p><b>respect</b> 34:4 103:16 169:22</p> <p><b>respiratory</b> 20:1,2</p> <p><b>respond</b> 28:18,22 29:6 118:19 174:2</p> <p><b>responded</b> 118:10 178:22 179:6</p> <p><b>responding</b> 117:10</p> <p><b>responds</b> 24:8</p> <p><b>response</b> 24:9 55:12 69:17 111:11 114:16 117:18,20 131:20 132:1 137:15 146:2 147:7,15 149:1 155:20 160:3 166:7 172:11</p> <p><b>responses</b> 36:5 136:19 168:1,19</p> <p><b>responsibility</b> 106:21</p>
---	---	--	--

Capital Reporting Company  
 Patient-Focused Drug Development 06-28-2013  
 Page 35

<b>responsive</b> 168:16	68:15 160:6	56:15	139:4 149:6
<b>rest</b> 38:19 41:22	<b>right-handed</b> 73:5	76:11,16,18	164:20 165:5
55:5 127:9	<b>rigidity</b> 163:4	131:2 154:11	<b>Sara</b> 2:5 4:12 5:5
128:20 134:12	<b>Rigney</b> 59:14	<b>ROSTER</b> 2:1 3:1	6:21 26:11,18
<b>restriction</b> 122:22	<b>ringing</b> 113:21	<b>rosy</b> 96:5	31:19 49:12
<b>restrictions</b> 161:15	114:1,2,8	<b>round</b> 61:10	56:15 83:9
<b>restroom</b> 34:9	<b>risk</b> 22:13 23:8,13	<b>rounds</b> 51:16	158:20 169:6
<b>restrooms</b> 6:13	48:16 73:16	116:10,15	176:10
<b>result</b> 102:22	104:8 121:18	<b>route</b> 101:22	<b>satellite</b> 122:12
<b>resulted</b> 103:22	122:12 134:2	<b>routine</b> 67:21	<b>save</b> 44:12 60:19
<b>results</b> 35:9 44:3	137:3 147:5	<b>routines</b> 46:17	77:14 100:22
83:19 92:2	178:1 179:13	<b>row</b> 81:9 161:2	125:8
126:14	<b>risk-benefit</b>	<b>rule</b> 107:6	<b>saved</b> 119:14
<b>resumed</b> 89:19	121:17	<b>rules</b> 30:1 34:12	<b>saw</b> 47:2 109:11
<b>retention</b> 83:17	<b>risks</b> 9:16 11:2	<b>run</b> 26:20 42:5	<b>scan</b> 41:21 42:6
<b>retired</b> 68:17	102:17 104:6	92:12	45:3 48:6 58:4
<b>retrospective</b> 51:9	107:15 135:1	<b>running</b> 44:9	90:17 91:2 93:18
<b>returning</b> 44:17	154:3 178:10,14	48:17 66:5	97:1 145:14
<b>reversible</b> 155:11	179:12	<b>rural</b> 100:6 146:18	164:10
<b>review</b> 11:7,20	<b>rivaled</b> 106:10	<b>Ruth</b> 3:15 149:17	<b>scans</b> 43:1,5,9 44:3
12:22 14:1	<b>road</b> 174:10	<b>Ruth's</b> 167:17	59:6 93:16
15:4,11	<b>roadblocks</b> 161:10	<b>Ryan</b> 3:16 67:12	<b>scanxiety</b> 75:1
24:11,12,13,16,2	<b>Robert</b> 2:17 32:10	85:13 96:16,17	<b>scar</b> 77:10
2 99:11 156:21	<b>rode</b> 55:21	<hr/> S <hr/>	<b>scenario</b>
<b>reviewed</b> 13:20	<b>role</b> 9:5,9 15:9		148:7,21,22
<b>Reviewer</b> 3:3	177:18	<b>sadly</b> 90:20	152:1 155:19
31:16	<b>rollercoaster</b>	<b>safe</b> 179:20	175:14
<b>reviewers</b> 17:2	168:1,19	<b>safety</b> 9:10 23:18	<b>scenarios</b> 147:19
<b>revisit</b> 14:9 77:15	<b>rolling</b> 106:8	167:4 171:15	148:1,3
<b>revisiting</b> 133:1	<b>room</b> 27:5 29:4	<b>sags</b> 59:19	<b>school</b> 85:11
<b>reword</b> 136:3	30:3 34:19,20	<b>salad</b> 43:22	<b>science</b> 81:11
<b>rib</b> 70:20 71:2	35:1,3 36:16	<b>sample</b> 51:12	122:7
97:17	37:21 38:14 39:1	138:13 151:6	<b>scientific</b> 2:20 32:6
<b>rich</b> 82:18	46:19 61:4,6,14	<b>Sandt</b> 3:16 39:14	34:21
<b>rid</b> 70:15 131:13	64:9 69:21 75:18	40:21 41:1,2	<b>scientist</b> 108:13
<b>ride</b> 55:22 65:16	79:18 83:15	74:22 116:9	<b>scope</b> 116:19
	95:14 96:19,21	128:4,12 132:12	<b>screening</b> 59:5
	138:6,19		96:6,9
	<b>Ross</b> 3:15 39:21		

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

Page 36

<p><b>screenings</b> 46:3  <b>Sean</b> 2:14 4:10  17:6,9 26:13,15  49:20 86:13  <b>search</b> 104:22  <b>searching</b> 90:12  <b>seated</b> 67:11  <b>seats</b> 82:12  <b>second</b> 7:19 17:14  27:10 28:9 58:22  64:12,19 92:4  98:6 109:9  119:13 127:11  139:16,17 146:7  170:11 172:10  <b>second-line</b> 98:18  <b>seconds</b> 64:2  <b>seed</b> 138:15  <b>seeing</b> 136:10  156:5 164:15  <b>seem</b> 55:7 130:18  <b>seems</b> 75:20  170:22 171:5  <b>seen</b> 117:3 122:3  <b>selected</b> 169:9  <b>self</b> 96:19  <b>selfish</b> 129:1  <b>Senior</b> 85:18  <b>sense</b> 20:4 35:1  36:16 125:15  138:13  <b>sensitive</b> 99:1  108:12,18  <b>sensitively</b> 171:5  <b>sent</b> 50:16  <b>separate</b> 80:17  <b>September</b> 13:16</p>	<p>14:13,15 170:18  <b>serial</b> 171:20  <b>serially</b> 171:19  <b>series</b> 8:7 169:7,14  172:2  <b>serious</b> 24:15  107:16 127:13  134:2 135:1  137:3,20 147:5  148:19 149:7  152:20,22 171:9  <b>seriousness</b> 76:14  <b>served</b> 13:9 169:14  <b>serves</b> 6:16  <b>services</b> 59:13,14  <b>session</b> 77:18,19  78:5  <b>setting</b> 5:16 11:17  <b>settled</b> 42:19  <b>seven</b> 73:4  <b>several</b> 101:9  118:5 120:4  160:9 165:1  <b>severe</b> 53:16 66:19  <b>severely</b> 40:13  <b>severity</b> 10:17  11:3 13:11 29:10  50:1,2  <b>shaking</b> 149:4  <b>Shakun</b> 2:19 32:5  114:19 164:4  <b>shape</b> 91:11  169:12  <b>share</b> 40:17  62:2,12 65:1  67:9 83:14 99:17  141:8 156:14</p>	<p>176:3  <b>shared</b> 28:4  61:3,6,16,19  62:8 68:7 69:10  99:14 102:21  109:12 131:19  <b>sharing</b> 83:4 170:1  176:19  <b>sharp</b> 75:17 76:20  <b>sharps</b> 43:18  <b>sheet</b> 40:5  <b>Sheila</b> 3:15 27:14  39:21 56:14  60:18 71:16  76:9,13 131:1  154:10  <b>shell</b> 58:13  <b>Shelley</b> 3:12 85:17  99:7 104:15  143:13 144:3  <b>Shelly</b> 52:13  <b>she's</b> 55:8 65:6  68:15,17 70:9,13  71:8 116:12  <b>shifted</b> 141:5  <b>shifting</b> 141:10  <b>shocked</b> 58:14  <b>short</b> 16:20 44:5  102:13 106:5  160:5  <b>shorthand</b> 27:2  <b>shortly</b> 116:7  <b>shortness</b> 20:2  22:13 23:3 52:18  54:12 63:10  64:13,18 65:18  68:12 69:19 70:1  71:12 73:2 83:16</p>	<p>92:13  <b>shot</b> 42:21 51:4  99:4 128:10  131:11,14,16  <b>shots</b> 43:19  <b>shoulder</b> 57:14  63:10 131:10,14  <b>showed</b> 58:4 96:22  144:8 145:15  148:12  <b>shower</b> 166:17  <b>shows</b> 154:12  <b>shrinking</b> 42:7  118:9 137:22  <b>shrinks</b> 112:11  <b>shrunk</b> 55:4  <b>sick</b> 46:12 47:3,5,8  113:7 145:12  <b>sign</b> 6:8 33:8 47:19  82:8  <b>significant</b> 5:22  7:18 27:8 40:8  55:6 63:7 69:9  72:15,20 95:17  100:3 112:17  113:3 126:12  134:2 135:1  147:5  <b>signs</b> 53:19  <b>silver</b> 1:13 121:15  <b>similar</b> 64:17 80:8  83:14 107:5  111:10 121:2  130:21 137:7  141:9  <b>similarly</b> 112:4  <b>simple</b> 163:14  <b>simply</b> 85:14</p>
---	--	---	--

(866) 448 - DEPO

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

Page 37

<p><b>sincerely</b> 165:9  <b>single</b> 19:16 48:21  89:11 100:16  106:20  <b>sink</b> 91:13 132:18  166:16  <b>sister</b> 92:19  <b>sit</b> 27:15 41:7  54:15 66:21  <b>site</b> 20:13  <b>sites</b> 8:17  <b>situation</b> 97:16  138:2 151:22  167:17  <b>situations</b> 9:18  24:4  <b>six</b> 51:16 92:15  94:7 107:4  133:12  <b>six-month</b>  93:17,18  <b>Sixteen</b> 45:9  <b>sixties</b> 37:16  <b>size</b> 18:16 20:14  21:6 52:4  <b>Skambis</b> 3:17  39:18 50:12  112:9 118:4  132:15 135:21  137:17 138:4  141:11 150:4,21  155:13 157:4  158:3  <b>skin</b> 22:19 46:22  59:18,19  <b>skip</b> 91:5,6  <b>slash-and-burn</b>  77:9</p>	<p><b>sleep</b> 45:4 55:14  66:9 79:7,8,11  81:17 173:18  <b>sleeping</b> 57:15  67:18 130:8  <b>slept</b> 66:8  <b>slide</b> 147:21,22  <b>slides</b> 10:7 14:17  158:8,9  <b>slow</b> 42:15 43:12  <b>small</b> 9:15 17:21  19:5,9,12,15  20:10,16 21:15  51:12,21 62:21  65:18 99:20  108:11 134:1,22  137:20 147:4  <b>smaller</b> 151:6  <b>smell</b> 42:9  <b>Smith</b> 3:17 129:6  <b>smoke</b> 88:14,16  120:7 130:4  <b>smoked</b> 88:17 95:3  115:22  <b>smoker</b> 45:11  47:22 88:19  119:22  <b>smokers</b> 95:6  96:11 130:5  <b>smoker's</b> 47:20  <b>smoking</b> 45:15  83:11 88:13,22  94:18  95:6,7,10,17,22  96:3,4,8 116:2  130:7 177:21  <b>smoothie</b> 42:11,15  <b>snapshot</b> 24:18</p>	<p><b>sneaking</b> 67:21  <b>snooze</b> 44:5  <b>snuggles</b> 44:2  <b>so-called</b> 21:9  <b>Society</b> 143:5  <b>soda</b> 113:10  <b>somebody</b> 95:16  172:5 174:16  <b>someone</b> 30:13  36:17,18 37:9  41:4 60:12 65:5  83:10 88:18  127:21 141:8  175:11  <b>someone's</b> 144:1  <b>somewhat</b> 121:6  167:17 177:13  <b>sore</b> 22:19  <b>sorry</b> 114:7 115:19  137:3 150:9  158:21  <b>sort</b> 10:15 12:6  14:2 34:3,11  70:22 111:14  133:19 141:18  151:21 168:19  177:15,19 178:7  179:6  <b>sorts</b> 134:10  <b>sound</b> 103:17  <b>sounds</b> 77:20  177:7,18  178:3,6,7 179:6  <b>source</b> 104:22  <b>speak</b> 28:15 34:5  <b>speaker</b> 17:6  49:13,17 78:21  155:18</p>	<p><b>speaking</b> 39:12  41:4 63:13 112:7  <b>special</b> 29:8 35:12  167:20  <b>specific</b> 21:21 25:7  28:19 33:13 40:8  69:15 70:18  111:20 114:18  125:11 138:1  164:8  <b>specifically</b> 8:10  54:4 66:14 67:1  86:18 132:7  <b>spectrum</b> 37:2  <b>spelled</b> 154:20  <b>spend</b> 5:15 33:15  44:10 100:9  <b>spent</b> 66:6 170:19  <b>spinning</b> 91:10  <b>split</b> 35:10 39:1  <b>spoke</b> 59:13  <b>spoken</b> 130:10  <b>sponsors</b> 171:14  <b>spread</b> 18:13,16  19:2 37:15  38:17,18 45:11  58:7 81:12 86:13  97:17 110:11  133:17 135:19  139:21  <b>Spring</b> 1:13  <b>spurred</b> 158:4  <b>squamous</b> 18:5  <b>stable</b> 38:13 105:6  <b>staff</b> 2:2 3:2 31:1  57:2 151:20  <b>stage</b>  18:10,12,14,17,1</p>
--	--	--	---

(866) 448 - DEPO

Capital Reporting Company  
 Patient-Focused Drug Development 06-28-2013  
 Page 38

<p>9,20,21          19:1,2,7,10,12,1          4,17,22 20:18          21:3,4 41:4          45:10 46:5 47:4          50:3,4 58:8 74:2          86:1 87:6 90:7          93:4,5,7 94:7,11          97:4 105:1          116:13 121:22          144:8</p> <p><b>stages</b> 18:9 19:9</p> <p><b>staging</b> 18:7 51:13</p> <p><b>stains</b> 167:20</p> <p><b>stair</b> 87:17</p> <p><b>stairs</b> 52:21 87:18</p> <p><b>stakeholder</b> 16:9</p> <p><b>stakeholders</b> 17:3</p> <p><b>stall</b> 46:19</p> <p><b>standard</b> 24:12          148:10,11,15,17          152:21</p> <p><b>standardization</b>          162:6</p> <p><b>standardized</b>          162:10</p> <p><b>start</b> 13:1 27:6          60:1 61:1,4          62:16,18 64:6,20          91:22 95:3 105:6          109:8,9 111:17          166:5 177:11</p> <p><b>started</b> 5:3 45:18          46:8 57:5 58:3          73:6 88:22 92:10          115:17 127:15          159:18</p> <p><b>starting</b> 40:20          58:6</p>	<p><b>state</b> 15:3 65:7          84:19 119:5          128:17 142:20          165:21,22          181:18</p> <p><b>statement</b> 6:6 33:7          55:11 157:20</p> <p><b>statements</b> 33:1</p> <p><b>States</b> 17:14,17</p> <p><b>statistic</b> 50:5</p> <p><b>statistician</b> 108:13</p> <p><b>statistics</b> 49:21          151:7</p> <p><b>status</b> 100:19</p> <p><b>stay</b> 30:20 55:16          59:20          67:11,14,16          106:12 156:8          165:16</p> <p><b>stayed</b> 87:11</p> <p><b>staying</b> 42:7</p> <p><b>Stephanie</b> 3:12          66:12 85:22          104:16,17 109:1          121:1 149:19          150:4 153:22</p> <p><b>steps</b> 10:15 73:1          106:9</p> <p><b>steroid</b> 130:12          131:10,14,16</p> <p><b>steroids</b> 125:19          126:17          132:7,8,13</p> <p><b>stethoscope</b> 57:17</p> <p><b>stick</b> 32:22 33:10          64:11 106:9          165:19</p> <p><b>stigma</b> 47:20          88:11,12 89:3</p>	<p>94:17 115:12          177:14</p> <p><b>stimulator</b> 71:1</p> <p><b>stimulators</b> 70:15</p> <p><b>stomach</b> 42:19          44:21</p> <p><b>stop</b> 43:2,16 73:13          87:1 117:10          133:6 143:4,8,9          155:11</p> <p><b>stopped</b> 87:19          88:12</p> <p><b>stories</b> 61:6,11,13          99:14 103:19          121:3</p> <p><b>story</b> 66:14 68:21          99:17</p> <p><b>straight</b> 6:14</p> <p><b>straightforward</b>          102:8</p> <p><b>Strategic</b> 2:6 3:6          4:8,13 5:7 31:19</p> <p><b>straying</b> 28:12</p> <p><b>street</b> 150:22</p> <p><b>strength</b> 61:7</p> <p><b>strengthen</b> 9:17</p> <p><b>strengthening</b>          97:18</p> <p><b>strikes</b> 66:13          170:18</p> <p><b>striking</b> 170:11</p> <p><b>string</b> 105:19          107:22 108:2</p> <p><b>stringing</b> 107:8</p> <p><b>strings</b> 106:9</p> <p><b>striving</b> 162:14</p> <p><b>strong</b> 55:7,11</p>	<p>56:3 59:3</p> <p><b>struggle</b> 9:14          68:20 118:12</p> <p><b>studied</b> 123:15          148:10</p> <p><b>studies</b> 73:21          122:21 151:8          163:16</p> <p><b>studying</b> 171:15</p> <p><b>style</b> 94:2</p> <p><b>subdivided</b> 18:5          21:16</p> <p><b>subject</b> 109:4</p> <p><b>submit</b> 9:8 29:17          62:7,8,10 111:6          157:12 159:1</p> <p><b>submitted</b> 9:9          157:14 159:2</p> <p><b>subpopulation</b>          13:14</p> <p><b>subpopulations</b>          13:9,13</p> <p><b>substantial</b> 23:16</p> <p><b>subtypes</b> 22:1</p> <p><b>success</b> 16:10</p> <p><b>sudden</b> 121:9</p> <p><b>suffer</b> 119:2</p> <p><b>suffering</b> 48:15</p> <p><b>sugar</b> 171:2</p> <p><b>suggest</b> 98:19,20</p> <p><b>suggested</b> 103:14</p> <p><b>summarize</b> 29:19          40:5 83:6 129:17          175:6</p> <p><b>summarized</b> 29:16          41:18</p>
--	--	---	---

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

Page 39

<p><b>summary</b> 158:2  <b>sums</b> 56:9  <b>super</b> 141:12  <b>supplemental</b>  125:19  <b>supplements</b>  125:21 126:18  127:3  <b>support</b> 20:17  50:15 56:20,21  59:13 89:9  138:11 145:13  175:9  <b>supportive</b> 86:14  100:15 144:6,9  145:2,18  <b>suppose</b> 111:16  <b>supposed</b> 37:5  51:15  <b>supposedly</b> 90:7  <b>suppressive</b> 23:9  <b>sure</b> 14:17 30:1  38:7,20 40:21  55:8 78:2 81:5  93:7 95:13 106:5  107:2,20 110:16  111:14 113:6  117:22 124:16  154:5 156:4  167:5  <b>surgeon</b> 58:9  <b>surgeries</b> 106:19  131:3  <b>surgery</b> 18:12,14  20:6,18,19  22:11,14 53:17  57:19 58:22  60:11 66:5  70:8,13,19,21  72:9 77:3,4,9</p>	<p>80:10 87:13,16  89:18 91:2  94:11,22 105:3  110:13 119:9,20  120:11 127:11  131:7,9,16  139:17,19  <b>surgical</b> 22:11  90:10,16  <b>surgically</b> 57:18  <b>surprised</b> 10:7  59:15  <b>surprising</b> 111:22  113:16 157:1  <b>surrogate</b> 24:5,9  <b>survey</b> 34:20  169:15 178:17  <b>survival</b> 23:22  24:2,9 51:11  108:15,19  148:13,14 153:3  <b>survive</b> 50:5  <b>surviving</b> 47:17  <b>survivor</b> 39:22  50:13 86:1 173:8  <b>survivors</b> 38:13  115:14 121:11  138:11  <b>Survivorship</b>  85:19  <b>Susan</b> 3:18 27:14  39:16 45:7 50:10  75:8,12 117:15  125:8 158:19  159:13 166:2,5  167:12  <b>swallowing</b> 22:20  <b>swear</b> 76:6  <b>sweetie</b> 44:6,11</p>	<p><b>swelling</b> 54:16  <b>swim</b> 54:14  <b>switch</b> 113:21  <b>symptom</b> 8:13  52:8 53:2 57:13  60:5,8,9,16  72:19 74:12,20  81:1,10,14 83:17  114:3 129:22  130:21 170:12  <b>symptomatic</b> 8:18  13:4 132:4  <b>symptom-free</b>  105:1  <b>symptoms</b> 5:22  8:1,16,19 18:21  19:19,22  20:1,2,3 21:6  22:15,17 27:9  40:6,17 45:22  46:3 47:11 48:4  51:4 53:18 54:10  57:11  59:12,16,20  62:22  63:2,6,9,15,17  64:8 75:10 83:15  84:8 85:10  86:15,19 100:15  103:9 105:6  125:17  126:2,3,9,10,11  129:13 133:22  137:2 142:5  144:13 177:4,9  178:20  <b>syndrome</b> 15:14  74:5 90:9  170:15,20  <b>syndromes</b> 74:14  <b>synergistically</b></p>	<p>19:14 21:3  <b>synthesize</b> 50:20  <b>system</b> 163:5  166:14  <b>systematic</b> 11:5  12:3  <b>systemic</b> 19:3 21:8  <hr/> <p style="text-align: center;">T</p> <hr/> <b>table</b> 4:1 27:15  29:5 33:8,21  82:9 176:4,6  <b>tablecloths</b> 30:20  <b>tags</b> 27:16  <b>tailor</b> 15:1,10  <b>taking</b> 67:17 69:1  86:14 97:19,22  119:12 125:16  129:1,2 136:9  140:1 143:17,20  149:14 154:14  171:17  <b>talk</b> 14:1 15:22  40:16,18 41:9  60:5,7 68:7  71:17 74:11  80:15 84:8 91:20  92:21 95:4  111:6,12 113:6  116:20 121:20  124:15 127:22  129:13 131:21  132:22 136:14  146:3 159:16  177:17  <b>talked</b> 20:6 49:21  68:10 75:8 86:15  109:18,19,20  110:2 111:18  125:10 127:8  130:20 139:5</p>
---	--	--	--

(866) 448 - DEPO

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

<p><b>talking</b> 7:16 38:12 39:9 73:13 75:4 84:10 87:1 103:20 134:5 177:3</p> <p><b>talks</b> 55:11</p> <p><b>Tarceva</b> 48:2,12,20,21 53:8 55:4,6 105:13 142:9 149:13 159:18</p> <p><b>target</b> 21:20 164:8</p> <p><b>targeted</b> 21:9 23:10 24:15 25:6 42:18 43:13 45:1,18 54:3 59:9 91:17 93:4,11 108:7 110:14 115:1,6 116:20 117:4,8,17 123:17 164:6 168:12</p> <p><b>targeting</b> 60:1</p> <p><b>targets</b> 122:4</p> <p><b>task</b> 41:13</p> <p><b>Taxotere</b> 92:4</p> <p><b>tea</b> 44:1 113:10</p> <p><b>teach</b> 74:8</p> <p><b>teacher</b> 103:19</p> <p><b>teaching</b> 73:13,14 104:2</p> <p><b>team</b> 2:3 31:13 32:3 92:15 98:2 169:6 175:10</p> <p><b>teams</b> 98:14</p> <p><b>tease</b> 63:3</p> <p><b>teaspoon</b> 96:20</p>	<p><b>technical</b> 25:20</p> <p><b>technician</b> 57:22</p> <p><b>techniques</b> 125:20 126:17</p> <p><b>technologies</b> 12:11 171:3</p> <p><b>technology</b> 16:17 137:13</p> <p><b>teenage</b> 95:8</p> <p><b>teenagers</b> 95:19 143:16</p> <p><b>Temel</b> 144:7</p> <p><b>tend</b> 47:7</p> <p><b>tendency</b> 19:6</p> <p><b>tends</b> 19:5</p> <p><b>Tennessee</b> 98:14</p> <p><b>tension</b> 163:21</p> <p><b>tensions</b> 163:8</p> <p><b>tent</b> 27:16 82:5</p> <p><b>term</b> 102:14</p> <p><b>terminal</b> 41:17</p> <p><b>terms</b> 67:22 85:20 168:1 178:8,17</p> <p><b>terrain</b> 54:15</p> <p><b>terrible</b> 113:20 178:6</p> <p><b>terribly</b> 101:4</p> <p><b>test</b> 12:11 57:20 116:12</p> <p><b>tested</b> 45:12 121:9</p> <p><b>testimony</b> 159:1 181:5,8</p> <p><b>testing</b> 59:10 96:6 116:13 164:21</p> <p><b>testosterone</b> 83:19</p>	<p><b>tests</b> 154:4</p> <p><b>Texas</b> 100:7</p> <p><b>thank</b> 6:21 9:19 26:13,14 32:14 41:1 45:5,6 50:10 56:12,13,15,16 60:17,18 67:8 68:5 71:11 72:17,22 74:18,19 75:3 81:21 82:1,3,6 83:3,9 84:2,3 86:3 87:3,4 90:1,2 96:13,14 99:5,6,8,9,13 104:14,15,17 108:22 109:1,2,6 117:15 119:8 120:12 124:21 128:2 129:4,12 130:22 140:22 143:10 145:20 149:17 154:11 164:2,3 165:5,6,9,13 167:12,14 168:21 169:1,4 172:2,7,8,18 173:9 174:18,21 175:4,22 176:9,10,15 179:19 180:4</p> <p><b>Thankfully</b> 43:6</p> <p><b>thanking</b> 176:11</p> <p><b>Thanks</b> 10:2 159:12 179:22</p> <p><b>that's</b> 6:6,11 10:6 11:17 12:1,5 17:3 19:20 20:7 21:17 22:17 26:10 32:22 33:14 34:10 36:1</p>	<p>39:4 51:18,19,21 52:20 54:20 55:8,9 57:17 59:8 60:7 63:4 64:10 68:17 71:8 72:19 74:12 76:18 78:2 89:7 96:12 97:8 99:2 101:18 102:9 107:6,21 108:15,22 113:8 123:8,19 126:1 127:9,17 128:11 129:7,10 130:1 131:22 136:19 138:7 141:2 142:17 151:1,6 152:3 154:21 156:17 159:11 162:1 163:12,17 166:12 167:11 168:13 172:4 174:22 177:15,16,19</p> <p><b>theme</b> 171:7</p> <p><b>themes</b> 109:18 169:19</p> <p><b>themselves</b> 31:2 39:11 115:20 141:8</p> <p><b>therapeutic</b> 17:12</p> <p><b>therapies</b> 2:18 8:2 10:18 11:4 13:7,8,10 15:16 21:10 23:10 25:6 59:9 105:3,4,7 107:8 108:7 110:14 115:1 116:20 117:4,17 123:17 125:16,22 126:9 127:5 164:6 171:15 173:11</p>
--	---	--	---

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

Page 41

<p><b>therapy</b> 19:1,3,12 20:9,10,17,20 21:5,8 22:16 32:13 43:13 70:14 91:17 93:4,11 105:20 107:12,18 110:13 115:8 121:8 145:11 168:5,12 178:7</p> <p><b>thereafter</b> 181:6</p> <p><b>therefore</b> 8:17 24:10</p> <p><b>there's</b> 53:6</p> <p><b>Theresa</b> 3:6 4:7,21 7:16 9:21 26:14 31:18 176:8,9</p> <p><b>they'll</b> 178:14</p> <p><b>they're</b> 29:3 34:20,22 40:4 48:10 56:11 57:11 89:14 94:7 95:8 97:17 113:7,12 121:3 123:9 124:16 156:5 162:20 163:20 166:13 173:19 174:2,5 176:4</p> <p><b>they've</b> 70:14 95:16 155:1</p> <p><b>thinner</b> 42:21 43:18</p> <p><b>third</b> 7:12 10:11 14:14 51:18 91:22 107:18 139:18 169:17</p> <p><b>thirties</b> 95:15</p> <p><b>Thomas</b> 1:18 181:3,17</p>	<p><b>Thoracic</b> 2:20 32:7</p> <p><b>thoracotomy</b> 92:5 173:19</p> <p><b>thorax</b> 23:1</p> <p><b>thoughts</b> 86:10 116:21 148:2,5 149:18 150:6 156:10 158:16</p> <p><b>threw</b> 132:18</p> <p><b>thrilling</b> 58:17</p> <p><b>throat</b> 22:19</p> <p><b>throughout</b> 55:3,10</p> <p><b>throw</b> 134:17 145:10</p> <p><b>thunderstorms</b> 35:14</p> <p><b>thyroid</b> 167:18 168:3</p> <p><b>thyroidectomy</b> 167:19 168:4</p> <p><b>tied</b> 10:13</p> <p><b>tightly</b> 42:2</p> <p><b>timers</b> 165:16,21</p> <p><b>tingling</b> 23:6</p> <p><b>tired</b> 58:14 59:19 66:21</p> <p><b>tires</b> 100:6</p> <p><b>tissue</b> 2:18 22:18 32:12 167:19</p> <p><b>titrate</b> 132:9</p> <p><b>tobacco</b> 85:2 95:1,19</p> <p><b>today</b> 5:3,21 6:5 7:6,7 8:21 10:4,6,18 11:9</p>	<p>13:7 15:16,17 27:5 28:3 29:16,19 30:5,14,17,19,21 31:4 32:18 33:5,11 37:1,5,22 38:14 40:17 41:9 42:22 45:3 48:8 53:10 58:14 61:7 62:8,11,14,20 70:6 85:15 86:14,16 98:15,16 99:14,19 103:4 109:12 111:3 116:19 129:9 138:17 156:2,15 165:10 169:17 174:19 176:14,20 178:22 179:19</p> <p><b>today's</b> 5:8 7:12 9:12</p> <p><b>toe</b> 42:21</p> <p><b>toes</b> 23:7</p> <p><b>tolerance</b> 103:15</p> <p><b>tolerate</b> 178:9,14</p> <p><b>toll</b> 71:9</p> <p><b>tomorrow</b> 44:2 153:13</p> <p><b>tool</b> 78:8</p> <p><b>tools</b> 9:2 78:4 170:21 171:4</p> <p><b>top</b> 64:1,15 127:1 177:19</p> <p><b>topic</b> 4:14,15,17,18 6:7 27:8 39:8 62:15 75:5 77:15 79:16,17 83:5</p>	<p>84:4,6 109:7 122:10 125:4</p> <p><b>topics</b> 27:7 33:4,10,12 118:1 158:17</p> <p><b>total</b> 41:22</p> <p><b>totally</b> 41:5 80:4 87:15</p> <p><b>tough</b> 109:4 144:18</p> <p><b>towards</b> 162:14</p> <p><b>towel</b> 145:10</p> <p><b>toxic</b> 113:12 144:22</p> <p><b>toxicities</b> 148:16,19 152:19</p> <p><b>toxicity</b> 123:22 152:3,5,7</p> <p><b>Track</b> 24:19</p> <p><b>tradeoff</b> 121:13 139:1,2 149:8 151:8</p> <p><b>tradeoffs</b> 102:9 107:3 121:17 133:9 150:19</p> <p><b>traditional</b> 21:12 66:17 67:2 105:8 117:7</p> <p><b>traditionally</b> 18:9</p> <p><b>Trail</b> 53:11</p> <p><b>transcribed</b> 65:8</p> <p><b>TRANSCRIBER</b> 182:1</p> <p><b>transcript</b> 158:13 170:8 182:3</p> <p><b>transcription</b> 181:7</p>
--	--	--	--

(866) 448 - DEPO

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

<p><b>transformed</b> 58:21 106:7 121:10</p> <p><b>transition</b> 145:4</p> <p><b>translate</b> 8:18</p> <p><b>translated</b> 179:10</p> <p><b>transparency</b> 174:4</p> <p><b>travel</b> 15:8 30:14 36:22 37:6 100:7 160:7 161:13</p> <p><b>traveled</b> 35:11,14</p> <p><b>traveling</b> 6:17 106:1</p> <p><b>travels</b> 179:20</p> <p><b>treat</b> 19:11 24:15 94:8 96:9 97:5 126:2</p> <p><b>treated</b> 54:7 57:18 59:21 60:9 83:12 148:17 160:5</p> <p><b>treating</b> 8:2 15:15 19:4 25:4 60:10 84:7 93:20 97:16</p> <p><b>treatment</b> 4:9 5:19 6:3 7:15 8:18 17:7,8 18:8,14,17,19 20:7 21:11,13,19,21 22:9,10 25:2,18 26:16 27:10 33:15 45:19 46:8 48:6 49:7 54:4,11,14 60:15 63:3 65:13 66:15 75:5,8 76:1 78:16 79:2,14 80:17 84:11 86:17 90:5,17,19 91:14 92:1,11</p>	<p>93:3 96:11 98:5 99:21,22 100:8 101:1,15,19 102:14,16 103:1,3,4,6,11,1 5,21 104:3,5,9,13 107:1 112:1,2,3 113:15 117:14 118:7 120:16,20 121:4 130:11 133:22 134:4,6,9,10,11, 20,22 135:5,6 136:2,6,9,21 137:2 140:5 141:4,5,6,21 143:1,4 144:6,12 146:4,14,19 147:3 155:11 170:14 171:10,14,20,21 175:12,15 177:12</p> <p><b>treatment-related</b> 77:21</p> <p><b>treatments</b> 8:4,9,11 9:14,15 15:19 33:13,17,18 49:6,9 54:19 63:15 82:19 86:11,14,22 88:8 98:17 99:3 100:10,18,21 102:19 106:15 107:3 108:5 110:10,12,15 111:2,16,21 117:22 118:1,6 121:11 125:10,12,15 132:4 133:16 135:18</p>	<p>141:14,16 143:8,9 145:1 146:16 166:10 178:3 179:8</p> <p><b>tremendous</b> 77:3</p> <p><b>tremendously</b> 132:20</p> <p><b>trial</b> 25:22 45:19 49:10 51:7,8 103:5 121:20 122:12,13,15 123:12 148:10,12 159:17,19 160:13,14 161:7,16,19 162:3,4,12,16,19 163:14 164:1,21</p> <p><b>trials</b> 9:6 13:7 23:17 25:21 98:22 120:22 121:21 122:10,19 123:2 159:16 160:1,16 161:9 164:7,8,12,14,16</p> <p><b>triathlon</b> 43:1</p> <p><b>Trick-or-treating</b> 106:2</p> <p><b>tried</b> 14:6 28:16 52:5 117:1 127:5 130:13</p> <p><b>trouble</b> 113:3</p> <p><b>trouble-free</b> 43:6</p> <p><b>true</b> 52:20 58:13 138:7,8 162:1 181:7</p> <p><b>trust</b> 127:21</p> <p><b>trusted</b> 107:13</p> <p><b>truth</b> 101:3</p>	<p><b>try</b> 5:4 12:22 14:8 29:14,19 31:4 32:17,22 34:12 46:11 50:20 56:20 67:20 73:9,14 90:12 101:14 102:2 107:18 122:19 124:10 129:17 138:20 144:11 154:18 175:19</p> <p><b>trying</b> 12:11,19 14:4 15:1,10,19 16:17 67:18 74:8 108:9 137:13 141:16 173:20</p> <p><b>tumor</b> 18:3,16 20:13,14,21,22 21:4,6,14,22 24:8 52:4,6 53:2 55:1,4 58:6 79:9 93:20 103:8 110:13 112:11 118:18,19 119:15,16 120:11 137:22 174:4,5,9</p> <p><b>tumors</b> 21:22 22:1,6 47:6 118:9 119:9 163:19</p> <p><b>turn</b> 5:12 6:19 9:20 17:5 26:11 87:1 111:13,16 176:7</p> <p><b>turned</b> 100:1</p> <p><b>turning</b> 31:8 59:10</p> <p><b>turns</b> 53:15</p> <p><b>twenties</b> 101:10</p> <p><b>twice</b> 53:5</p> <p><b>two-year</b> 104:22</p>
---	---	---	---

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

Page 43

<p><b>type</b> 22:10 53:7 93:21 119:20 120:7 174:12</p> <p><b>types</b> 21:10 22:4 24:5 25:9 50:22 99:16 147:20 148:3</p> <p><b>typewriting</b> 181:6</p> <p><b>typical</b> 42:4 61:12,13 151:21 152:4</p> <p><b>typically</b> 11:15</p> <p><b>typing</b> 118:18</p> <hr/> <p style="text-align: center;">U</p> <hr/> <p><b>U.S</b> 7:21</p> <p><b>ulcerative</b> 52:14</p> <p><b>ultimately</b> 141:19</p> <p><b>unable</b> 44:10 139:19</p> <p><b>unacceptable</b> 165:2</p> <p><b>unblinded</b> 45:20</p> <p><b>uncomfortable</b> 142:10</p> <p><b>undergo</b> 99:21 121:3</p> <p><b>undergoing</b> 86:11 100:10 121:11 127:18</p> <p><b>undergone</b> 86:12 110:9,15 111:1 142:22</p> <p><b>underlying</b> 78:1 80:11</p> <p><b>understand</b> 31:21 40:15 50:1 52:9 77:11 86:10 93:8 94:16,17</p>	<p>102:13,17 103:9 104:7,12 120:10 145:3 169:8</p> <p><b>understanding</b> 7:14 9:13 33:12 111:17 120:2 133:13 179:8</p> <p><b>understood</b> 143:7 145:8 171:22</p> <p><b>undertaken</b> 123:14</p> <p><b>uneven</b> 54:15</p> <p><b>unfortunately</b> 139:15 150:17 159:20</p> <p><b>UNIDENTIFIED</b> 49:13,17 78:21 155:18</p> <p><b>uniform</b> 58:20</p> <p><b>unique</b> 26:4 177:14,15</p> <p><b>uniquely</b> 11:2</p> <p><b>United</b> 17:14,17</p> <p><b>universities</b> 174:6</p> <p><b>unless</b> 147:17</p> <p><b>unmet</b> 10:18</p> <p><b>unnecessary</b> 88:18 160:12</p> <p><b>unrelated</b> 45:14 53:15</p> <p><b>unwell</b> 20:5</p> <p><b>upload</b> 157:13 159:7,9,12</p> <p><b>upon</b> 28:5 84:9 105:20 113:4 150:7 166:10</p> <p><b>upper</b> 73:22</p>	<p><b>urgency</b> 50:7</p> <p><b>urgent</b> 14:2</p> <p><b>URL</b> 159:2</p> <p><b>useful</b> 26:2 29:3 179:15</p> <p><b>usefulness</b> 105:21</p> <p><b>usual</b> 51:17</p> <p><b>usually</b> 18:13,20 23:6,9 75:21 151:22</p> <p><b>utter</b> 106:17</p> <hr/> <p style="text-align: center;">V</p> <hr/> <p><b>Vaidya</b> 3:8 83:9 175:4</p> <p><b>valid</b> 162:11</p> <p><b>validate</b> 47:22</p> <p><b>validated</b> 24:5</p> <p><b>value</b> 9:13</p> <p><b>Vanderbilt</b> 98:7</p> <p><b>varies</b> 90:20 118:15 178:3</p> <p><b>variety</b> 14:5</p> <p><b>various</b> 118:12,22</p> <p><b>vary</b> 41:19 178:4,8</p> <p><b>varying</b> 12:8</p> <p><b>vascular</b> 73:20</p> <p><b>VATS</b> 77:4,5</p> <p><b>vehicle</b> 157:11</p> <p><b>veins</b> 106:8</p> <p><b>venture</b> 43:10</p> <p><b>venues</b> 16:7</p> <p><b>verification</b> 98:6</p> <p><b>version</b> 43:1</p> <p><b>versus</b> 80:11 86:18</p>	<p>119:17 128:10 136:9 139:3 143:7 147:9 148:11,15 175:16</p> <p><b>viable</b> 98:22 99:3</p> <p><b>video</b> 159:1,2</p> <p><b>view</b> 8:1 21:13,19,20</p> <p><b>viewed</b> 169:16</p> <p><b>views</b> 16:2 21:11 52:11,19</p> <p><b>violent</b> 52:14</p> <p><b>visibility</b> 96:18</p> <p><b>visit</b> 44:6</p> <p><b>visits</b> 134:13</p> <p><b>visual</b> 23:13 46:20</p> <p><b>voice</b> 29:20 36:22 37:8 54:12 63:12 99:1 138:21</p> <p><b>voluntary</b> 33:21 34:22</p> <p><b>volunteer</b> 39:19 143:6</p> <p><b>volunteered</b> 143:5</p> <p><b>vomiting</b> 23:4 97:22 105:10</p> <hr/> <p style="text-align: center;">W</p> <hr/> <p><b>wait</b> 92:1</p> <p><b>waiting</b> 43:16 48:20 97:14</p> <p><b>wake</b> 42:9</p> <p><b>walk</b> 44:19 58:17 65:15,17 68:15 75:18 87:13 89:18 92:14,19 140:3</p>
--	---	--	---

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013

<p><b>walked</b> 92:11,14  <b>walking</b> 54:15  55:17 77:8  <b>wall</b> 52:4 139:20  <b>wandering</b> 97:2  <b>Warmerdam</b> 3:18  39:16 45:8  49:15,20 68:9  81:5 117:5 142:7  159:14 160:4  164:3 166:2,9  167:11  <b>Washington</b> 56:19  <b>wasn't</b> 74:4 91:19  96:22 101:3  102:5 106:5  107:12 112:20  114:11 120:7  140:6,20 141:15  <b>waste</b> 59:18  <b>wastes</b> 59:18  <b>wasting</b> 59:18  <b>watching</b> 58:16  <b>water</b> 73:14  112:19,21  113:7,12 127:8  166:16  <b>waved</b> 49:13,16  <b>ways</b> 12:11 50:21  72:12 124:4  170:4  <b>weaker</b> 57:22  <b>weakness</b> 22:12  <b>wearable</b> 171:3  <b>wearing</b> 47:19  <b>wears</b> 105:20  <b>web</b> 7:6 27:5 28:18  29:6,8,13,21</p>	<p>34:16 36:6,7  37:8 39:6 61:22  62:1,9 64:6,15  78:14  83:7,10,14,21  110:8 111:5,8  126:20 129:15  133:10 137:6  156:12 161:4  165:12,13 170:5  175:1,5,7,11,14,  19  <b>webcast</b>  29:7,17,20 62:3  158:9,10,12  169:16 170:6  <b>webcasts</b> 16:18  <b>webpage</b> 62:6  159:10  <b>website</b> 65:9 156:7  157:9,18  <b>Wednesday</b> 42:5,6  <b>week</b> 145:16  158:12 159:22  160:10  <b>weekend</b> 179:21  180:4  <b>weeks</b> 52:7 67:17  85:15 92:3,6  96:18 97:3  127:16 136:8  142:19 145:1  160:19 161:3  169:17  <b>weeping</b> 42:2  <b>weigh</b> 84:12 86:17  178:10  <b>weighed</b> 23:17  <b>weighing</b> 8:16  <b>weight</b> 20:4 55:8</p>	<p>63:12 100:4  <b>weights</b> 65:17  <b>welcome</b> 4:3 5:13  6:20,22 10:3  29:8  <b>we'll</b> 5:2 6:1,9  12:18 14:8,14  27:22 28:10  29:19 32:15 33:9  37:11,17 44:7,18  60:20 62:19 64:1  69:18 76:9 77:15  78:10,13 79:15  80:14 84:10  86:6,7 90:3 99:7  107:22 111:16  120:12 125:8  126:7,10,14  129:17 133:1,7  135:8 143:12  150:8 152:15  165:16 166:5  <b>well-controlled</b>  23:16 25:22  <b>well-informed</b>  175:9  <b>well-known</b> 72:6  <b>we're</b> 5:15,20  7:5,10,21 8:21  10:3,4 11:18  12:2,7 13:2,3  14:12,14,20 15:9  16:16,19  28:16,22 30:17  32:21  33:11,14,16  34:12,15 35:8  36:12 37:22  39:1,20 46:5  59:11 75:4,6  77:19 80:14  81:22 82:17 83:4</p>	<p>84:5,9 91:12  95:13,15 96:3,5  98:20 108:8  110:4 117:8  127:4 129:8,9  134:5 136:18  137:13 148:1,3  158:17 162:14  163:12 164:17  165:7,14,15  168:13,17,18  <b>we've</b> 14:7  16:11,13,16 22:3  68:4 80:9 82:13  83:2,6 86:4  99:19 103:3  111:14 122:3  127:8 132:22  175:2 178:11  <b>whack</b> 106:16  <b>whatever</b> 40:18  101:17 102:7,18  106:19 140:11  144:16 146:15  178:14  <b>whatnot</b> 76:21  <b>whatsoever</b> 73:17  <b>wheezing</b> 63:10  64:13 69:19  70:1,11  <b>whenever</b> 112:20  113:7  <b>Whereupon</b> 82:10  180:6  <b>wherever</b> 67:21  <b>whether</b> 15:20  61:3 66:15 90:13  96:11 102:14  115:1 118:8,9  124:3,9 133:21  134:1,13 136:6</p>
---	---	--	---

Capital Reporting Company  
 Patient-Focused Drug Development 06-28-2013  
 Page 45

<p>137:1 152:12                  153:13 155:15                  166:13 168:15                  170:12</p> <p><b>white</b> 1:11 30:19                  58:20</p> <p><b>whole</b> 10:6 64:7                  66:19 111:4                  121:17 139:8                  169:6</p> <p><b>whom</b> 50:18 181:3</p> <p><b>who's</b> 34:19 35:1</p> <p><b>wide</b> 11:19 13:11                  29:10 50:21                  110:22 126:15</p> <p><b>wife</b> 99:22</p> <p><b>Wigger</b> 101:10</p> <p><b>willing</b> 15:21 72:7                  101:14 106:11                  121:3,14 142:10                  146:15</p> <p><b>willingness</b>                  178:9,13</p> <p><b>wine</b> 44:15</p> <p><b>wings</b> 48:20</p> <p><b>wire</b> 72:8</p> <p><b>wish</b> 129:19                  156:19</p> <p><b>woke</b> 130:9</p> <p><b>woman</b> 143:5</p> <p><b>women</b> 7:21 17:15                  40:12 120:4                  141:11</p> <p><b>wonder</b> 118:16</p> <p><b>wondered</b> 160:6</p> <p><b>wonderful</b> 36:10                  57:1,8 59:5,22                  60:14 77:6 89:8</p>	<p>141:22 142:1                  179:21</p> <p><b>wonderfully</b>                  108:16</p> <p><b>wondering</b> 75:12                  168:14</p> <p><b>Woodcock</b> 169:5</p> <p><b>work</b> 9:1 13:8                  16:18 17:3 19:14                  21:2 39:6 43:2,7                  44:7,14 46:13,18                  47:15 55:15                  56:22 57:2 67:16                  68:1 69:6 71:15                  72:10,12 82:4                  85:1 106:6,7                  108:4,17 155:16                  160:6 163:8</p> <p><b>worked</b> 12:21                  101:8,18 105:16                  108:16 129:10                  139:14 151:21                  168:12 169:2</p> <p><b>working</b> 13:3 32:8                  67:21 68:1 104:8                  107:8 115:17                  127:7,9 141:15                  162:9</p> <p><b>works</b> 71:6 110:17</p> <p><b>workshop</b>                  169:14,17,18                  170:9</p> <p><b>workshops</b>                  169:7,9,12 172:4</p> <p><b>workup</b> 73:8,20</p> <p><b>workups</b> 73:9</p> <p><b>workweek</b> 160:8</p> <p><b>worried</b> 48:17</p> <p><b>worries</b> 40:14</p>	<p><b>worry</b> 48:14,15,19                  63:19 143:17</p> <p><b>worse</b> 45:4 100:12</p> <p><b>worst</b> 65:14</p> <p><b>worth</b> 178:13</p> <p><b>wow</b> 58:21</p> <p><b>wrapped</b> 52:6</p> <p><b>write</b> 74:8 80:5</p> <p><b>writing</b> 62:21</p> <p><b>written</b> 28:8 50:17                  102:22</p> <p><b>wrong</b> 77:1,13                  134:17</p> <p><b>wrote</b> 41:12 55:13                  56:2</p> <hr/> <p style="text-align: center;"><b>X</b></p> <hr/> <p><b>Xalkori</b> 105:15</p> <p><b>x-ray</b> 20:11 45:16                  51:6 52:15 53:14                  57:20 58:1 96:22</p> <p><b>x-rays</b> 161:2</p> <hr/> <p style="text-align: center;"><b>Y</b></p> <hr/> <p><b>yesterday</b> 35:14                  58:13,15</p> <p><b>yet</b> 72:19 73:3 83:8                  127:7 142:22                  173:17</p> <p><b>yoga</b>                  127:12,13,14,15,                  19,20</p> <p><b>York</b> 87:9</p> <p><b>you'll</b> 6:15 32:22                  50:21 120:14                  170:17</p> <p><b>young</b> 41:9                  68:19,22 102:1</p>	<p>106:13,20                  119:11 120:1,3                  138:4 139:5,7                  178:12</p> <p><b>youngest</b> 66:18</p> <p><b>yourself</b> 38:2                  61:15 126:13                  129:1,2</p> <p><b>yourselves</b> 31:10                  84:17 121:2                  176:17</p> <p><b>YouTube</b> 159:2</p> <p><b>you've</b> 40:6 117:3                  133:18 138:5                  144:18 172:3                  176:16 179:18</p> <hr/> <p style="text-align: center;"><b>Z</b></p> <hr/> <p><b>zero</b> 51:11</p>
--	---	---	---

Capital Reporting Company  
Patient-Focused Drug Development 06-28-2013  
Page 46