

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 malignances 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> \$	19 168:10	28 1:8 65:12	50 17:21 173:20
\$5,000 89:13	1984 172:21	2-hour 44:5	5-1/2 86:2
<u> </u> 1	1998 52:13	<u> </u> 3	5-year 14:10 153:2
1 4:14,15 6:7 27:13	1999 51:2 54:22	3 14:8 50:4 82:16	<u> </u> 6
35:4,17 38:5	<u> </u> 2	83:1 86:5 105:14	6 4:3 24:17 52:7
39:8 42:19 56:2	24:17,18 6:7	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
1,400 169:16	67:13,17 74:11	30 42:17 44:22	161:2
10 4:6 24:13 35:21	82:4 83:5 84:4,6	95:16 97:21	6:00 58:19
66:7 145:6	91:3 106:2	30-year-olds 94:3	60 96:1 116:1
148:15 175:16	108:14 109:7	3-1/2 50:6	62 4:15
10:00 43:4	148:13 149:21	39 4:14 13:17	<u> </u> 7
100 153:15	151:4 169:17	3A 91:6	7 46:7 52:7 90:5
100-mile 55:22	173:3 175:15	3-year 151:16	7-1/2 92:5
109 4:18	179:6	<u> </u> 4	74 142:19
10903 1:12	20 12:15,19 13:10	4 49:12 86:5 91:2	79 100:1
11 88:13 92:10	14:7 95:13,17	4,500 13:19	7-year 173:8
11th 14:19	115:22	4:00 168:9	<u> </u> 8
12 24:13 67:13	20,000 161:1	40 42:1 46:21	8 24:17
91:1 92:3 98:2	200 55:20 161:2	40-year-olds 94:3	8:00 42:9 58:18
122:3 148:14	200,000 17:17	41 51:2	8:23 1:9
12:28 180:6	2005 53:2	47 45:10	80th 100:2
13 58:22 77:10	2010 53:13	48 91:9	82 4:16
14 153:2,4,6	2011 41:11 55:1	49 57:13	84 4:17 46:4
15 22:22 74:1 79:9	2012 54:1	4-year 106:2	85 18:1 121:22
95:8 143:6	2013 1:8 173:6	<u> </u> 5	86 153:6
15-minute 81:22	20993 1:13	5 12:15 22:22	8-block 44:18
16 14:7 74:3 95:8	20-year-olds 94:3	38:6,9 46:7 50:5	<u> </u> 9
160,000 17:18	22 36:8 169:4	51:11 66:5,17	9 96:18
165 4:19	170:19	120:19 122:7	90 13:19 66:6
17 4:9	24 77:8	142:19	
176 4:20	25 36:8		
18 95:12	26 4:12 70:7		
	119:10,15		
	173:14,19		

(866) 448 - DEPO

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

<p>93 153:14 94 161:5 99 52:2</p> <hr/> <p style="text-align: center;">A</p> <hr/> <p>a.m 1:9 42:9 43:4 168:9</p> <p>abdomen 43:6 45:12 160:18,20,21</p> <p>ability 12:12 26:4 59:5 72:10 74:7 104:1 182:4</p> <p>ablated 168:4</p> <p>able 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>abnormalities 21:21 22:4,6 115:7</p> <p>abnormality 25:8</p> <p>abnormally 43:12</p> <p>absolutely 65:20</p> <p>academic-based 164:16</p> <p>Academy 58:16,17</p> <p>Accelerated 24:22</p> <p>accept 88:1 107:10</p> <p>access 99:3 122:9</p>	<p>accidentally 177:10</p> <p>accommodate 33:9</p> <p>according 50:5</p> <p>account 86:20,21 97:13 137:1</p> <p>accurate 160:2 161:5</p> <p>accurately 24:1</p> <p>ache 71:4</p> <p>acid 53:16 98:1</p> <p>acknowledge 37:3,7 111:3</p> <p>acne 106:18</p> <p>across 169:19 171:7</p> <p>act 50:6</p> <p>action 181:10,14 182:6,7</p> <p>active 52:21 55:16 65:12 67:14,16 71:21 144:6,12</p> <p>activities 13:4 40:9 48:5 55:12 69:8</p> <p>activity 24:21 56:5</p> <p>actually 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>acupuncture</p>	<p>128:5,9</p> <p>acutely 40:17</p> <p>adamant 119:13</p> <p>add 43:2 150:10 152:4</p> <p>added 48:15 179:9</p> <p>addicted 95:11,19</p> <p>addiction 89:2 95:20</p> <p>addictive 177:21</p> <p>adding 154:15</p> <p>addition 16:13 19:13 118:18 148:12,16 161:3</p> <p>additional 16:8 152:3 161:6</p> <p>address 21:1 79:17 83:22 100:12 119:9 123:1 133:8 137:19 167:8 173:15</p> <p>addressed 84:1 129:14 131:22 162:15</p> <p>addresses 103:1</p> <p>addressing 126:10 173:21</p> <p>adenocarcinoma 18:6</p> <p>adequate 23:16 96:10</p> <p>adjourned 180:8</p> <p>adjustment 149:15</p> <p>adjuvant 90:13</p> <p>Adkins 3:10 70:4,19 119:8 142:16 166:4</p>	<p>172:13,16</p> <p>administer 146:16</p> <p>administered 134:11,22 136:22 146:4,14</p> <p>administration 1:1,10 146:8 179:1</p> <p>Admiral 169:5</p> <p>adrenal 45:11 81:12</p> <p>advance 8:3 34:13,14 35:9</p> <p>advanced 10:8 18:19 19:22 21:3 46:5 100:3</p> <p>advances 24:15 97:16</p> <p>advice 96:4 107:14</p> <p>advisory 11:16</p> <p>advocacy 9:7 16:5 56:17 57:6</p> <p>advocate 30:9 59:3 70:5 85:12,20 120:18 139:14 169:2</p> <p>advocates 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>affect 8:11 13:4,5</p> <p>affected 13:12,13 87:22</p> <p>affects 51:1 65:2 118:8</p> <p>affiliation 84:20</p>
--	--	---	--

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

Page 3

<p>165:22 afternoon 44:2 afterwards 16:10 131:17 against 85:1 104:10 age 37:12 42:1 70:7 119:11,15 120:5 142:19 173:14,19,20 Agency's 163:1 agenda 5:11,14,15 28:9 86:9 agent 118:20 agents 112:22 113:13 aggressive 19:6 94:2,4 106:15 aging 76:16,21 171:9 ago 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 agreed 90:15 ahead 5:2 74:21 81:4 112:15 131:1 142:15 143:12 164:4 AIDS 49:4 aim 25:19 aimed 18:20 air 166:17</p>	<p>airplane 151:1 ALA 85:1 aligned 70:20 alive 106:12 139:7,9 ALK 98:9 105:15 ALK- rearrangement 25:8 allergies 73:16 allergy 46:2 alleviate 100:15 Alliance 39:22 56:17 71:16 85:12 92:16 140:8 allow 49:3 56:6 63:16 122:14 alluded 133:1 alone 148:12,16 alongside 144:11 already 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 alternative 125:22 altitude 51:21 alumni 58:18 am 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 amazing 140:17 Ambassadors 39:15 41:3 American 39:17,19 87:8 143:5 among 141:18 179:5 amount 6:11 100:3 106:17 112:18 AM's 42:14 Amy 3:11 71:14,15 72:17 139:12 140:22 141:6 analysis 2:6 4:13 179:18 Andrea 2:7 3:11 120:15,17 135:2 137:6 151:9 152:17 155:7 169:6 announcement 82:12 annoying 45:22 answer 36:19,20 37:9 40:3 110:8 129:17 134:17 163:10 167:6 174:11 answered 116:7 137:18 answering 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 answers 50:17 135:11,14 Anti 44:22 antibodies 25:10 antidepressant 44:22 anti-nausea 42:17 anxiety 63:14 anybody 65:20 74:15 91:18 93:2 anymore 47:10 70:20 88:10 92:12 117:12 142:12 143:18,21 anyone 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 anything 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>anytime 34:9</p> <p>anyway 75:19 95:4 107:18 151:13</p> <p>anyways 49:6</p> <p>anywhere 74:4 87:11 139:21</p> <p>apartment 65:15,16</p> <p>appear 105:17</p> <p>appearing 181:5</p> <p>appetite 20:4 63:12 101:13 134:9</p> <p>applaud 109:5</p> <p>applause 61:10</p> <p>apples 107:12,13</p> <p>applications 9:8,9 24:14</p> <p>apply 110:16</p> <p>appointment 41:19,21 160:9</p> <p>appointments 106:1 161:12</p> <p>apportioned 164:14</p> <p>appreciate 35:12,13 99:12 129:2 172:18</p> <p>appreciative 173:6</p> <p>approach 10:13 11:7 78:4</p> <p>approaches 27:11</p>	<p>84:7</p> <p>appropriate 33:14 159:15</p> <p>approval 24:22 99:12</p> <p>approved 22:8 25:2 121:7</p> <p>approving 23:15</p> <p>approximately 55:20</p> <p>apps 171:3</p> <p>April 14:19</p> <p>apt 122:14</p> <p>ARBOGAST 182:12</p> <p>archived 170:6</p> <p>area 12:10 23:2 35:4,6,11 146:18 155:6 169:3</p> <p>areas 13:17,18,20,21 157:1</p> <p>aren't 49:7 108:2 117:7 129:14 138:17 166:9</p> <p>arm 53:2</p> <p>arrive 43:4</p> <p>Arscott 3:10 72:22 85:8,9 90:4 112:16 127:10 129:22 152:16</p> <p>artery 52:7</p> <p>aside 67:19</p> <p>asleep 81:9</p> <p>aspect 177:15</p> <p>aspects 8:10 13:5 33:2 112:3</p>	<p>124:16 125:1</p> <p>assessment 10:14,16</p> <p>assistance 98:17</p> <p>associate 84:20</p> <p>associated 74:6 90:9 107:15</p> <p>Association 39:17,19 87:8</p> <p>assumed 106:4</p> <p>ate 43:22</p> <p>attached 94:17 115:12</p> <p>attacking 88:3</p> <p>attempts 21:20</p> <p>attendance 7:7</p> <p>attended 26:21</p> <p>attending 9:19</p> <p>attention 59:6 124:9</p> <p>attitude 129:7,10 138:12 153:5,10,16 166:14</p> <p>attorney 181:12</p> <p>attribute 76:15 138:2</p> <p>attributed 79:21 80:16</p> <p>atypical 120:6</p> <p>audible 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>audience 7:6 9:4 28:2 30:17 109:11</p> <p>audio 182:3</p> <p>augment 98:17</p> <p>August 53:1 55:1 156:9</p> <p>Austin 100:8</p> <p>available 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>Avenue 1:12</p> <p>average 108:15 148:13</p> <p>avoid 97:21 124:4</p> <p>aware 14:3 114:11</p> <p>awareness 53:12 172:21</p> <p>away 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</p> <hr/> <p>B-12 97:22</p> <p>babysitting 58:2</p> <p>background 4:9 5:16 9:21 10:10 17:6,8,11 26:15,16,17</p> <p>backside 28:9</p> <p>bad 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 balancing 23:18 47:13 ball 52:4 barrier 123:4,6,13,18 based 18:3 21:11 22:1,5 164:16 166:22 173:12 bases 21:13 basic 6:16 10:13 167:15 basically 20:13 56:19 86:9 108:12 117:9 168:18 basics 128:20 basis 41:18 70:10 162:19 bay 48:12 beach 141:22 beat 141:14 144:11 beautiful 106:8 became 73:7 95:18 become 73:6 95:11,20 102:10 becomes 54:8 becoming 59:3 76:17 bed 42:2,16 44:19 45:2 66:9 69:5 140:2,20 144:2 begin 42:20 44:4 48:14 87:2 95:1,7 176:11 177:3</p>	<p>beginning 144:7 behalf 41:4 71:17 85:20 165:9 172:19 174:19 behind 74:16 81:12 believe 6:8 35:22 98:4 130:2 143:22 159:5,10 believed 112:18 believes 53:18,20 beneficial 112:4 118:17 127:17 benefit 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 benefit-risk 9:18 10:14 benefits 8:19 11:2 102:18 111:15 117:4 178:10 besides 89:16 125:14 160:10 best 34:6 38:15 67:19 99:4 100:5 103:11 104:12 110:1 140:13 145:5 182:3 Bethesda 98:6,14 better 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 bevacizumab 25:13 beyond 19:2,16 45:14 98:18 107:20 122:21 bicycles 55:19 bigger 124:7 biggest 70:12 117:6 160:11 166:20 178:7 bike 55:20,22 bilateral 55:2 bill 52:2 89:12 bind 25:11 Biologics 32:11 biomarkers 91:19 biopsied 52:15 53:3 bit 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 bizarre 131:6 blanket 161:14 bleed 80:21 bleeding 22:13 23:8,13 blessed 105:4</p>	<p>blindly 107:9 blocked 58:6 blood 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 Blumenthal 2:3 32:2 132:6 blur 63:4 body 8:16 22:16,18 38:19 46:7 56:8 139:21 174:1 bone 23:10 70:14 71:1 97:18,19 105:11 106:17 bones 72:4 88:3 boost 44:6 bottles 42:16 bound 69:5 box 29:17 78:14 159:10 brachial 73:21 74:4 brain 22:22 46:11 75:9,13,15 76:6 122:1 123:3,18 brave 58:10 break 4:16 6:2,9 33:9 80:14,18 81:3 82:1,3 121:5 breaks 95:11 Breakthrough 24:19</p>
---	---	---	--

(866) 448 - DEPO

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

<p>breast 17:15</p> <p>breath 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>breathe 79:11 130:16</p> <p>breathing 63:11 64:13 69:20 87:17 125:20 126:17 127:2</p> <p>brief 5:5 17:11 82:10 172:16</p> <p>briefly 44:7 59:12 74:22</p> <p>brigade 97:21</p> <p>bring 27:15 77:16 81:1 123:20 142:16 159:15 172:21</p> <p>brings 62:11</p> <p>brittle 72:4</p> <p>broad 7:6 17:20 24:11</p> <p>broaden 27:22</p> <p>broke 70:21</p> <p>bronchioloalveolar r 51:10</p> <p>bronchus 58:6,7,11</p> <p>brought 72:14 113:8 124:13 150:16 156:19</p> <p>bucket 97:21 151:17 157:11</p>	<p>build 28:4 48:13</p> <p>building 6:14 48:19 83:2</p> <p>bullet 121:15</p> <p>bumped 112:22</p> <p>BUN 113:1</p> <p>bunch 150:16</p> <p>burden 17:19 89:10 100:11 102:16</p> <p>burdens 171:12</p> <p>buttock 53:3</p> <p>button 31:11 110:17</p> <hr style="width: 100%;"/> <p style="text-align: center;">C</p> <hr style="width: 100%;"/> <p>cab 160:6</p> <p>cachexia 59:17 60:2</p> <p>calculation 144:17 161:4</p> <p>Campus 1:11</p> <p>cancer 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>cancer-free 66:4 70:8</p> <p>cancers 77:5 177:17</p> <p>candidate 20:19</p> <p>capable 97:4</p> <p>Capital 1:19</p> <p>capture 8:9 12:4 14:4 26:7</p> <p>captured 13:6 16:22</p> <p>capturing 26:2</p> <p>car 106:6 150:22</p> <p>carboplatin 92:4</p> <p>carboplatinum 113:22</p> <p>carcinoma 18:5 51:10</p> <p>cards 27:16 82:5</p> <p>care 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 careful 127:20 carefully 9:10 caregiver 30:9 70:6 71:17 120:19 caregivers 30:6 71:17 171:13 caretakers 16:5 27:4 30:12 36:3 Caring 39:15 41:3 carried 55:18 case 78:2 89:7 94:20 97:8 105:5 119:10 139:17 146:17 162:19 173:14 case-by 162:18 cases 19:10 20:12,19,21 24:9 60:6 177:7 cat 44:2 58:4 90:17 91:2 93:16 164:9 catch 19:7 44:5 142:21 categories 17:20 18:6 21:17 24:11 171:6 category 25:10 catnap 46:19 cause 7:20 17:16 48:17 caused 72:2 88:21 causes 23:5 causing 21:6 cavity 54:3</p>	<p>CBER 2:18 CDER 1:2 2:4,6,8,11,13,16, 21 3:5,7,8 4:5,8,11,13,21 celebrate 44:9 cell 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 cells 20:14 88:2 Cellular 2:18 32:12 center 1:2 5:6 7:3 10:13 32:11 43:16 72:7 98:11 147:2 centimeter 91:3 centimeters 79:10 87:7 central 100:6 177:6 certain 24:4 25:9 144:17 152:11 certainly 11:5 26:6 60:9 100:11 163:1,9 170:14 178:11 CERTIFICATE 181:2 182:1 certify 181:4 182:2 cessation 95:1 cetera 134:9,14 Chad 29:1 135:9,12 challenges 25:20</p>	<p>41:15 46:13 171:14 challenging 146:19 chance 50:4 51:11 157:19 161:6 172:10 change 56:20 60:15 118:7 122:2 142:3,13,14 144:17 168:6 174:16 changed 93:22 116:11 121:6,15 152:12 166:20 changes 8:18 18:18 23:14 48:3 49:8 125:21 changing 122:9 charged 20:12 chart 21:17 chat 44:7 chats 120:4 check 91:18 checked 42:7 115:6 check-in 43:4 checks 96:21 chemicals 120:8 chemo 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 chemo-responsive 105:19 chemotherapeutic s 25:4 chemotherapies 118:13 119:1 152:20,21 chemotherapy 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 chest 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 children 68:22 69:7 102:1 139:5,7 142:19 143:2,3,15,18 178:12,15 choice 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 choices 48:11 108:3 110:4 choose 48:8 63:8 110:16,17 144:2 150:22 choosing 107:12 chores 47:15 chose 93:16 chosen 102:19 chronic 13:4 15:13 49:1 70:8,13 119:17 170:15,19 chronicity 171:11 chute 151:2 cigarette 130:4 circumstances 178:8 179:11 cisplatin 25:5 92:6 113:20 114:1 City 87:9 clarify 78:2 122:18 class 91:10 classifications 21:15 claw-like 73:7 clean 91:2 clear 58:1 102:20 116:13 148:21 179:8,14 clear-cut 102:5 149:16 clearly 102:13,22 105:3 154:20 Clermont 56:1</p>	<p>click 62:7 clicker 16:17 34:17 clickers 28:20,21 29:2,21 34:15 110:7 climb 52:21 87:18 clinic 32:8 51:9 119:14 clinical 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 clinician 32:9 clocking 43:9 close 49:12 80:20 82:21 85:2 164:18 closed 180:3 closely 107:17 closer 161:11 closes 157:22 158:1 closing 4:20 176:9,11 clothes 44:19 clots 134:3 Coalition 85:19 coffee 6:16 42:10</p>	<p>113:10 cognitive 22:21 75:10,13 76:8 80:1 coincidence 177:8 colitis 52:14 colleagues 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 collect 29:15 collecting 152:14 combination 18:22 100:17 combined 92:9 comes 17:4,15 82:21 89:3 108:1 117:11 120:10 comfortable 81:15 100:16 114:4 139:3 142:9 144:19 145:17 coming 64:19 65:5 115:8 122:6 136:10 152:10 154:6 178:20 commend 67:20 169:21 comment 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 comments 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 commercial 163:2 commitment 35:12,13 160:11 161:10 committed 12:14 57:1 committees 11:17 common 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 communicated 102:22 communication 102:20 community 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>community-based 164:14</p> <p>comorbidities 171:8</p> <p>companies 60:1</p> <p>company 1:19 94:21</p> <p>compared 87:14 104:10</p> <p>comparing 148:10</p> <p>comparison 104:5,19</p> <p>compassion 169:22</p> <p>complementary 125:22 126:18</p> <p>complete 43:10</p> <p>completely 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>complicate 171:12</p> <p>complicated 31:5</p> <p>complications 22:11</p> <p>components 10:16</p> <p>comprised 21:8</p> <p>comprises 10:19</p> <p>compromised 103:22</p> <p>computer 42:16</p> <p>concentration 83:16</p>	<p>concept 23:20</p> <p>concepts 26:8</p> <p>concern 11:20,21 77:21 98:3 107:21 160:11 178:8</p> <p>concerned 178:21</p> <p>concluded 92:11 98:8</p> <p>conclusions 162:11</p> <p>concurrently 21:2</p> <p>condition 10:17 11:3 15:16 29:10 33:2 38:13,16 40:15 162:17 170:13 177:21</p> <p>conditions 13:12 24:16 169:9 171:12,16,22</p> <p>conduct 9:6</p> <p>conducted 169:15,20 170:4</p> <p>confirmation 80:19</p> <p>connection 128:17</p> <p>consequence 170:13</p> <p>consequences 171:10</p> <p>consider 10:16 49:9 81:10 94:9 146:21 175:17</p> <p>consideration 121:16 147:11</p> <p>considerations 14:6 84:13 120:13 132:3</p>	<p>considered 103:16</p> <p>consistent 42:11 169:22</p> <p>consistently 178:19</p> <p>constantly 162:14</p> <p>constituency 79:19</p> <p>constituents 123:8 151:12</p> <p>constitutional 20:1,3</p> <p>consultation 169:11</p> <p>consumed 88:7</p> <p>contact 138:10</p> <p>container 43:18</p> <p>cont'd 3:1</p> <p>contemplation 101:2</p> <p>CONTENTS 4:1</p> <p>context 5:16 10:20 11:14,22 15:2 110:6 135:16 169:8</p> <p>continue 28:17 32:8 34:3 46:12 55:15,16 94:4 110:1 163:5,7 173:11</p> <p>continued 3:2 72:12 93:11</p> <p>continuing 165:10</p> <p>contribute 26:5 30:7,10 32:18,20 156:11</p> <p>contributed 176:14</p> <p>control 45:14 48:8</p>	<p>49:9 86:12 110:11 133:17 135:19 166:11</p> <p>controlled 53:9</p> <p>convene 12:14</p> <p>conversation 28:12 30:10 44:18 82:2,20 124:22</p> <p>conversations 33:9 34:7</p> <p>conveyed 157:17</p> <p>conveys 168:16</p> <p>convinced 88:6</p> <p>Coordinator 2:8</p> <p>copay 89:12</p> <p>copays 89:13</p> <p>COPD 52:18</p> <p>Copeland 3:11 71:15 139:13</p> <p>copied 56:2</p> <p>correct 35:22</p> <p>cost 100:18 116:16,18 154:22</p> <p>costs 155:4</p> <p>cotton 42:21</p> <p>couch 66:9</p> <p>cough 20:2 23:3 45:17 46:1 52:3,10 53:14,15 73:2,12</p> <p>coughing 57:22 63:11 96:20</p> <p>council 56:16</p> <p>counsel 181:9,12 182:5</p>
---	--	---	---

(866) 448 - DEPO

Capital Reporting Company
 Patient-Focused Drug Development 06-28-2013
 Page 10

<p>counterpoint 132:16 countless 103:19 country 7:19 counts 44:16 couple 38:3 93:3 144:4,8 145:14 147:18 148:1 169:18 courage 61:7 109:4,5 176:15 courageous 133:3 courageously 83:4 course 57:21 59:9 87:13 108:17 150:13 159:19 courtesy 34:4 cover 11:12 13:10,11 14:15 covered 111:14 covering 13:10,19 14:12,21 coworkers 95:10 C-Path 170:22 crass 162:4 crawling 73:1 create 171:11,12 created 95:20 creates 171:14 creating 169:9 creatinine 113:1 Crest 53:11 criteria 12:21 13:1 critical 16:10 104:6 crizotinib 25:7</p>	<p>121:6 cross 123:17 171:5 crossing 150:22 crossover 66:15 cruise 140:4,7,16 CT 43:5 59:6 160:17,18,20,21 cup 42:10 curative 102:15 cure 15:21,22 16:2 18:18 20:20 90:16 97:5 98:4 103:2,4,7 143:22 cured 18:12 20:8 47:9 141:20 168:4 current 8:8 11:4 13:9 15:2,19 17:7,12 24:19 38:16 84:7 110:12 currently 38:20 40:13 49:5 53:10 86:11 93:4 103:6 125:16 CVs 73:9 cycle 67:14 68:4 cycling 55:17,18 Cymbalta 173:16 <hr style="width: 20%; margin-left: 0;"/> _____ D D.C 35:4,5 56:19 daily 6:1 15:14 27:9 42:18,21 43:18 45:18 47:1,15 63:8 67:20 70:1,10 Dallas 100:8</p>	<p>damage 22:17 23:5 155:12 damaging 20:15 Dan 101:10,22 102:3,6 dark 97:2 99:1 data 169:15 date 117:8 daughter 66:17,18 70:6 77:3 119:10 173:14 174:7 daughters 106:3,20 day 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 daypack 42:22 days 45:4 57:17 66:5,7 81:9 143:1 145:6,15 dead 50:6 89:16 deal 48:22 50:22 139:10 153:11 178:4 dealing 15:17 68:4 81:8 139:16 deals 70:8 dealt 105:22 death 7:20 134:4 143:1</p>	<p>deaths 17:16,18 debilitating 29:9 66:11 69:6 140:1 178:6 DEBORAH 182:12 decades 115:13 172:6 decide 44:8 98:1 109:22 decided 51:12 deciding 144:10 decipher 41:14 decision 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 decision-making 145:3 decisions 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 decline 165:18 decreases 163:6 define 24:7 56:8</p>
---	--	--	--

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

<p>defined 23:21 26:7 60:8</p> <p>definitely 60:16 72:9 76:19 79:4</p> <p>definition 75:1</p> <p>degree 10:17,18 11:4</p> <p>Delaney 57:4</p> <p>delay 103:8 115:10,11</p> <p>deletion 168:10</p> <p>delighted 168:17</p> <p>delivered 20:13</p> <p>demonstrated 24:3</p> <p>Denise 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>depend 143:14</p> <p>dependent 178:12</p> <p>depending 6:10 18:15 77:5 97:6 118:7,8 157:16</p> <p>depressed 60:13</p> <p>depression 60:7,10,16 63:14</p> <p>describe 78:13,15 80:10 124:10</p> <p>described 27:7 86:13 141:13</p> <p>describes 38:15</p> <p>describing 176:17</p> <p>deserve 164:22</p> <p>deserves 83:12</p>	<p>96:10</p> <p>deserving 83:13</p> <p>designer 55:15 71:20</p> <p>despite 100:5 103:20 109:22</p> <p>detail 7:17 62:3</p> <p>detailed 97:13</p> <p>detect 19:20</p> <p>detection 46:3</p> <p>determine 6:11 122:21 124:3</p> <p>determined 52:16 56:11 141:14</p> <p>devastating 8:3 106:4</p> <p>develop 9:6 13:2 19:22 78:4 94:6 104:8 116:2</p> <p>developed 12:21 77:2 104:4 148:8</p> <p>developer 123:5</p> <p>developers 7:9 9:7</p> <p>developing 12:3 154:9 161:6</p> <p>development 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>diabetes 49:4</p> <p>diagnosed 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>diagnoses 17:18,22 18:2</p> <p>diagnosis 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>diagnostic 171:6</p> <p>dialog 169:10</p> <p>dialogue 27:1 30:8 82:2 89:4 121:5</p> <p>diaphragm 70:19</p> <p>diarrhea 23:12 105:14 106:18 117:12 148:18</p> <p>Dickran 2:12</p> <p>dictated 105:2</p> <p>die 89:5,6 107:17 108:1 151:2,13,15 152:17,18,22 163:15</p> <p>died 57:7 142:18 145:5,6 150:11 154:18 163:15 172:21</p> <p>diet 42:12 125:21 166:21,22</p> <p>dietary 125:21 126:18 127:2</p>	<p>differ 8:19 118:12</p> <p>difference 54:9 67:5 75:21 76:14 78:12 116:12 128:7 136:7 147:8,11 166:21</p> <p>differences 123:22</p> <p>different 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>differently 26:20 48:9 161:22</p> <p>difficult 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>difficulties 63:11 64:14 69:20</p> <p>difficulty 8:16 22:20 63:13</p> <p>Diko 31:12 123:21 150:8</p> <p>dimension 171:5</p>
---	---	--	---

Capital Reporting Company
 Patient-Focused Drug Development 06-28-2013
 Page 12

<p>diminished 55:5</p> <p>dinner 44:8,11</p> <p>direct 25:17</p> <p>directed 87:8 97:8 98:12</p> <p>direction 96:19 181:7</p> <p>directly 7:22 11:1 36:17,22 167:8</p> <p>director 2:10 3:6 4:4,7,21 7:2 31:18 32:1 41:2 59:14 85:18</p> <p>disabled 87:15</p> <p>disabling 170:12</p> <p>disappoint 143:2</p> <p>disappointing 67:7</p> <p>disclaimer 31:3</p> <p>discovered 141:9 177:11</p> <p>discuss 11:12</p> <p>discussed 102:9,10 164:1,10</p> <p>discussing 12:18 33:11 158:17</p> <p>discussion 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>discussions 5:21 27:17 33:5 60:21 98:19 162:3</p> <p>disease 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>disease-directed 99:21</p> <p>diseases 12:18,20 13:3 14:1,9,12,20</p> <p>distinctly 78:12</p> <p>distinguished 76:17</p> <p>dividing 21:22 22:1</p> <p>division 2:4,10,13,15,21 4:4,10 7:3 15:4,11 17:10 31:13 32:1,3,7</p> <p>divisions 11:21</p>	<p>12:22 14:1</p> <p>DNA 20:15</p> <p>docket 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>doctor 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>doctors 87:7 89:8 119:10</p> <p>doctor's 96:19 107:14</p> <p>document 124:13 157:13,14 159:7,9,12</p> <p>dominant 8:13</p> <p>done 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>Donna 3:10 70:4 119:8 120:12 142:15 143:10 166:3 172:13,14</p>	<p>174:21</p> <p>DOP 32:7</p> <p>dose 124:8 132:8,9 149:13</p> <p>dose-finding 122:21</p> <p>doses 44:20</p> <p>dosing 124:4,19</p> <p>double 98:5</p> <p>downsides 75:5 111:15 112:4 113:14 114:14</p> <p>dozens 172:5</p> <p>Dr 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

<p>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 drained 155:1 drank 44:1 drastic 48:3 49:8 drastically 166:19 draw 162:10 drawing 170:1 drawn 43:7</p>	<p>draws 161:11 dress 42:20 44:19 drink 34:10 73:14 112:21 113:7,11 drinking 112:19 drip 52:10 driven 115:4 120:21 162:12 driving 57:3 drop 44:10 83:19 dropped 58:18 149:13 drown 130:9 drowning 130:17 drug 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 drugable 122:4</p>	<p>drugs 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 dry 52:3,10 due 23:9 79:8,14 96:19 130:2 175:12 duration 24:8 during 121:5 131:8 160:8,12 dusky 73:6 dwell 56:7 dying 42:1 47:12 142:21 145:12 151:15 173:4 dynamic 121:15 <hr/>earlier 21:15 27:8 44:15 55:21 78:18 86:16 96:17 102:10 108:11 139:15 155:14 early 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 ears 113:21 114:1,2,9 easier 146:16 easily 100:6</p>	<p>easy 35:2 41:13 44:18 92:18 104:19 106:12 142:11 eat 42:11 43:22 eating 128:20 educate 124:18 educated 119:11 education 119:21 120:2,9 educational 123:13 124:14 effect 150:15 154:17 effective 8:4 30:2 112:2 175:12 effectiveness 9:10 100:17 178:3 effects 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</p>
--	--	---	---

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

<p>171:10,21 175:13,21 178:4 179:2,13 efficacy 23:19 152:6 171:15 effort 10:12,21 11:18 12:20 123:13 efforts 17:4 100:5 124:10,15 169:8 173:9 effusion 54:2 EGF 168:10 EGFR 25:9 45:13 98:9 Eggers 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 eight 50:18 either 8:11 25:11 40:14 77:18 159:6 EKG 43:2,10,11 elaborate 78:6,19 111:20 elderly 13:15 electromagnetic 166:18 eligible 123:10,11 eliminate 42:12 135:22 136:1 else 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 e-mailed 168:9 embed 159:6 emergency 96:19,21 emerging 169:19 EMGs 73:8 emotional 47:11 83:22 168:19 emphysema 100:3,12 employed 181:9,12 employee 181:12 empty 43:19 encourage 6:7 28:3 30:6 60:16 156:11 encouragement 92:20 encourages 26:6 Endpoints 3:3,4 31:16 endure 106:17 121:14 energized 97:14 energy 44:10 63:14 64:12,18,21 65:2 66:10 69:1</p>	<p>117:11 engage 26:22 engaged 101:16 enhance 9:12 99:4 enhancement 97:19 enhancements 172:3 enjoy 100:13 enroll 121:21 122:11 ensuing 97:3 ensure 30:3 100:15 enter 159:19 161:16 entered 159:17 entire 38:11 66:6 101:18 119:19 entirely 52:20 epidermal 91:20 93:10 epiphany 67:3 episode 102:20 equal 35:10 135:5 equally 96:9 equated 137:22 erlotinib 25:9 48:2 168:17 errors 163:6 escaping 46:18 esophagus 22:20 especially 35:15 72:12 73:12 89:14 101:15 111:5 146:17</p>
--	--	---	---

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

Page 15

<p>156:12,22 essence 26:4 essential 162:8,9,13,21 essentially 18:3,10 19:8,14 20:11 22:10 25:18 105:6 162:4 established 163:5 et 134:9,13 evaluate 9:10,14 evaluating 124:2 evaluation 1:2 5:6 7:4 32:12 33:20 78:4 176:2 evening 44:20 71:8 98:10 event 57:9,16 eventually 89:3 91:20 158:13 every-4-month 90:17,22 everybody 96:10 160:17 161:22 everybody's 163:9 everyday 74:9 every-four-month 93:16 everyone 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 everyone's 35:13 174:1 everything 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 evidence 23:16,17 24:21 evident 176:16 exact 64:1 exactly 37:20 example 13:14 15:13 22:20 24:7 33:13 37:4 101:8 167:3 examples 70:18 102:4 except 45:22 104:21 111:1 117:7 134:21 exception 108:7 exceptionally 103:15 excessive 48:16 130:3 exchange 43:17 excited 7:5 30:17 excitedly 168:8 exciting 84:14 excuse 76:5 Executive 41:2 exercise 67:18 68:2 83:20 125:20 128:21 exertion 57:15 exhaustion 106:17</p>	<p>exist 122:7 existing 8:1 9:1 exon 168:10 expand 28:5 84:9 150:7 expect 170:17 expectancy 49:3 expectations 162:12 expected 105:13 133:22 134:6,8 135:7 137:2,4 147:12,13 expecting 159:20 expedited 24:14,17,19 experience 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 experienced 40:6 46:21 69:16 81:2 114:4 141:6 experiences 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 experiencing 11:1 12:13 63:1,2</p>	<p>experiment 28:16,17 162:5 expert 31:4,20 experts 28:13 explain 47:22 75:12 132:11 137:14 146:9 150:6 157:7 explained 133:4 explanation 120:5 132:13 exploration 12:7 explore 11:19 147:19 exploring 16:16 75:6 exposed 45:17 124:7 130:4,16 160:14 178:11 exposure 160:11,12 ex-smoker 88:12,19 extend 82:16,19 178:15 extended 144:12 extending 144:1 extensive 19:10,17 145:15 160:12 extent 18:15 124:14 163:3 extra 151:4 extraordinarily 54:18 extreme 79:12 102:3 extremely 62:21</p>
--	---	---	---

(866) 448 - DEPO

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

<p>143:20 eye 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>face 105:14 154:12 171:8 faced 101:21 123:9 141:18 facial 46:22 facilitate 25:15 facilitated 4:15,18 28:11 32:16 61:2 62:15 86:8 109:7,9 164:18 facilitator 5:8 26:19 facing 151:12 fact 10:22 60:7 73:11 107:1 108:20 113:2 119:21 167:18 factor 91:21 93:10 100:16 133:14 146:22 factoring 76:20 133:21 factors 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 facts 94:13 failure 134:3 150:12 151:15,16 fair 157:8</p>	<p>fairest 30:2 fairly 72:4 92:8 139:20 178:5 fairness 97:15 faith 166:15 faithfully 16:22 57:21 fall 72:2 81:9 93:5 108:18 families 155:2 family 50:7,8 89:9 98:4,7 141:22 142:18 143:9 144:20 172:19 178:16 fancy 53:7 fast 24:19 87:20 95:12 fatal 151:12 father 172:21 173:8 father-in 102:5 father-in-law 99:18 102:3 146:17 father's 173:2 fatigue 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 fatigued 53:19 fault 95:18 favor 82:14 FDA 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 FDA's 4:6 9:22 24:18 155:3 fear 44:15 175:12 feature 170:14 February 45:16 federal 13:16 14:18 172:5 feedback 33:19,22 176:2 feel 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 feeling 20:5 57:21 63:17 68:2 130:9 feels 23:21 24:1 25:19 26:3 47:9 53:19 78:19 feet 72:1 felt 14:1 56:4 61:6 65:17 67:19 89:16,17 128:8 140:13 143:8 female 37:18 49:13,17 78:21 155:18 Ferris 3:11 120:17 123:7 151:10 155:8 fever 171:2 fewer 161:9 field 19:17 26:5 166:18 fight 91:7 92:8,10 fighters 56:11 fighting 59:4 figure 8:17 12:19 14:9 fill 176:5 filled 142:3 filtering 166:18</p>
--	--	---	--

Capital Reporting Company
 Patient-Focused Drug Development 06-28-2013
 Page 17

<p>filters 166:16,17</p> <p>final 176:8</p> <p>finally 43:19 44:4 56:14 58:4 60:12 73:20,21 104:16 116:11 171:16</p> <p>financial 89:10</p> <p>financially 181:13</p> <p>finding 90:8 137:10</p> <p>findings 137:12</p> <p>fine 57:18,20 66:5 79:13</p> <p>finger 174:14</p> <p>fingers 23:7</p> <p>finish 99:4</p> <p>finished 55:18 60:11</p> <p>finishing 85:16</p> <p>firm 106:8</p> <p>first 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</p> <p>first-line 98:18</p> <p>fiscal 14:12,13,21</p> <p>fish 166:22</p> <p>fit 12:9 15:2 31:8</p>	<p>108:8</p> <p>five 75:16,21,22 76:11 80:3 81:7,21 82:13,15 87:6 101:14 104:20 130:14 165:17</p> <p>Flexeril 173:16</p> <p>flexibility 162:2,22 163:1,2,22</p> <p>floats 70:22</p> <p>floors 43:10</p> <p>Florida 56:1</p> <p>flu 51:4,5</p> <p>focus 12:20 33:11 59:8 116:5 119:3 124:1</p> <p>focused 5:10,22 7:13 12:6 15:14,18</p> <p>focuses 36:13</p> <p>focusing 28:12 56:6 132:22</p> <p>folic 98:1</p> <p>folks 6:17 30:16 39:1 62:1 63:16 64:6 78:14 82:4,15 110:20</p> <p>follicular 168:2,3</p> <p>follow-up 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</p> <p>follow-ups 94:10</p> <p>food 1:1,10 6:16</p>	<p>44:21 167:3</p> <p>foods 167:4</p> <p>forego 141:21 175:12</p> <p>foregoing 181:4,5</p> <p>foreshadow 126:7</p> <p>forget 47:7,8 75:19</p> <p>forgot 62:3 70:11</p> <p>forgotten 51:4 119:7 131:3</p> <p>form 8:3 142:3 179:1</p> <p>format 4:12 5:20 15:1,10 26:12,18 27:6 34:12 169:12 170:3,9</p> <p>former 42:14</p> <p>forms 33:20 137:17 176:2</p> <p>forth 167:20</p> <p>forties 143:15</p> <p>fortunate 48:5 59:1 93:15 107:7 153:7 160:4 177:8</p> <p>Fortunately 77:4</p> <p>forward 7:10,22 9:20 10:5 163:7 173:10 179:17</p> <p>foundation 27:18 70:5 98:13 120:18</p> <p>foundational 10:15</p> <p>four-hour 131:8</p> <p>fracture 72:5</p> <p>framework 104:8</p>	<p>free 29:16 34:8 40:18 84:21 85:2,9 180:3</p> <p>frequent 75:20 105:22</p> <p>frequently 56:22 100:5</p> <p>fresh-brewed 42:9</p> <p>Friday 1:8</p> <p>friend 52:2,13 53:1,13,22 54:21 77:6 142:18 145:5</p> <p>front 29:2 64:22 85:14 101:1</p> <p>frustrated 68:11</p> <p>frustrating 130:1</p> <p>frustration 43:20</p> <p>Fuld 3:12 85:17,18 99:8 144:4 146:13</p> <p>fulfill 106:21</p> <p>full 5:3 37:2 43:18 62:3,7 65:7 135:16</p> <p>full-time 46:13 71:6 160:8</p> <p>fully 19:8 20:8 40:10 111:4 177:1</p> <p>function 51:19 127:15,19 149:13 154:5</p> <p>functional 118:8</p> <p>functions 23:22 24:2 25:20</p> <p>Furia-Helms 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 future 34:3 78:3 116:16 133:19 151:5 <hr/> <p style="text-align: center;">G</p> <hr/> Gail 53:13 gamma 20:11 gathered 141:21 gear 55:19 gene 2:18 32:13 45:13 121:13 general 10:10 17:20 20:4 33:17,18 59:18 94:14,15 133:5 generally 21:8 28:10 34:19 111:9 112:7 126:9,20 133:20 generosity 176:18 genetic 21:21 22:2,3,5 25:8 98:15 116:12,13 118:20 155:15 179:11 genomes 98:12 gentle 83:11 127:13,14 gentleman 37:4 101:8 gets 44:7 54:11,14 71:7 80:4 153:19 156:4 getting 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 GI 42:12 Gideon 2:3 32:2 girls 106:14 given 26:3 70:14 115:7 153:12 155:14 181:8 gives 36:16 44:5 92:21 174:11 giving 26:14,15 30:14 76:3 96:3 128:21 144:10 176:19 glad 10:3 92:22 150:14 gland 45:11 81:13 glass 44:15 goal 18:17,19 26:22 31:4 102:15 139:8 163:9,10 goals 86:17,21 102:14 162:12 god 68:3 golf 52:3 68:15 gone 58:20 116:10 140:19 154:7 176:17 Gosh 45:8 gotten 149:22 176:3 government 7:9	30:19 graces 58:9 Graham 169:6 grandchildren 58:3 69:8 139:8 143:16 grandson 58:16,20 grappling 15:5 grasping 42:2 grateful 35:15 54:18 58:12 91:1 105:18 gray 157:1 great 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 greatest 98:3 greatly 41:19 172:17 gripping 99:2 ground 30:1 33:12 34:12 group 50:15 141:12 groups 9:7 16:5,14 57:6 171:8 growing 42:8 growth 71:1 91:21 93:10 guaranteed 153:13 guess 152:1 155:9 160:15 166:12 177:5 guidance 25:14	guys 54:20 74:22 gym 68:13 <hr/> hair 23:7 46:21 58:20 Haiti 130:6 half 5:16 28:9 70:21 92:15 104:20 130:14 149:20 hall 58:18 Halloween 106:6 Hampshire 1:12 hand 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 handed 28:20 handle 124:2 hands 61:3,8,14,17,21 81:18,19 109:13,16 114:6 Haney 3:12 66:13 85:22 104:17,18 149:20 154:1 hang 121:11 happen 36:5 105:18 116:16 134:6 147:13 173:10 happened 91:7 118:10 131:12 145:5 165:1 happens 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>happily 177:11</p> <p>happy 7:10 58:22 89:17 116:3,4 129:8 150:14</p> <p>hard 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>harder 15:8</p> <p>hate 132:13</p> <p>haven't 83:7,8 113:15 156:14 165:12 176:3</p> <p>having 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>head 42:20 69:12 131:18 149:4 166:17 180:4</p> <p>Heads 69:11</p> <p>health 2:8 7:18 100:19 169:3 171:3,11</p> <p>healthy 47:7 91:9 106:13 151:14</p> <p>hear 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>heard 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>hearing 7:22 9:16 10:5 69:4 80:12 85:5 113:20 114:9,10 127:4 181:10</p> <p>heart 43:12</p> <p>heating 42:3</p> <p>Hello 17:9 32:5,10 85:8,17</p> <p>help 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>helped 83:21 90:9 132:19</p> <p>helpful 16:3,6,8,12 98:16 104:11</p>	<p>124:20 148:5 152:2 176:22</p> <p>helping 126:9 166:13,14</p> <p>helps 56:7 128:19</p> <p>hemorrhaging 58:3</p> <p>herbal 44:1</p> <p>hereby 181:4 182:2</p> <p>hereto 181:13</p> <p>herself 52:19</p> <p>he's 37:7 100:2 101:2 123:21</p> <p>Hi 32:2 39:16 50:12 66:3 70:4</p> <p>hide 164:22</p> <p>high 17:19 23:13 51:20 103:15 122:11 132:8</p> <p>high-energy 20:11</p> <p>higher 124:8</p> <p>highlight 26:4 112:6 113:17 114:15 126:7 127:6</p> <p>highlighted 171:17</p> <p>highly 177:21</p> <p>hiking 53:10</p> <p>hill 77:8 115:15</p> <p>hills 56:1</p> <p>hindsight 45:22 81:10</p> <p>hip 72:3,5</p> <p>histological 18:2 21:14,22</p>	<p>histology 21:14 167:20</p> <p>histories 83:12</p> <p>history 95:18</p> <p>hit 91:8,11,13 92:3,6 97:15 150:21 153:17</p> <p>hits 95:16</p> <p>hitting 94:3 120:3</p> <p>HIV 15:18 169:17 170:15</p> <p>hoarseness 54:12 63:13</p> <p>Hogan 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>hold 63:22 66:22 107:18 130:4</p> <p>holding 56:16</p> <p>hole 58:11</p> <p>holistic 166:16</p> <p>Holland 55:18</p> <p>home 43:20 44:7,17 66:8 71:7 89:18 136:9 145:16 146:21 166:17 179:20</p> <p>homes 161:12</p> <p>homogenous 122:19</p> <p>Honestly 41:17</p> <p>honeymoon 51:6</p> <p>honor 41:7</p> <p>hope 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 hopefully 39:5,6 116:6 hopes 42:12 hoping 8:21 11:18 48:20 horrible 55:22 65:21 118:14 119:2 hospice 71:6 140:5 143:6 145:9,17 hospital 77:7 131:6 145:12 160:5 161:15 172:22 hospitalization 134:4,13 hospitalizations 106:19 hospitalized 152:8 hospitals 164:12 hosting 99:9 hot 127:13 hour 5:16 42:19 hours 43:15,16 74:3 77:8 100:7 106:7 160:9 housekeeping 5:12 huge 128:7 humbled 41:5 Hundred 55:22 hungry 43:21 hurt 131:10 177:19 hurts 77:11</p>	<p>husband 90:11 92:19 140:3,8,15,17 hush 173:1 hydrated 89:12 <hr/>I IA 74:2 90:7 94:11 idea 50:21 108:12 118:21 157:5 identified 14:7 identify 22:3 identifying 13:19 ignorant 94:13 II 2:4,10,13,15,21 4:4,10 7:3 18:12,14 31:14 32:1,4,7 45:19 87:6 III 18:17,20,22 IIIA 91:19 93:4 IIIB 93:5 ill 29:12 30:13 36:22 37:6 44:12 I'll 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 illness 49:1 88:21 illusiv 106:8</p>	<p>I'm 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 image 43:8 47:5 immediate 17:3 22:14 171:9 immediately 89:5 92:1 immobilized 42:2 immune 166:14 immunotherapies 122:6 impact 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 impairment 22:21 impairs 70:9 implicit 47:19 importance 86:18 139:2 144:5 154:13 important 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>impossible 54:8</p> <p>impressed 113:4</p> <p>impressive 172:4,6</p> <p>improve 86:15</p> <p>improved 34:2 128:13 144:13</p> <p>improvement 23:21</p> <p>improves 127:14,19</p> <p>improving 18:20 86:19</p> <p>inability 46:14</p> <p>incidental 90:8</p> <p>incision 131:5</p> <p>include 20:2 27:19,22 110:11</p> <p>included 29:18</p> <p>includes 25:10 83:18 175:8</p> <p>including 7:7 22:12 74:15 83:15 91:13 164:13 177:4</p> <p>inconvenience 48:10 100:19</p> <p>incorporate 158:1</p> <p>increase 178:1</p> <p>increased 23:8,13 103:6</p> <p>increases 104:4</p> <p>incredibly 16:11</p> <p>independent 169:2</p>	<p>Indicating 131:8</p> <p>indication 34:18 136:22</p> <p>individual 171:13 179:10</p> <p>individual's 103:17</p> <p>induced 96:20</p> <p>inducted 58:16</p> <p>indulgence 44:16</p> <p>industry 30:18 95:19 122:13</p> <p>inevitable 107:19</p> <p>inevitably 48:13</p> <p>inexcusable 94:12 96:6</p> <p>infection 22:13 23:8</p> <p>infections 46:22</p> <p>inflammation 23:2 148:20</p> <p>inflammatory 150:12</p> <p>influence 122:13 152:9</p> <p>influenced 100:20</p> <p>inform 9:1 11:3 99:11</p> <p>information 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>informed 97:3</p> <p>inhaler 130:12</p>	<p>initial 10:15 12:20 13:2 90:6 167:18 168:3</p> <p>initially 8:6</p> <p>initiative 4:6 5:10,17 7:13,16 10:1,10 11:10</p> <p>initiatives 9:22</p> <p>injection 43:8 97:10</p> <p>injections 97:18</p> <p>injury 23:14 148:19 154:4 177:20</p> <p>inoperable 55:3</p> <p>in-person 28:21</p> <p>input 9:20 11:6,11 12:4 13:22 14:5 15:6 16:4 161:8,21</p> <p>insatiable 101:13</p> <p>INSERT 182:2</p> <p>inside 54:1</p> <p>insight 11:7 17:1 176:21</p> <p>insights 16:6</p> <p>insisted 87:9</p> <p>insomnia 46:2 81:8,17 168:9</p> <p>inspired 10:22 61:6 121:10</p> <p>inspiring 61:11</p> <p>instance 106:1 152:7</p> <p>instead 21:22 33:16 136:5</p> <p>Institute 97:12</p>	<p>instructor 127:12,21</p> <p>instruments 25:18 26:7</p> <p>insult 177:19</p> <p>insurance 94:21</p> <p>intend 16:21</p> <p>interactions 124:6 171:20</p> <p>interactive 16:17</p> <p>interest 7:10 80:13 179:5</p> <p>interested 80:12 133:13 181:14 182:6</p> <p>interesting 57:10 64:9 73:4 74:17 105:16 158:4 159:21</p> <p>Interestingly 105:17</p> <p>interior 55:15</p> <p>interviewed 68:10</p> <p>intricate 72:9</p> <p>intro 96:17</p> <p>introduce 31:2,10 39:11 84:17</p> <p>invasion 139:20</p> <p>invisible 47:6 106:8</p> <p>invite 28:18</p> <p>inviting 28:14</p> <p>involved 22:21 25:12</p> <p>involvement 16:9</p> <p>irradiation 22:22</p>
--	---	---	---

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

<p>irrelevant 107:16</p> <p>irrespective 83:11</p> <p>irreversible 155:10</p> <p>IRS 106:10</p> <p>isn't 75:17 93:6,12 152:10</p> <p>issue 67:16 81:17 123:19,21 124:7 152:4</p> <p>issued 25:14</p> <p>issues 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</p> <p>it's 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</p> <p>IV 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</p> <p>I've 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;">J</p> <hr/> <p>James 3:14 166:3 167:13,14 168:21</p> <p>January 59:7</p> <p>Jennifer 144:7</p> <p>job 26:17 70:9 71:6,20,21 95:9 155:3</p> <p>John 3:16 53:1 67:11,12 85:13</p>	<p>96:15,17 99:6 120:22</p> <p>journey 104:21</p> <p>judgment 47:19 138:3</p> <p>jump 150:22</p> <p>jumping 180:2</p> <p>June 1:8</p> <hr/> <p style="text-align: center;">K</p> <hr/> <p>Karen 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</p> <p>Karen's 129:6</p> <p>Kathleen 3:17 27:14 39:18 50:11,12 56:13 78:16 118:3 132:14 135:20 150:3,20 157:3</p> <p>Kazandjian 2:12 31:12 150:9</p> <p>Keegan 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</p> <p>key 9:5 155:10</p> <p>Khozin 2:14 4:10 17:9</p> <p>kicks 43:22</p> <p>kidney 134:3 145:5</p> <p>kids 68:19,21 69:3</p>	<p>kill 20:14 97:5 105:9</p> <p>killed 173:7</p> <p>killing 88:1</p> <p>Kim 3:14 41:10 158:15,20,22 159:12 166:3 168:22 169:1 172:8 177:5</p> <p>kiosk 6:16</p> <p>kitchen 91:13 132:18</p> <p>knew 67:15 91:7 127:12 142:21 168:11 173:2,4</p> <p>known 93:17 118:11 122:3</p> <p>Kweder 169:5</p> <hr/> <p style="text-align: center;">L</p> <hr/> <p>labeling 3:4 124:11,16 167:4</p> <p>lack 46:2,3 63:13 64:12,18,21 65:2 83:16 110:2</p> <p>ladies 62:8 68:9</p> <p>lady 41:9 68:19 139:7</p> <p>lady's 46:18</p> <p>landscape 71:20</p> <p>lap 66:22</p> <p>laptop 44:1</p> <p>large 9:16 12:9 55:1,4 138:8 163:14</p> <p>large-group 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 largely 120:21 larger 155:15 last 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 lastly 49:5 late 93:4,5 103:2 lately 68:4 later 14:17 42:17 45:1,18 49:11 74:3 90:19 91:3 140:4 145:15 174:16 late-stage 154:21 latte 43:11 laughs 131:18 law 102:6 lawyer 51:7,8 lay 45:2 144:2 Le 2:17 32:10 lead 134:3 177:22 Leader 2:3 32:3 leading 7:20 17:16 leads 28:13 learn 12:12 30:21 33:17 learned 44:20 128:21 learning 12:7,16 130:19 least 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 leave 29:4 34:9 43:19 136:2,13 156:18 176:6 leaves 42:1 led 104:22 Lee 3:13 65:10 79:3 80:2 113:19 leg 54:16 legislation 59:7 legs 52:14 length 38:4 lesion 167:21 less 38:5 117:3 178:21 let's 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 level 83:19 162:6 Liaison 2:20 32:6 57:6 life 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 life-impacting 170:12 lifestyle 48:3,11 49:8 177:15,18 lifting 65:17 71:4 ligands 25:12 light 42:22 74:1 likelihood 137:20 likely 24:2 100:22 103:5,7 146:21 155:15 163:22 limit 12:1 48:4 limitations 48:7 52:11,12,20 limited 11:10 19:9,11,14,15 47:14 91:15 102:16 110:3 line 79:13 145:11 lines 101:14 121:8 179:15 lingering 46:1 53:18 link 62:6 157:10 159:6,8</p>	<p>links 98:22 159:1 Lisa 54:21 55:20 list 13:1,2,17 14:19 25:1 64:10,11 146:5,11 listed 54:4 listen 31:1 158:6 listening 30:21 31:20 77:19 79:18 99:10,12 157:5 literally 58:3 81:10 130:17 140:20 literature 90:15 little 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 live 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 lived 71:20 105:5 142:20 150:10 liver 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>lives 13:5 15:14 51:1 100:6 117:9 121:10 146:18</p> <p>living 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>lobe 73:22</p> <p>local 35:10 87:7</p> <p>localized 18:10,12 20:8 22:19 38:16 139:21</p> <p>located 6:13</p> <p>long 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>longer 58:20 76:11 90:5 108:5 134:7 135:7 149:6 150:11 151:6 158:11,14</p> <p>Longevity 120:17</p> <p>long-term 38:13 103:2 171:10</p> <p>Lorren 3:16 27:14 39:14 40:20 41:2 45:6 74:21 116:8 128:3 132:10 149:4</p> <p>losing 46:21 74:7</p> <p>loss 20:3,4 23:7 63:12 113:20</p>	<p>134:9</p> <p>lost 55:7 100:3 106:6 114:9 118:11 141:17</p> <p>lot 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>lots 5:4 7:5 106:6 126:16</p> <p>love 92:15 106:15</p> <p>loved 27:4 30:12 36:2,18 37:9 63:1 71:21 104:1</p> <p>loves 68:17</p> <p>low 79:12</p> <p>lower 132:17</p> <p>luckily 72:5</p> <p>lucky 50:13 52:11 59:1 87:10,16 97:6</p> <p>lumps 53:4</p> <p>lunch 82:22 180:4</p>	<p>lung 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>lungs 19:3 38:17 43:5 51:3,7,11,19 55:3</p> <p>lymph 18:13 45:12 51:14,15 91:3</p> <hr/> <p style="text-align: center;">M</p> <hr/> <p>main 26:22 166:12</p> <p>maintenance 115:8</p> <p>major 24:15 72:14 97:18 111:14</p> <p>makeup 22:2 155:15 179:12</p> <p>male 37:17</p> <p>malignances 24:16</p> <p>malignant 25:12</p> <p>Malik 2:19 32:5 114:20 136:3,5 164:5 165:4</p> <p>man 101:4 145:11</p> <p>manage 86:15 125:17 142:5</p> <p>managed 126:13</p>
--	--	---	---

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

Page 25

<p>129:20 160:7 management 77:12 128:11 manager 94:21 managing 47:12,15 manifestation 77:22 manufacturers 163:3 marathon 92:12 marathons 92:14,15 Marie 3:17 129:5,12 138:9 marker 93:20 marketing 98:10 married 51:5,7 101:16 marrow 23:10 Maryland 181:18 mass 45:17 matchable 98:21 math 35:21,22 matter 47:21 63:5 Maureen 59:13,17 maximize 12:12 may 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 maybe 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 Mayo 51:9 119:14 mccleary 169:1 McCleary 3:14 166:3 168:22 169:2 177:5 MD 1:13 2:3,9,12,14,17,1 9 4:3,10 ME/CFS 169:13,16 170:20 meal 44:17 meals 44:13 68:2 mean 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 meaning 18:2 meaningful 44:17 means 75:2,13 103:10 108:14 meantime 73:19 measure 21:5 25:19 43:3 171:1 measurement 170:21 measurements 25:21 measures 9:2 25:17 26:1 measuring 8:8 170:21 mechanisms 11:11 median 148:14 mediastinal 91:4 92:5 mediastinum 91:4,6 medical 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 medication 53:9 77:2 97:19 107:15 119:3 medications 125:19 126:17 127:3 171:18,20 medicine 122:2</p>	<p>146:20 150:15 173:22 medicines 126:18 meet 11:4 131:12 meeting 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 meetings 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 member 50:8,14 85:11 members 27:19 121:1 142:18 memory 75:17 83:16 men 7:21 17:15 37:21 mental 41:15 75:9,13 mentally 88:1 92:7 mention 60:4 62:3 70:11 77:16 112:12 114:3 115:3,9 mentioned 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

<p>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</p> <p>mess 31:6</p> <p>met 94:10,14 120:4</p> <p>metabolize 124:3</p> <p>metastases 72:3 122:1 123:3</p> <p>metastasis 91:5,6 93:19 94:6</p> <p>metastasized 21:4 38:19</p> <p>metastasizes 8:15</p> <p>metastasizing 19:6</p> <p>metastatic 19:2 148:9 167:21</p> <p>methods 16:16</p> <p>metrics 24:6</p> <p>metro 35:11</p> <p>Metropolitan 35:4,6</p> <p>mets 122:1</p> <p>mic 49:19 79:3 135:12</p> <p>microphones 65:6</p> <p>microscope 18:4</p> <p>middle 54:1 130:8</p> <p>miles 55:20 106:6</p> <p>millimeters 74:1</p> <p>millisieverts 161:1</p>	<p>mind 47:5 89:14 135:9 136:11 149:3 150:13</p> <p>mind-body 128:16</p> <p>minds 138:15</p> <p>mine 77:7</p> <p>minimal 108:19</p> <p>minimum 34:7</p> <p>minor 178:5</p> <p>minus 18:15</p> <p>minute 29:1 31:2 32:15 37:6 165:8</p> <p>minutes 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</p> <p>miracle 131:15 159:20</p> <p>miraculously 48:3</p> <p>mirror 47:2</p> <p>misdiagnosed 46:2</p> <p>Miskala 3:3 31:15 80:8</p> <p>missed 106:2</p> <p>missing 51:18 129:7 154:20</p> <p>mission 130:6</p> <p>mixed 54:11</p> <p>mobile 171:3</p> <p>mobility 15:8</p> <p>modalities 103:8</p> <p>modality 18:14 20:7</p> <p>mode 12:16 30:21 31:20</p>	<p>molecular 21:20 59:10 98:16</p> <p>Mommy 66:19,20,22 67:3</p> <p>Monday 97:10</p> <p>money 89:14 100:9 115:16</p> <p>monitored 107:17 154:3,8 155:9</p> <p>monstrous 46:22</p> <p>Montessa 3:13 65:4,10 78:10 79:22 81:6 113:18</p> <p>month 45:18 100:1 136:10 140:4 142:1 156:7,9</p> <p>monthly 41:18</p> <p>months 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</p> <p>month's 42:3</p> <p>morning 5:3 6:22 39:14 42:8,10,14 46:16 58:19 84:22 87:4 96:16 170:16</p> <p>mornings 46:15</p> <p>morning's 5:14 40:4</p> <p>morph 59:20</p> <p>mother 70:6 71:18 106:20 120:19 129:6 174:7</p>	<p>mother-in-law 173:8</p> <p>mouth 94:22</p> <p>move 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</p> <p>moved 166:21</p> <p>moving 97:9</p> <p>MPH 2:7,14 4:10</p> <p>MRI 43:8 73:21</p> <p>MSPH 3:3</p> <p>mucous 130:3,17</p> <p>Mullin 3:6 4:7,21 7:16 9:21 10:2 31:18 169:5 176:8,10</p> <p>multilayer 169:10</p> <p>multiple 34:14 55:2 73:9 121:8 171:18</p> <p>muscles 59:18 71:3</p> <p>mutation 105:15 116:11 121:9,13 122:5 165:3 168:10,15</p> <p>mutations 25:10 97:7 122:4 164:21</p> <p>myself 42:15,21 46:5,17 48:1 50:14,19 74:8,16 118:4 166:11</p>
---	---	--	--

(866) 448 - DEPO

Capital Reporting Company
 Patient-Focused Drug Development 06-28-2013
 Page 27

<p style="text-align: center;"><u>N</u></p> <p>nagging 73:12</p> <p>nap 44:5 67:20</p> <p>naps 67:17,21</p> <p>Naptime 44:1</p> <p>narcolepsy 14:15 170:17</p> <p>Nasso 3:12 85:17,18 99:8 144:4 146:13</p> <p>Natalia 1:18 181:3,17</p> <p>National 65:11 70:5 85:19</p> <p>natural 82:21</p> <p>nausea 23:4 42:19 43:22 44:22 97:21 105:10 134:9</p> <p>nauseous 112:20</p> <p>Naval 58:16</p> <p>navigating 43:21</p> <p>NCCS 101:9,18</p> <p>NCI 59:8 115:3 164:13 167:15 168:7</p> <p>nearby 18:13</p> <p>nebulous 57:12 59:15</p> <p>necessarily 138:6</p> <p>necessary 123:1 124:8 160:21 163:10</p> <p>neck 127:1,2</p> <p>needle 43:6</p> <p>negatively 8:12</p>	<p>46:9</p> <p>neighbor's 65:16</p> <p>neither 181:9 182:5</p> <p>nerve 23:5</p> <p>nervous 38:18</p> <p>neuropathy 23:6 51:18 71:22 83:17 103:22 118:14,15</p> <p>never-smokers 96:8</p> <p>newer 21:9,19 25:6 108:7</p> <p>newest 24:20</p> <p>news 98:10 140:15</p> <p>nice 37:14 43:22 76:18</p> <p>night 44:8,18 67:18 130:8</p> <p>Nine 85:14</p> <p>nines 97:14</p> <p>nobody 135:21</p> <p>nodding 69:11,13</p> <p>node 91:3</p> <p>nodes 18:13 45:12 51:14,15</p> <p>nods 131:19</p> <p>nodule 73:22 74:4 91:3</p> <p>nodules 55:2</p> <p>nominated 8:6</p> <p>nondrug 127:5</p> <p>none 19:20 49:6 153:12</p> <p>nonessential</p>	<p>162:15</p> <p>nonproductive 52:3</p> <p>nonrepresentative 138:13</p> <p>non-small 17:22 18:4,8,9 20:10,16 21:16 87:6 148:9 168:5</p> <p>non-smokers 96:11</p> <p>nor 181:9,13 182:5,6</p> <p>normal 22:18 49:3 67:20 96:21</p> <p>normalcy 46:11</p> <p>normally 56:4</p> <p>Notary 181:2,18</p> <p>nothing 87:19 96:22 106:11 115:2,13 120:8</p> <p>Notice 13:17 14:18</p> <p>noticed 67:2 76:14 128:7</p> <p>November 53:22</p> <p>nudge 165:20</p> <p>numbness 23:6 72:1 87:15</p> <p>nurse 70:9 71:4,6 94:20 173:1 174:8</p> <p>nurses 94:15</p> <p>nutrition 83:20</p> <p style="text-align: right;"><u>O</u></p> <p>Oak 1:11</p> <p>observations</p>	<p>169:19</p> <p>obvious 103:18 109:19,20 112:9 117:3</p> <p>obviously 145:11,12</p> <p>occasional 166:22</p> <p>occasions 131:7,9</p> <p>occur 154:7</p> <p>occurred 73:17 74:15</p> <p>odd 72:5</p> <p>offer 103:5 169:18</p> <p>offered 144:11</p> <p>office 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>officer 2:3,12,15,17,20 17:10 31:13 32:6,11 181:3</p> <p>officially 45:1 180:2</p> <p>officials 7:9</p> <p>offset 97:22</p> <p>oftentimes 163:17</p> <p>oh 43:13 47:3 49:20 60:12 65:5 114:7 123:21 129:5 156:19 158:21 164:4</p> <p>okay 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>old 51:3 57:13 65:12 66:18 106:3 131:11 153:15</p> <p>older 55:21 138:4 139:6</p> <p>old-fashioned 93:21 94:1,5</p> <p>oncologist 130:10 145:7,8,9,13</p> <p>oncologists 97:4</p> <p>oncology 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>ones 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>ongoing 117:14 123:2</p> <p>online 120:4</p> <p>on-staff 56:21</p> <p>onto 122:14</p> <p>open 4:19 6:4,8 82:13 89:4 151:3 156:7,8 165:5,8,15 168:2 174:22</p> <p>opened 62:4 169:14</p> <p>opening 6:19</p> <p>openness 123:16</p> <p>opinion 88:8 98:6</p> <p>opinions 90:14 119:13</p> <p>opportunity 29:8,14 92:21 174:18</p> <p>opposed 95:5,6</p> <p>optimal 124:4</p> <p>optimally 124:17</p> <p>optimistic 141:12,18</p> <p>optimum 124:18</p> <p>option 94:8 105:2 146:20 151:14 159:18</p> <p>options 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>oral 45:18 54:4 97:8 136:7 146:20</p> <p>oranges 107:13</p> <p>order 52:1 84:18 121:14 124:3 125:5 162:5,10 166:2</p> <p>ordered 160:20</p> <p>organization 56:17 99:16</p> <p>organs 19:3</p> <p>orthopedist 72:6</p> <p>OSP 2:6 3:6 4:8,13,21</p> <p>others 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>otherwise 106:13 155:12 181:13</p> <p>outbreak 52:14</p> <p>outcome 9:2 72:10 119:15,18 181:14 182:6</p> <p>outcomes 25:15 45:3 174:6,9</p> <p>outside 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>overall 86:17 100:19 108:14,19</p> <p>overarching 68:1</p> <p>overkill 97:20</p> <p>overlap 23:11</p> <p>overview 4:6,12 9:22 18:7 26:11</p> <p>overwhelming 67:22</p> <p>overwhelmingly 136:21 137:21</p> <p>oxygen 52:19 125:20</p> <hr/> <p style="text-align: center;">P</p> <hr/> <p>p.m 180:6</p> <p>Pacific 53:10</p> <p>pack 42:22</p> <p>paclitaxel 25:5</p> <p>pad 42:3</p> <p>PAGE 4:2</p> <p>pages 181:5</p> <p>pain 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>painful 77:10</p>
--	--	--	---

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

Page 29

<p>106:18 pairs 98:21 Paivi 3:3 31:15 80:6 palliation 18:18 palliative 21:5 102:15 145:4 panel 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 panelists 32:15 39:10,12 82:2 86:4 109:2,5 panels 84:10 panel's 37:1 paper 159:4 paperwork 106:10 paradigm 121:20 paraneoplastic 74:5,14 90:9 parenting 108:4 park 87:14 parking 43:21 partial 25:1 participant 33:19 175:14,19 participants 3:9 28:18 29:6,9 36:6 40:2 83:14,21 84:15</p>	<p>175:7 participate 11:14,16 15:21 28:3 92:17 120:21 170:5 participated 49:10 169:13 participating 27:13 37:7 138:10 participation 25:16 29:13 particles 20:12 particular 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 particularly 13:13 30:12 60:1 123:16 126:16 133:13 169:5 172:6 179:9,13 parties 181:8,10,13 partner 39:16 Partnership 65:11 partnerships 171:1 party 131:12 182:5 pass 175:15 passed 59:7 120:19 139:15 past 26:21 86:12 126:3,4 Pat 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 patch 58:11 pathology 97:7 patient 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 patient-focused 1:6 4:6 5:17 7:1 9:22 10:11,21 11:18 169:3,7 180:7 patient-friendly 154:13 patient-reported 25:15 patients 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 patient's 26:4 30:11 142:17 Patricia 2:9 4:3 7:2 31:22 Pat's 78:11 153:21 Patty 57:4,8 pay 89:12 106:12</p>
--	--	--	---

(866) 448 - DEPO

Capital Reporting Company
 Patient-Focused Drug Development 06-28-2013
 Page 30

<p>paying 68:3 124:9 PDUFA 12:14 peace 98:8 99:22 peaceful 100:13 pediatric 13:14 peers 40:16 79:20 111:6 pelvis 160:18,20,21 people 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 people's 47:21 178:9</p>	<p>perceived 48:9 percent 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 perceptions 47:21 perform 42:22 perhaps 151:16 159:11 179:11 period 6:4 33:6 129:18 158:1 165:15 periodic 16:14 periodically 28:17 peripheral 71:22 103:22 permanent 51:17 155:12 permitting 86:6 persistent 52:3,10 person 28:18 29:12 42:14 47:3,6 64:7 90:20,21 141:13 170:5 personal 157:16 personalized 160:16 161:20 164:7 173:13,22 personnel 138:11 perspective 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 perspectives 6:3 7:15 17:1 27:10 33:18 34:19 99:11 110:22 111:7 116:22 156:13 peskier 43:9 ph 101:11 171:4 Phang 3:14,15 149:12 166:3 167:14 pharmacy 43:3,17 phase 45:19 85:16 168:18 PhD 2:5,17 3:3,6 4:7,12,21 phlegm 63:12 96:21 phone 34:8 135:2 161:12 phrase 47:13 physical 41:15 46:8 48:7 56:5 70:14 83:20 physically 55:7,11,16 87:22 physician 73:6 85:9 90:11,12 93:22 94:12 95:5 103:9,20 145:7 168:7 physicians 94:14 95:22 96:3 102:21 piano 103:19 104:2 pick 66:20 67:1,3 146:8</p>	<p>picked 135:21 146:6 picking 68:21 pie 21:17 piece 154:20 piggyback 142:8 151:10 piles 106:10 pill 42:17,18,20 44:22 136:9 -pills 42:16 places 51:21 123:18 164:13 plan 103:1 planning 14:22 169:13 plans 140:3 plant 166:21 plants 166:18 platin 112:22 play 15:9 147:1 played 177:18 plays 9:5 68:14 89:13 please 27:16 29:4,22 37:9 50:6 62:10 83:1 96:15 131:16 151:19 165:22 pleasure 57:2 58:15 101:11 plebe 58:17 plenty 33:1 120:14 pleural 54:2 plexus 73:22 74:4 plop 42:15</p>
---	---	--	---

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

Page 31

<p>plug 79:16 80:15 plus 18:14 148:11,14 podium 26:11 point 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 pointed 177:4 points 133:1 144:5 155:14 175:3 policy 56:20,21 85:18 169:3 poll 29:6 70:12 polling 29:21 34:16 36:13 39:5 110:7,8 125:5,14 133:7 Pollyanna 128:17 poor 170:20 poorly 44:16 population 15:7 38:11 94:14,15 111:4 122:20 164:9 populations 13:8,12 15:7 port 19:16</p>	<p>portion 165:6 pose 46:12 133:4 posed 28:7 position 77:6 88:19 positioned 11:2 positive 45:13 91:21 93:20 97:7 98:9 105:4 129:7,10 152:1 153:10 positively 8:12 possibilities 154:14 possibility 98:22 120:1 possible 5:5 45:3 46:12 103:2,11 118:20 124:5 139:3 154:3 161:19 possibly 134:7 135:7 147:9,13 178:18 postnasal 52:10 postop 127:16 post-treatment 59:21 potential 8:2 9:13 13:17 18:18 98:17 104:6 potentially 18:11 20:8,20 26:2 149:7 Powell 98:7 power 55:17 85:1 powerful 108:21 Powers 166:3</p>	<p>172:9 PPT 171:4 practice 28:22 34:15 105:2 123:7 practices 166:16 praying 48:21 precaution 87:12 143:18 precursor 120:6 prediagnosis 45:21 predict 150:17 predominantly 130:3 preferences 103:17 prep 106:9 preparation 34:1 prepare 42:20 44:12,20 86:4 prepared 92:7 182:3 prescribers 124:15 present 19:21 23:2 29:13 presented 83:15 152:10 preserve 103:11 press 35:3,5 pressing 79:10 pressure 23:13 79:12 140:11 142:18 pressured 143:8 pretty 38:22 55:5</p>	<p>92:9 142:9 160:2 prevalence 171:8 prevalent 37:15 64:11 prevent 48:4 161:15 previous 137:11 price 105:8 106:12 primarily 37:15 166:21 primary 19:4 20:7 167:22 170:13 principally 51:20 prior 11:9 56:4 73:4 143:1 173:3 priorities 141:10 142:13 Priority 24:22 PRO 26:7 probably 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 problem 42:13 58:2 130:19 problems 81:17 154:17 process 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>produced 130:3</p> <p>producing 16:20</p> <p>product 17:4 95:20 98:13,15 124:10,16</p> <p>products 2:4,10,13,15,21 4:4,10 7:3 9:8,11 17:10 31:14 32:1,4</p> <p>profession 103:21 104:1</p> <p>professor 73:12 85:10</p> <p>profile 22:5 23:11 98:16</p> <p>program 2:6 4:13 11:13 24:20 26:15 39:15 41:3 95:1</p> <p>programs 2:8 3:6 4:8 5:7 24:14,17,19 31:19</p> <p>progress 48:14</p> <p>progresses 100:14</p> <p>progression 72:12 103:8</p> <p>prolong 134:5,7,20 135:6,7 142:11 147:9,10</p> <p>prolongation 23:22</p> <p>prolonged 148:13 175:17</p> <p>prolonging 18:21 86:18 137:21 139:2 142:4</p>	<p>178:18</p> <p>prolongs 24:2</p> <p>prominence 170:11</p> <p>promising 24:21</p> <p>promote 71:1</p> <p>proper 26:1</p> <p>properly 128:20</p> <p>PROs 25:15,17,21 26:3</p> <p>prostate 17:15</p> <p>protectors 166:18</p> <p>protein 42:10 166:22</p> <p>protocols 115:4</p> <p>provide 9:21 17:1 30:11 33:1 34:18 83:11</p> <p>provided 16:6 124:19 176:21</p> <p>providing 16:7 169:15 170:4</p> <p>proximity 147:2</p> <p>psychological 47:11</p> <p>public 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</p> <p>published 13:16 14:19</p>	<p>Pujita 3:8 34:14 80:19 84:3 175:1,22</p> <p>pull 138:20</p> <p>pulmonary 52:6 127:14,18,19</p> <p>purpose 27:17 28:4</p> <p>purposes 34:21 134:18</p> <p>push 31:11</p> <p>puts 88:19</p> <p>putting 76:18 148:2 159:3 166:16</p> <p style="text-align: center;">_____ Q</p> <p>qualified 161:16</p> <p>qualify 122:1</p> <p>qualities 103:12</p> <p>quality 85:21 88:4,5 89:21 99:17 103:10 140:6,12 143:4,7,16 144:1,13 175:8,9</p> <p>quantity 143:7</p> <p>quarters 130:8</p> <p>question 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</p> <p>questioned 140:10</p> <p>questioning 170:2</p> <p>questions 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</p> <p>quick 34:17 43:2,5 46:19 164:19</p> <p>quickie 43:17</p> <p>quickly 14:11 54:8 108:18 125:1 164:20</p> <p>quit 96:2,4,7 116:1</p> <p>quite 57:5,18 64:8 168:6</p> <p>quote 158:11</p> <p>quote/unquote 160:16</p>
--	---	--	---

Capital Reporting Company
 Patient-Focused Drug Development 06-28-2013
 Page 33

<p>quotes 109:20</p> <hr/> <p style="text-align: center;">R</p> <hr/> <p>radiate 20:22</p> <p>radiation 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>radioiodine 168:5</p> <p>radiologist 97:1</p> <p>raise 28:15 32:20 33:5 34:5 53:11 61:2,14 81:18 117:3 158:18 172:14</p> <p>raised 33:13 40:4 64:16 81:3 114:22 134:21 141:6 144:5 146:5 165:12</p> <p>raises 81:20,21</p> <p>raising 81:16 114:4 141:7</p> <p>range 7:7 13:10,11 27:20 29:10 50:21 64:8 104:3 110:22 126:15 154:14</p> <p>ranging 11:19</p> <p>rank 133:15 135:17</p>	<p>rare 57:17 91:5 148:18 149:7</p> <p>rarely 19:7</p> <p>rash 23:12 46:22 148:18</p> <p>rashy 105:14</p> <p>rate 43:12</p> <p>rather 44:12 100:13 124:13 161:13 167:16</p> <p>ray 161:4</p> <p>Raymond 166:3 172:9</p> <p>Raynaud's 73:8</p> <p>reach 121:14</p> <p>reaction 22:19</p> <p>reactions 148:3 149:2</p> <p>readable 16:21</p> <p>reading 97:11</p> <p>ready 43:19 44:2,19 45:1,2 46:16 65:6 80:18 98:20</p> <p>real 35:21 52:19 68:20 112:6 179:2</p> <p>reality 106:22 141:18</p> <p>realize 96:1 115:21 117:14 167:1</p> <p>really 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>real-world 169:8</p> <p>reason 8:12 34:17 123:14</p> <p>reasons 8:6 19:21 138:8</p> <p>reassured 140:13</p> <p>reauthorization 14:10</p> <p>recap 177:1</p> <p>receive 90:13</p> <p>received 13:18,22</p>	<p>50:8 94:20 174:12 175:5</p> <p>recent 121:15</p> <p>recently 95:22 99:19 114:12</p> <p>receptor 91:21 168:11</p> <p>receptor-positive 93:10</p> <p>receptors 25:11</p> <p>recess 82:10</p> <p>recognize 10:22 29:11</p> <p>recommended 13:21</p> <p>record 29:18 65:8,9 167:7,9 181:8</p> <p>recorded 170:6 181:6</p> <p>recording 158:5,9,10,12</p> <p>recordings 170:6</p> <p>recuperates 22:16</p> <p>recurrence 74:12 91:4 139:16</p> <p>recurring 112:11</p> <p>recurs 91:22</p> <p>red 105:14</p> <p>reduce 20:14 21:6 86:12 100:11 110:10 133:16 135:18</p> <p>reduced 144:13 181:6</p> <p>reflect 27:20 37:2 44:16 92:21</p>
---	--	---	---

Capital Reporting Company
Patient-Focused Drug Development 06-28-2013
Page 34

reflective 38:11 138:6	relaxation 41:22 125:20 127:2	repeatedly 123:9	9:7 22:1
reflux 53:16	relevant 6:7 33:4 158:17	replace 20:18	resect 19:8
refuse 56:8	reliable 26:7 108:5	report 16:21 158:2 170:9	resected 20:9,21 115:5
regard 39:3 107:1 133:3 162:18	relieve 54:16 103:8 133:22 137:2	Reported 1:18	resection 74:3 90:10 92:5
regarding 33:12 82:19	relieved 74:3	Reporting 1:19	residual 20:22 21:1 53:21
regimen 103:21 154:15	relieving 178:20	reports 167:20	resistance 48:13,19 49:2 168:16 171:21
register 13:17 14:18 82:14	rely 8:14 31:6	represent 25:17 41:7 84:16 118:5 121:2	resolve 22:15
registered 70:9 82:15	remain 129:14	representative 11:13,14 37:21 111:4	resolved 144:16
registrants 6:9,10	remainder 117:9 138:19	representatives 27:1,3,12 28:1 29:22 30:4,7 36:2 39:13	resonates 40:19
registration 33:8,21 82:8 122:13 176:4,6	remaining 36:12 52:8 53:20 126:12	representing 30:13 36:17,18 39:2	resources 155:1,2
regular 76:16	remains 129:19	require 90:16 106:9 152:8	respect 34:4 103:16 169:22
regularly 91:10	remarks 4:20 5:5,13 6:20 40:3 86:5 176:8,9	required 44:5	respiratory 20:1,2
regulars 77:9	remember 29:4 46:14 53:7 66:14,19 67:1 115:18	requires 23:15 134:13	respond 28:18,22 29:6 118:19 174:2
regulatory 123:6,13 171:22	reminder 9:4 47:3 82:7 83:11 176:1	rescue 48:22	responded 118:10 178:22 179:6
reiterate 49:22 175:3	remission 38:20 88:9	research 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	responding 117:10
relate 22:10 45:9 68:20	removal 120:11	researchers 7:8	responds 24:8
related 22:17 66:15,16 78:16 80:10 81:6 148:16 179:4 181:9	remove 58:10 110:13 119:9		response 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
relates 80:9	removed 52:17 53:4,5 119:14 173:3		responses 36:5 136:19 168:1,19
relationship 167:3	removing 119:16 161:14		responsibility 106:21
relative 181:11	renewed 166:15		
relatively 16:20 104:19 178:5			

Capital Reporting Company
 Patient-Focused Drug Development 06-28-2013
 Page 35

responsive 168:16	68:15 160:6	56:15	139:4 149:6
rest 38:19 41:22	right-handed 73:5	76:11,16,18	164:20 165:5
55:5 127:9	rigidity 163:4	131:2 154:11	Sara 2:5 4:12 5:5
128:20 134:12	Rigney 59:14	ROSTER 2:1 3:1	6:21 26:11,18
restriction 122:22	ringing 113:21	rosy 96:5	31:19 49:12
restrictions 161:15	114:1,2,8	round 61:10	56:15 83:9
restroom 34:9	risk 22:13 23:8,13	rounds 51:16	158:20 169:6
restrooms 6:13	48:16 73:16	116:10,15	176:10
result 102:22	104:8 121:18	route 101:22	satellite 122:12
resulted 103:22	122:12 134:2	routine 67:21	save 44:12 60:19
results 35:9 44:3	137:3 147:5	routines 46:17	77:14 100:22
83:19 92:2	178:1 179:13	row 81:9 161:2	125:8
126:14	risk-benefit	rule 107:6	saved 119:14
resumed 89:19	121:17	rules 30:1 34:12	saw 47:2 109:11
retention 83:17	risks 9:16 11:2	run 26:20 42:5	scan 41:21 42:6
retired 68:17	102:17 104:6	92:12	45:3 48:6 58:4
retrospective 51:9	107:15 135:1	running 44:9	90:17 91:2 93:18
returning 44:17	154:3 178:10,14	48:17 66:5	97:1 145:14
reversible 155:11	179:12	rural 100:6 146:18	164:10
review 11:7,20	rivaled 106:10	Ruth 3:15 149:17	scans 43:1,5,9 44:3
12:22 14:1	road 174:10	Ruth's 167:17	59:6 93:16
15:4,11	roadblocks 161:10	Ryan 3:16 67:12	scanxiety 75:1
24:11,12,13,16,2	Robert 2:17 32:10	85:13 96:16,17	scar 77:10
2 99:11 156:21	rode 55:21	<hr/>	scenario
reviewed 13:20	role 9:5,9 15:9	S	148:7,21,22
Reviewer 3:3	177:18	sadly 90:20	152:1 155:19
31:16	rollercoaster	safe 179:20	175:14
reviewers 17:2	168:1,19	safety 9:10 23:18	scenarios 147:19
revisit 14:9 77:15	rolling 106:8	167:4 171:15	148:1,3
revisiting 133:1	room 27:5 29:4	sags 59:19	school 85:11
reword 136:3	30:3 34:19,20	salad 43:22	science 81:11
rib 70:20 71:2	35:1,3 36:16	sample 51:12	122:7
97:17	37:21 38:14 39:1	138:13 151:6	scientific 2:20 32:6
rich 82:18	46:19 61:4,6,14	Sandt 3:16 39:14	34:21
rid 70:15 131:13	64:9 69:21 75:18	40:21 41:1,2	scientist 108:13
ride 55:22 65:16	79:18 83:15	74:22 116:9	scope 116:19
	95:14 96:19,21	128:4,12 132:12	screening 59:5
	138:6,19		96:6,9
	Ross 3:15 39:21		

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

Page 36

<p>screenings 46:3 Sean 2:14 4:10 17:6,9 26:13,15 49:20 86:13 search 104:22 searching 90:12 seated 67:11 seats 82:12 second 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 second-line 98:18 seconds 64:2 seed 138:15 seeing 136:10 156:5 164:15 seem 55:7 130:18 seems 75:20 170:22 171:5 seen 117:3 122:3 selected 169:9 self 96:19 selfish 129:1 Senior 85:18 sense 20:4 35:1 36:16 125:15 138:13 sensitive 99:1 108:12,18 sensitively 171:5 sent 50:16 separate 80:17 September 13:16</p>	<p>14:13,15 170:18 serial 171:20 serially 171:19 series 8:7 169:7,14 172:2 serious 24:15 107:16 127:13 134:2 135:1 137:3,20 147:5 148:19 149:7 152:20,22 171:9 seriousness 76:14 served 13:9 169:14 serves 6:16 services 59:13,14 session 77:18,19 78:5 setting 5:16 11:17 settled 42:19 seven 73:4 several 101:9 118:5 120:4 160:9 165:1 severe 53:16 66:19 severely 40:13 severity 10:17 11:3 13:11 29:10 50:1,2 shaking 149:4 Shakun 2:19 32:5 114:19 164:4 shape 91:11 169:12 share 40:17 62:2,12 65:1 67:9 83:14 99:17 141:8 156:14</p>	<p>176:3 shared 28:4 61:3,6,16,19 62:8 68:7 69:10 99:14 102:21 109:12 131:19 sharing 83:4 170:1 176:19 sharp 75:17 76:20 sharps 43:18 sheet 40:5 Sheila 3:15 27:14 39:21 56:14 60:18 71:16 76:9,13 131:1 154:10 shell 58:13 Shelley 3:12 85:17 99:7 104:15 143:13 144:3 Shelly 52:13 she's 55:8 65:6 68:15,17 70:9,13 71:8 116:12 shifted 141:5 shifting 141:10 shocked 58:14 short 16:20 44:5 102:13 106:5 160:5 shorthand 27:2 shortly 116:7 shortness 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 shot 42:21 51:4 99:4 128:10 131:11,14,16 shots 43:19 shoulder 57:14 63:10 131:10,14 showed 58:4 96:22 144:8 145:15 148:12 shower 166:17 shows 154:12 shrinking 42:7 118:9 137:22 shrinks 112:11 shrunk 55:4 sick 46:12 47:3,5,8 113:7 145:12 sign 6:8 33:8 47:19 82:8 significant 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 signs 53:19 silver 1:13 121:15 similar 64:17 80:8 83:14 107:5 111:10 121:2 130:21 137:7 141:9 similarly 112:4 simple 163:14 simply 85:14</p>
---	--	---	--

(866) 448 - DEPO

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

Page 37

<p>sincerely 165:9 single 19:16 48:21 89:11 100:16 106:20 sink 91:13 132:18 166:16 sister 92:19 sit 27:15 41:7 54:15 66:21 site 20:13 sites 8:17 situation 97:16 138:2 151:22 167:17 situations 9:18 24:4 six 51:16 92:15 94:7 107:4 133:12 six-month 93:17,18 Sixteen 45:9 sixties 37:16 size 18:16 20:14 21:6 52:4 Skambis 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 skin 22:19 46:22 59:18,19 skip 91:5,6 slash-and-burn 77:9</p>	<p>sleep 45:4 55:14 66:9 79:7,8,11 81:17 173:18 sleeping 57:15 67:18 130:8 slept 66:8 slide 147:21,22 slides 10:7 14:17 158:8,9 slow 42:15 43:12 small 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 smaller 151:6 smell 42:9 Smith 3:17 129:6 smoke 88:14,16 120:7 130:4 smoked 88:17 95:3 115:22 smoker 45:11 47:22 88:19 119:22 smokers 95:6 96:11 130:5 smoker's 47:20 smoking 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 smoothie 42:11,15 snapshot 24:18</p>	<p>sneaking 67:21 snooze 44:5 snuggles 44:2 so-called 21:9 Society 143:5 soda 113:10 somebody 95:16 172:5 174:16 someone 30:13 36:17,18 37:9 41:4 60:12 65:5 83:10 88:18 127:21 141:8 175:11 someone's 144:1 somewhat 121:6 167:17 177:13 sore 22:19 sorry 114:7 115:19 137:3 150:9 158:21 sort 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 sorts 134:10 sound 103:17 sounds 77:20 177:7,18 178:3,6,7 179:6 source 104:22 speak 28:15 34:5 speaker 17:6 49:13,17 78:21 155:18</p>	<p>speaking 39:12 41:4 63:13 112:7 special 29:8 35:12 167:20 specific 21:21 25:7 28:19 33:13 40:8 69:15 70:18 111:20 114:18 125:11 138:1 164:8 specifically 8:10 54:4 66:14 67:1 86:18 132:7 spectrum 37:2 spelled 154:20 spend 5:15 33:15 44:10 100:9 spent 66:6 170:19 spinning 91:10 split 35:10 39:1 spoke 59:13 spoken 130:10 sponsors 171:14 spread 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 Spring 1:13 spurred 158:4 squamous 18:5 stable 38:13 105:6 staff 2:2 3:2 31:1 57:2 151:20 stage 18:10,12,14,17,1</p>
--	--	--	---

(866) 448 - DEPO

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

<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>stages 18:9 19:9</p> <p>staging 18:7 51:13</p> <p>stains 167:20</p> <p>stair 87:17</p> <p>stairs 52:21 87:18</p> <p>stakeholder 16:9</p> <p>stakeholders 17:3</p> <p>stall 46:19</p> <p>standard 24:12 148:10,11,15,17 152:21</p> <p>standardization 162:6</p> <p>standardized 162:10</p> <p>start 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>started 5:3 45:18 46:8 57:5 58:3 73:6 88:22 92:10 115:17 127:15 159:18</p> <p>starting 40:20 58:6</p>	<p>state 15:3 65:7 84:19 119:5 128:17 142:20 165:21,22 181:18</p> <p>statement 6:6 33:7 55:11 157:20</p> <p>statements 33:1</p> <p>States 17:14,17</p> <p>statistic 50:5</p> <p>statistician 108:13</p> <p>statistics 49:21 151:7</p> <p>status 100:19</p> <p>stay 30:20 55:16 59:20 67:11,14,16 106:12 156:8 165:16</p> <p>stayed 87:11</p> <p>staying 42:7</p> <p>Stephanie 3:12 66:12 85:22 104:16,17 109:1 121:1 149:19 150:4 153:22</p> <p>steps 10:15 73:1 106:9</p> <p>steroid 130:12 131:10,14,16</p> <p>steroids 125:19 126:17 132:7,8,13</p> <p>stethoscope 57:17</p> <p>stick 32:22 33:10 64:11 106:9 165:19</p> <p>stigma 47:20 88:11,12 89:3</p>	<p>94:17 115:12 177:14</p> <p>stimulator 71:1</p> <p>stimulators 70:15</p> <p>stomach 42:19 44:21</p> <p>stop 43:2,16 73:13 87:1 117:10 133:6 143:4,8,9 155:11</p> <p>stopped 87:19 88:12</p> <p>stories 61:6,11,13 99:14 103:19 121:3</p> <p>story 66:14 68:21 99:17</p> <p>straight 6:14</p> <p>straightforward 102:8</p> <p>Strategic 2:6 3:6 4:8,13 5:7 31:19</p> <p>straying 28:12</p> <p>street 150:22</p> <p>strength 61:7</p> <p>strengthen 9:17</p> <p>strengthening 97:18</p> <p>strikes 66:13 170:18</p> <p>striking 170:11</p> <p>string 105:19 107:22 108:2</p> <p>stringing 107:8</p> <p>strings 106:9</p> <p>striving 162:14</p> <p>strong 55:7,11</p>	<p>56:3 59:3</p> <p>struggle 9:14 68:20 118:12</p> <p>studied 123:15 148:10</p> <p>studies 73:21 122:21 151:8 163:16</p> <p>studying 171:15</p> <p>style 94:2</p> <p>subdivided 18:5 21:16</p> <p>subject 109:4</p> <p>submit 9:8 29:17 62:7,8,10 111:6 157:12 159:1</p> <p>submitted 9:9 157:14 159:2</p> <p>subpopulation 13:14</p> <p>subpopulations 13:9,13</p> <p>substantial 23:16</p> <p>subtypes 22:1</p> <p>success 16:10</p> <p>sudden 121:9</p> <p>suffer 119:2</p> <p>suffering 48:15</p> <p>sugar 171:2</p> <p>suggest 98:19,20</p> <p>suggested 103:14</p> <p>summarize 29:19 40:5 83:6 129:17 175:6</p> <p>summarized 29:16 41:18</p>
--	---	---	--

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

Page 39

<p>summary 158:2 sums 56:9 super 141:12 supplemental 125:19 supplements 125:21 126:18 127:3 support 20:17 50:15 56:20,21 59:13 89:9 138:11 145:13 175:9 supportive 86:14 100:15 144:6,9 145:2,18 suppose 111:16 supposed 37:5 51:15 supposedly 90:7 suppressive 23:9 sure 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 surgeon 58:9 surgeries 106:19 131:3 surgery 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 surgical 22:11 90:10,16 surgically 57:18 surprised 10:7 59:15 surprising 111:22 113:16 157:1 surrogate 24:5,9 survey 34:20 169:15 178:17 survival 23:22 24:2,9 51:11 108:15,19 148:13,14 153:3 survive 50:5 surviving 47:17 survivor 39:22 50:13 86:1 173:8 survivors 38:13 115:14 121:11 138:11 Survivorship 85:19 Susan 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 swallowing 22:20 swear 76:6 sweetie 44:6,11</p>	<p>swelling 54:16 swim 54:14 switch 113:21 symptom 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 symptomatic 8:18 13:4 132:4 symptom-free 105:1 symptoms 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 syndrome 15:14 74:5 90:9 170:15,20 syndromes 74:14 synergistically</p>	<p>19:14 21:3 synthesize 50:20 system 163:5 166:14 systematic 11:5 12:3 systemic 19:3 21:8 <hr/> <p style="text-align: center;">T</p> <hr/> table 4:1 27:15 29:5 33:8,21 82:9 176:4,6 tablecloths 30:20 tags 27:16 tailor 15:1,10 taking 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 talk 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 talked 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>talking 7:16 38:12 39:9 73:13 75:4 84:10 87:1 103:20 134:5 177:3</p> <p>talks 55:11</p> <p>Tarceva 48:2,12,20,21 53:8 55:4,6 105:13 142:9 149:13 159:18</p> <p>target 21:20 164:8</p> <p>targeted 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>targeting 60:1</p> <p>targets 122:4</p> <p>task 41:13</p> <p>Taxotere 92:4</p> <p>tea 44:1 113:10</p> <p>teach 74:8</p> <p>teacher 103:19</p> <p>teaching 73:13,14 104:2</p> <p>team 2:3 31:13 32:3 92:15 98:2 169:6 175:10</p> <p>teams 98:14</p> <p>tease 63:3</p> <p>teaspoon 96:20</p>	<p>technical 25:20</p> <p>technician 57:22</p> <p>techniques 125:20 126:17</p> <p>technologies 12:11 171:3</p> <p>technology 16:17 137:13</p> <p>teenage 95:8</p> <p>teenagers 95:19 143:16</p> <p>Temel 144:7</p> <p>tend 47:7</p> <p>tendency 19:6</p> <p>tends 19:5</p> <p>Tennessee 98:14</p> <p>tension 163:21</p> <p>tensions 163:8</p> <p>tent 27:16 82:5</p> <p>term 102:14</p> <p>terminal 41:17</p> <p>terms 67:22 85:20 168:1 178:8,17</p> <p>terrain 54:15</p> <p>terrible 113:20 178:6</p> <p>terribly 101:4</p> <p>test 12:11 57:20 116:12</p> <p>tested 45:12 121:9</p> <p>testimony 159:1 181:5,8</p> <p>testing 59:10 96:6 116:13 164:21</p> <p>testosterone 83:19</p>	<p>tests 154:4</p> <p>Texas 100:7</p> <p>thank 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>Thankfully 43:6</p> <p>thanking 176:11</p> <p>Thanks 10:2 159:12 179:22</p> <p>that's 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>theme 171:7</p> <p>themes 109:18 169:19</p> <p>themselves 31:2 39:11 115:20 141:8</p> <p>therapeutic 17:12</p> <p>therapies 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>therapy 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>thereafter 181:6</p> <p>therefore 8:17 24:10</p> <p>there's 53:6</p> <p>Theresa 3:6 4:7,21 7:16 9:21 26:14 31:18 176:8,9</p> <p>they'll 178:14</p> <p>they're 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>they've 70:14 95:16 155:1</p> <p>thinner 42:21 43:18</p> <p>third 7:12 10:11 14:14 51:18 91:22 107:18 139:18 169:17</p> <p>thirties 95:15</p> <p>Thomas 1:18 181:3,17</p>	<p>Thoracic 2:20 32:7</p> <p>thoracotomy 92:5 173:19</p> <p>thorax 23:1</p> <p>thoughts 86:10 116:21 148:2,5 149:18 150:6 156:10 158:16</p> <p>threw 132:18</p> <p>thrilling 58:17</p> <p>throat 22:19</p> <p>throughout 55:3,10</p> <p>throw 134:17 145:10</p> <p>thunderstorms 35:14</p> <p>thyroid 167:18 168:3</p> <p>thyroidectomy 167:19 168:4</p> <p>tied 10:13</p> <p>tightly 42:2</p> <p>timers 165:16,21</p> <p>tingling 23:6</p> <p>tired 58:14 59:19 66:21</p> <p>tires 100:6</p> <p>tissue 2:18 22:18 32:12 167:19</p> <p>titrate 132:9</p> <p>tobacco 85:2 95:1,19</p> <p>today 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>today's 5:8 7:12 9:12</p> <p>toe 42:21</p> <p>toes 23:7</p> <p>tolerance 103:15</p> <p>tolerate 178:9,14</p> <p>toll 71:9</p> <p>tomorrow 44:2 153:13</p> <p>tool 78:8</p> <p>tools 9:2 78:4 170:21 171:4</p> <p>top 64:1,15 127:1 177:19</p> <p>topic 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>topics 27:7 33:4,10,12 118:1 158:17</p> <p>total 41:22</p> <p>totally 41:5 80:4 87:15</p> <p>tough 109:4 144:18</p> <p>towards 162:14</p> <p>towel 145:10</p> <p>toxic 113:12 144:22</p> <p>toxicities 148:16,19 152:19</p> <p>toxicity 123:22 152:3,5,7</p> <p>Track 24:19</p> <p>tradeoff 121:13 139:1,2 149:8 151:8</p> <p>tradeoffs 102:9 107:3 121:17 133:9 150:19</p> <p>traditional 21:12 66:17 67:2 105:8 117:7</p> <p>traditionally 18:9</p> <p>Trail 53:11</p> <p>transcribed 65:8</p> <p>TRANSCRIBER 182:1</p> <p>transcript 158:13 170:8 182:3</p> <p>transcription 181:7</p>
--	--	--	--

(866) 448 - DEPO

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

<p>transformed 58:21 106:7 121:10</p> <p>transition 145:4</p> <p>translate 8:18</p> <p>translated 179:10</p> <p>transparency 174:4</p> <p>travel 15:8 30:14 36:22 37:6 100:7 160:7 161:13</p> <p>traveled 35:11,14</p> <p>traveling 6:17 106:1</p> <p>travels 179:20</p> <p>treat 19:11 24:15 94:8 96:9 97:5 126:2</p> <p>treated 54:7 57:18 59:21 60:9 83:12 148:17 160:5</p> <p>treating 8:2 15:15 19:4 25:4 60:10 84:7 93:20 97:16</p> <p>treatment 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>treatment-related 77:21</p> <p>treatments 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>tremendous 77:3</p> <p>tremendously 132:20</p> <p>trial 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>trials 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>triathlon 43:1</p> <p>Trick-or-treating 106:2</p> <p>tried 14:6 28:16 52:5 117:1 127:5 130:13</p> <p>trouble 113:3</p> <p>trouble-free 43:6</p> <p>true 52:20 58:13 138:7,8 162:1 181:7</p> <p>trust 127:21</p> <p>trusted 107:13</p> <p>truth 101:3</p>	<p>try 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>trying 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>tumor 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>tumors 21:22 22:1,6 47:6 118:9 119:9 163:19</p> <p>turn 5:12 6:19 9:20 17:5 26:11 87:1 111:13,16 176:7</p> <p>turned 100:1</p> <p>turning 31:8 59:10</p> <p>turns 53:15</p> <p>twenties 101:10</p> <p>twice 53:5</p> <p>two-year 104:22</p>
---	---	---	---

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

<p>type 22:10 53:7 93:21 119:20 120:7 174:12</p> <p>types 21:10 22:4 24:5 25:9 50:22 99:16 147:20 148:3</p> <p>typewriting 181:6</p> <p>typical 42:4 61:12,13 151:21 152:4</p> <p>typically 11:15</p> <p>typing 118:18</p> <hr/> <p style="text-align: center;">U</p> <hr/> <p>U.S 7:21</p> <p>ulcerative 52:14</p> <p>ultimately 141:19</p> <p>unable 44:10 139:19</p> <p>unacceptable 165:2</p> <p>unblinded 45:20</p> <p>uncomfortable 142:10</p> <p>undergo 99:21 121:3</p> <p>undergoing 86:11 100:10 121:11 127:18</p> <p>undergone 86:12 110:9,15 111:1 142:22</p> <p>underlying 78:1 80:11</p> <p>understand 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>understanding 7:14 9:13 33:12 111:17 120:2 133:13 179:8</p> <p>understood 143:7 145:8 171:22</p> <p>undertaken 123:14</p> <p>uneven 54:15</p> <p>unfortunately 139:15 150:17 159:20</p> <p>UNIDENTIFIED 49:13,17 78:21 155:18</p> <p>uniform 58:20</p> <p>unique 26:4 177:14,15</p> <p>uniquely 11:2</p> <p>United 17:14,17</p> <p>universities 174:6</p> <p>unless 147:17</p> <p>unmet 10:18</p> <p>unnecessary 88:18 160:12</p> <p>unrelated 45:14 53:15</p> <p>unwell 20:5</p> <p>upload 157:13 159:7,9,12</p> <p>upon 28:5 84:9 105:20 113:4 150:7 166:10</p> <p>upper 73:22</p>	<p>urgency 50:7</p> <p>urgent 14:2</p> <p>URL 159:2</p> <p>useful 26:2 29:3 179:15</p> <p>usefulness 105:21</p> <p>usual 51:17</p> <p>usually 18:13,20 23:6,9 75:21 151:22</p> <p>utter 106:17</p> <hr/> <p style="text-align: center;">V</p> <hr/> <p>Vaidya 3:8 83:9 175:4</p> <p>valid 162:11</p> <p>validate 47:22</p> <p>validated 24:5</p> <p>value 9:13</p> <p>Vanderbilt 98:7</p> <p>varies 90:20 118:15 178:3</p> <p>variety 14:5</p> <p>various 118:12,22</p> <p>vary 41:19 178:4,8</p> <p>varying 12:8</p> <p>vascular 73:20</p> <p>VATS 77:4,5</p> <p>vehicle 157:11</p> <p>veins 106:8</p> <p>venture 43:10</p> <p>venues 16:7</p> <p>verification 98:6</p> <p>version 43:1</p> <p>versus 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>viable 98:22 99:3</p> <p>video 159:1,2</p> <p>view 8:1 21:13,19,20</p> <p>viewed 169:16</p> <p>views 16:2 21:11 52:11,19</p> <p>violent 52:14</p> <p>visibility 96:18</p> <p>visit 44:6</p> <p>visits 134:13</p> <p>visual 23:13 46:20</p> <p>voice 29:20 36:22 37:8 54:12 63:12 99:1 138:21</p> <p>voluntary 33:21 34:22</p> <p>volunteer 39:19 143:6</p> <p>volunteered 143:5</p> <p>vomiting 23:4 97:22 105:10</p> <hr/> <p style="text-align: center;">W</p> <hr/> <p>wait 92:1</p> <p>waiting 43:16 48:20 97:14</p> <p>wake 42:9</p> <p>walk 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>walked 92:11,14 walking 54:15 55:17 77:8 wall 52:4 139:20 wandering 97:2 Warmerdam 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 Washington 56:19 wasn't 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 waste 59:18 wastes 59:18 wasting 59:18 watching 58:16 water 73:14 112:19,21 113:7,12 127:8 166:16 waved 49:13,16 ways 12:11 50:21 72:12 124:4 170:4 weaker 57:22 weakness 22:12 wearable 171:3 wearing 47:19 wears 105:20 web 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 webcast 29:7,17,20 62:3 158:9,10,12 169:16 170:6 webcasts 16:18 webpage 62:6 159:10 website 65:9 156:7 157:9,18 Wednesday 42:5,6 week 145:16 158:12 159:22 160:10 weekend 179:21 180:4 weeks 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 weeping 42:2 weigh 84:12 86:17 178:10 weighed 23:17 weighing 8:16 weight 20:4 55:8</p>	<p>63:12 100:4 weights 65:17 welcome 4:3 5:13 6:20,22 10:3 29:8 we'll 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 well-controlled 23:16 25:22 well-informed 175:9 well-known 72:6 we're 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 we've 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 whack 106:16 whatever 40:18 101:17 102:7,18 106:19 140:11 144:16 146:15 178:14 whatnot 76:21 whatsoever 73:17 wheezing 63:10 64:13 69:19 70:1,11 whenever 112:20 113:7 Whereupon 82:10 180:6 wherever 67:21 whether 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>white 1:11 30:19 58:20</p> <p>whole 10:6 64:7 66:19 111:4 121:17 139:8 169:6</p> <p>whom 50:18 181:3</p> <p>who's 34:19 35:1</p> <p>wide 11:19 13:11 29:10 50:21 110:22 126:15</p> <p>wife 99:22</p> <p>Wigger 101:10</p> <p>willing 15:21 72:7 101:14 106:11 121:3,14 142:10 146:15</p> <p>willingness 178:9,13</p> <p>wine 44:15</p> <p>wings 48:20</p> <p>wire 72:8</p> <p>wish 129:19 156:19</p> <p>woke 130:9</p> <p>woman 143:5</p> <p>women 7:21 17:15 40:12 120:4 141:11</p> <p>wonder 118:16</p> <p>wondered 160:6</p> <p>wonderful 36:10 57:1,8 59:5,22 60:14 77:6 89:8</p>	<p>141:22 142:1 179:21</p> <p>wonderfully 108:16</p> <p>wondering 75:12 168:14</p> <p>Woodcock 169:5</p> <p>work 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>worked 12:21 101:8,18 105:16 108:16 129:10 139:14 151:21 168:12 169:2</p> <p>working 13:3 32:8 67:21 68:1 104:8 107:8 115:17 127:7,9 141:15 162:9</p> <p>works 71:6 110:17</p> <p>workshop 169:14,17,18 170:9</p> <p>workshops 169:7,9,12 172:4</p> <p>workup 73:8,20</p> <p>workups 73:9</p> <p>workweek 160:8</p> <p>worried 48:17</p> <p>worries 40:14</p>	<p>worry 48:14,15,19 63:19 143:17</p> <p>worse 45:4 100:12</p> <p>worst 65:14</p> <p>worth 178:13</p> <p>wow 58:21</p> <p>wrapped 52:6</p> <p>write 74:8 80:5</p> <p>writing 62:21</p> <p>written 28:8 50:17 102:22</p> <p>wrong 77:1,13 134:17</p> <p>wrote 41:12 55:13 56:2</p> <hr/> <p style="text-align: center;">X</p> <hr/> <p>Xalkori 105:15</p> <p>x-ray 20:11 45:16 51:6 52:15 53:14 57:20 58:1 96:22</p> <p>x-rays 161:2</p> <hr/> <p style="text-align: center;">Y</p> <hr/> <p>yesterday 35:14 58:13,15</p> <p>yet 72:19 73:3 83:8 127:7 142:22 173:17</p> <p>yoga 127:12,13,14,15, 19,20</p> <p>York 87:9</p> <p>you'll 6:15 32:22 50:21 120:14 170:17</p> <p>young 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>youngest 66:18</p> <p>yourself 38:2 61:15 126:13 129:1,2</p> <p>yourselves 31:10 84:17 121:2 176:17</p> <p>YouTube 159:2</p> <p>you've 40:6 117:3 133:18 138:5 144:18 172:3 176:16 179:18</p> <hr/> <p style="text-align: center;">Z</p> <hr/> <p>zero 51:11</p>
--	---	---	---

Capital Reporting Company
Patient-Focused Drug Development 06-28-2013
Page 46