1 FOOD AND DRUG ADMINISTRATION (FDA)
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
NARCOLEPSY PUBLIC MEETING ON
PATIENT-FOCUSED DRUG DEVELOPMENT
Tuesday, September 24, 2013
Food and Drug Administration
White Oak Campus
10903 New Hampshire Avenue
Silver Spring, MD 20993
Reported by: Bryan Young
Capital Reporting Company

Capital Reporting Company

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013	
	2

1	CONTENTS	PAGE
2	Welcome	4
3	Soujanya Giambone, MBA	
4	Office of Strategic Programs (OSP),	
5	Center for Drug Evaluation and Research	
6	(CDER), FDA	
7	Opening Remarks	8
8	Ellis Unger, MD	
9	Director, Office of Drug Evaluation I,	
10	CDER, FDA	
11	Overview of FDA's Patient-Focused Drug	
12	Development Initiative	13
13	Theresa Mullin, PhD	
14	Director, OSP, CDER, FDA	
15	Background on Narcolepsy and	
16	Therapeutic Options	24
17	Ronald Farkas, MD, PhD	
18	Lead Medical Officer, Division of	
19	Neurology Products, CDER, FDA	
20	Overview of Discussion Format	31
21	Soujanya Giambone, FDA	
22	OSP, CDER, FDA	

Capital Reporting Company FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013

			3
1	C O N T E N T S (Contd.)	PAGE	
2	Panel #1 Comments on Topic 1	44	
3	Topic 1: Patients' perspectives on		
4	disease symptoms and daily impacts that		
5	matter the most. A panel of patients		
6	and patient representatives will provide		
7	comments to start the discussion.		
8	Large-Group Facilitated Discussion on Topic 1	77	
9	Patients and patient representatives in		
10	the audience are invited to add to the		
11	dialogue.		
12	Break	103	
13	Panel #2 Comments on Topic 2	104	
14	Topic 2: Patients' perspectives on		
15	current approaches to treating narcolepsy.		
16	Large-Group Facilitated Discussion: Topic 2	133	
17	Open Public Comment	171	
18	Closing Remarks	188	
19	Eric Bastings, MD		
20	Acting Director		
21	Division of Neurology Products		
22	CDER, FDA		

1 PROCEEDINGS 2 Welcome 3 MS. GIAMBONE: You know what I want to do, I want to just quickly do a round of applause for each 4 other because you've all come out to join us, and there 5 are so many people joining us on the web, so thank you 6 7 so much. 8 (Applause.) MS. GIAMBONE: Thank you for starting us off 9 on such a successful note. 10 11 So my name is Soujanya Giambone, and I will 12 be the facilitator for today's meeting. And I've 13 spoken to quite a few of you now, so it's great to put some faces to the people I've spoken to. 14 15 So I'm with the FDA Center for Drug Evaluation and Research, CDER, Office of Strategic 16 Programs. And we've been preparing for this meeting 17 18 for a long time, so I'm so glad the day is here because 19 we get to hear from you directly. 20 So what I'll do quickly is go over the 21 agenda, and you all should have a copy of it, so you can follow along there. And I'll go over a few 22

Capital Reporting Company FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013

5

1	housekeeping items. And then we'll get started.
2	So first we're going to hear from Dr. Ellis
3	Unger. He is the Director of the Office of Drug
4	Evaluation I at CDER, the Office of New Drugs.
5	Then we're going to have Dr. Theresa Mullin,
6	who is the Director of the Office of Strategic
7	Programs, and she is going to go over the FDA's
8	Patient-Focused Drug Development Program.
9	Following Theresa, we'll have Dr. Ron Farkas,
10	who is a medical officer within the Division of
11	Neurology Products, and he is going to give us a
12	background on narcolepsy and current treatment options.
13	And then I'll come back and go over the
14	discussion topics and discussion format.
15	So, as you know, we have two discussion
16	topics today. The first is on the most significant
17	symptoms of narcolepsy and their impact on daily
18	activities. And the second topic is on patients'
19	perspectives to current treatment options.
20	So we'll do Panel 1 for Topic 1. We'll do
21	the panelists and then we'll have a group discussion.
22	Then we'll take a break. We'll come back. We'll do

(866) 448 - DEPO www.CapitalReportingCompany.com © 2013

1	the same thing for Topic 2, so panel discussion
2	followed by group discussion. And then once that's
3	done, we'll have the Open Public Comment period, which
4	is basically if anybody wants to provide some comments,
5	but it's sort of outside the scope of Topic 1 or Topic
6	2, we welcome you to sign up for public comment, and
7	you can sign up for it out on the registration desk,
8	and you can sign up for it until break time, I believe,
9	and what we'll do is we'll go back and see how many
10	people have signed up and how much time each speaker
11	will have during public comment.
12	And then we'll have closing remarks by Dr.
12 13	And then we'll have closing remarks by Dr. Eric Bastings, who is the Acting Director for the
13	Eric Bastings, who is the Acting Director for the
13 14	Eric Bastings, who is the Acting Director for the Division of Neurology Products.
13 14 15	Eric Bastings, who is the Acting Director for the Division of Neurology Products. So just a few housekeeping items. Bathrooms
13 14 15 16	Eric Bastings, who is the Acting Director for the Division of Neurology Products. So just a few housekeeping items. Bathrooms are located out the door, back into the lobby area, and
13 14 15 16 17	Eric Bastings, who is the Acting Director for the Division of Neurology Products. So just a few housekeeping items. Bathrooms are located out the door, back into the lobby area, and if you make a right, go all the way down the hallway
13 14 15 16 17 18	Eric Bastings, who is the Acting Director for the Division of Neurology Products. So just a few housekeeping items. Bathrooms are located out the door, back into the lobby area, and if you make a right, go all the way down the hallway and you'll see the bathrooms over there. And as you're
13 14 15 16 17 18 19	Eric Bastings, who is the Acting Director for the Division of Neurology Products. So just a few housekeeping items. Bathrooms are located out the door, back into the lobby area, and if you make a right, go all the way down the hallway and you'll see the bathrooms over there. And as you're going there, you'll pass a kiosk that serves coffee,

1	just need a break, you can feel free to go down to
2	those rooms also, which are down as you're going
3	towards the bathrooms. Okay?
4	And if you have any questions, please feel
5	free to ask me or any of my FDA colleagues, and we'll
6	be happy to help you.
7	So what I'll do is I'm going to ask my FDA
8	panel, my colleagues here, to introduce themselves, and
9	if you can just say what office you're from.
10	DR. UNGER: Good afternoon. I'm Ellis Unger.
11	I'm from Office of Drug Evaluation I.
12	DR. MULLIN: Hi. I'm Theresa Mullin, and I
13	head up the Office of Strategic Programs in the Center
14	for Drugs.
15	DR. BASTINGS: Hi. I'm Eric Bastings, Acting
16	Director of the Division of Neurology Products.
17	DR. FARKAS: Ron Farkas. I'm a medical
18	officer in the Division of Neurology Products.
19	DR. YASUDA: Sally Yasuda. I'm a safety team
20	leader in Division of Neurology Products.
21	MR. BAUER: I'm Larry Bauer, from the Office
22	of New Drugs, Rare Diseases Program.

Capital Reporting Company FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013

1	DR. BONA: And Jim Bona, from the Office of
2	Orphan Products Development here at the FDA.
3	MR. THOMPSON: Graham Thompson, Office of
4	Strategic Programs.
5	MR. VALENTINE: James Valentine, FDA's Office
6	of Health and Constituent Affairs.
7	MS. VAIDYA: Pujita Vaidya, Office of
8	Strategic Programs.
9	MR. MILBURN: Chad Milburn, CDER.
10	MS. TAN: Hi, everyone. I'm Andrea Tan, with
11	CDER's Office of Strategic Programs.
12	MS. GIAMBONE: Thank you. Okay. So with
13	that, I am going to turn it over to Dr. Ellis Unger for
14	his remarks.
15	Ellis?
16	Opening Remarks
17	DR. UNGER: Okay. Good afternoon, everybody.
18	And we're delighted you're here. I'm delighted to be
19	here. As I mentioned, I'm Ellis Unger. I'm the
20	Director of the Office of Drug Evaluation I in the
21	Office of New Drugs. Our office oversees the Division
22	of Neurology, and the Division of Neurology regulates

1	drugs for narcolepsy. So you have the relevant people
2	here. And we're so happy to see patients here and
3	patient advocates here in the audience and reaching out
4	to the government. We're the FDA. And I know you all
5	have a commitment to the development of safe and
6	effective drugs for narcolepsy. That's why you're
7	here, that's why we're here, and there is no cure for
8	this, and we need to do our best for patients.
9	This is actually the fourth meeting in a
10	series of meetings. We have Patient-Focused Drug
11	Development meetings, but this is the first one on a
12	rare disease in our series of meetings, and the
13	Patient-Focused Drug Development initiative involves
14	obtaining, trying to obtain, a better understanding of
15	patients' perspectives on particular diseases and
16	treatment. And Theresa Mullin is going to talk about
17	the initiative a little more in a couple minutes.
18	Admittedly, White Oak is a little bit of an
19	"ivory tower," I'll be the first to admit that. We're
20	mostly working here and not seeing patients, most of
21	us, too much anymore, and we get isolated, and it's
22	really good to have patients here who can say, "This is

1	what's important to us," to kind of shake us up a bit
2	so that we understand what it is we're actually trying
3	to do. We play an important role obviously in
4	protecting and promoting the health of the public, so
5	we ensure that drugs are safe and effective and all
6	that, but this I hope will take us a little farther
7	than where we usually go.
8	And we play a critical role in drug
9	development. A key role is to ensure that clinical
10	trials that are done are safe, and then we ultimately
11	evaluate the safety and the effectiveness of drugs that
12	are submitted for marketing approval.
13	There is a misperception out there, I hear
14	all the time that we test drugs at the FDA. Well, we
15	don't test any drugs at the FDA, we're not directly
16	involved with drug development, but the companies come
17	in to us and they say, "Here is a study we want to do.
18	We want to do this study in order to show the safety
19	and efficacy, or the effectiveness, of a drug in a
20	particular disease." They come in. We opine on their
21	study plan. We say this is a pretty good study, but
22	what we want to do is make sure that at the end of the

1	day that the study is focused on the symptoms that
2	matter to the patients, that we get data that we can
3	actually interpret, that we don't get a big pile of
4	spaghetti that we can't understand. We want to get
5	clarity at the end of the day so we can say without any
6	hesitation that the drug is effective for a given
7	condition and that it's safe. And so that's our role
8	when the studies are being planned. So you're here to
9	help us understand what symptoms are important, so when
10	the studies are planned we can put appropriate emphasis
11	on that.
12	The other side of this is that after the
13	studies are completed, which is 2 or 3 years later,
14	whatever it is, the company comes in and they say,
15	"Okay, we think we showed the drug is safe and
16	effective and we want you to approve it for marketing,"
17	and that's where we have to analyze the data extremely
18	carefully, make sure it is as it's represented, that it
19	shows the drug is safe and effective, and that it
20	focuses on symptoms and concerns of patients, and
21	that's our role. It's kind of a dual role, but we

22 don't actually test drugs here.

1	For us to approve a drug, we have to show
2	that the benefits outweigh the risks, and that's a
3	large part of what we end up doing here. So this
4	benefit and risk decision is an integral part of our
5	review process, and we hope today we can gain a better
6	understanding of how you view benefits and risks in
7	this particular disease that's a devastating disease,
8	and that's why we're here.
9	Narcolepsy is rare, it's underrecognized,
10	it's underrepresented, it's a terrible devastating
11	disease, and it's an area where we really wanted to
12	understand better how you think about your condition,
13	what's important to you. We wanted to hear directly
14	from you in terms of how you experience the different
15	symptoms of narcolepsy, how those symptoms affect your
16	daily lives, and what you're looking for in terms of
17	future treatments.
18	My approach when I used to take care of
19	patients, which wasn't that long ago, when I saw
20	patients with complex diseases, I would basically say,
21	"Mrs. Smith, if we could fix one thing, I understand
22	you have all these symptoms, if we could fix one thing

1	for you, what would you like us to fix?" and then if we
2	could get there, we might even get to, "Okay, what
3	would be the second thing you would like us to fix?"
4	And that's a way to kind of focus on what's important,
5	and maybe you might kind of put that in the back of
6	your head during these discussions and think about,
7	what's really important to you? What is it, for
8	example, that you cannot do in your life that you wish
9	you could do and that a drug could potentially help you
10	with? So I would like you to think about that.
11	So once again I really thank you for coming.
12	Some of you probably traveled from far away, and
12 13	Some of you probably traveled from far away, and welcome.
13	welcome.
13 14	welcome. And with that, I will turn it over to Theresa
13 14 15	welcome. And with that, I will turn it over to Theresa Mullin, and she'll talk more about our efforts in
13 14 15 16	<pre>welcome. And with that, I will turn it over to Theresa Mullin, and she'll talk more about our efforts in Patient-Focused Drug Development. Thanks.</pre>
13 14 15 16 17	<pre>welcome. And with that, I will turn it over to Theresa Mullin, and she'll talk more about our efforts in Patient-Focused Drug Development. Thanks. Overview of FDA's Patient-Focused</pre>
13 14 15 16 17 18	<pre>welcome. And with that, I will turn it over to Theresa Mullin, and she'll talk more about our efforts in Patient-Focused Drug Development. Thanks. Overview of FDA's Patient-Focused Drug Development Initiative</pre>
13 14 15 16 17 18 19	<pre>welcome. And with that, I will turn it over to Theresa Mullin, and she'll talk more about our efforts in Patient-Focused Drug Development. Thanks. Overview of FDA's Patient-Focused Drug Development Initiative DR. MULLIN: I'm going to just ask a</pre>
13 14 15 16 17 18 19 20	<pre>welcome. And with that, I will turn it over to Theresa Mullin, and she'll talk more about our efforts in Patient-Focused Drug Development. Thanks. Overview of FDA's Patient-Focused Drug Development Initiative DR. MULLIN: I'm going to just ask a technical question. Am I going to advance my slides,</pre>

1	
1	So hi again. I'm Theresa Mullin, and I'm
2	going to take a minute to tell you about the overall
3	initiative that this meeting is a part of. We planned
4	a series of meetings, and we're very happy to have this
5	be this is actually the final meeting for our fiscal
6	year.
7	Can you do it? Okay. Pujita is going to
8	help me out here. Okay.
9	So this begins and as Dr. Unger was saying
10	and he talked about the benefit-risk assessment in
11	which we consider various information that we get from
12	a drug sponsor, you know, the person who develops the
13	drug and wants it to get approved for marketing, but we
14	realize that in that weighing of benefit and risk,
15	critical considerations for that decision relate to the
16	severity of the disease and the degree to which it
17	meets some unmet medical need. So what treatments are
18	available today? How well do they work? How severe is
19	this disease as the patients experience it? And we
20	came to realize that, you know, patients, it's not a
21	new realization, but we realized that we could take
22	steps like this meeting and do something about it to

1 get more information.

2	Patients are uniquely positioned, of course,
3	to help us understand better that clinical context, the
4	severity of the condition, and the degree of unmet need
5	and that we would benefit from having a more systematic
6	way to reach out to patients and hear from them
7	directly about how it is to live with the disease.
8	What do they think about the treatments that are
9	available? Even beyond what we got from the clinical
10	evidence in the submission package from the drug
11	developer and all that, what do patients make of what's
12	available to them? And what are they doing to treat
13	their disease when there is no approved therapy? And
14	the mechanisms that FDA had in place already didn't
15	really fill this need.
16	We can get the help of individual patient
17	representatives in the context of an advisory committee
18	meeting, those are typically about a particular drug
19	product to treat a particular disease. And so what we
20	didn't have was a broader opportunity to hear from
21	patients more as a community around a disease area, not

22 just in the context of a particular drug but really to

1	help us understand better the whole context of that
2	disease area so that we can use your input today not
3	just with one drug coming in that may be able to treat
4	narcolepsy but really informing us for any future drugs
5	that may come in and development programs where
6	companies are interested in developing a drug to treat
7	narcolepsy.
8	So, Pujita, next slide, please.
9	So we thought we needed a more systematic way
10	to do this, and this is a new effort, and every time we
11	do another one of these meetings we try to improve it
12	and do better about how to get input and help us
13	understand and hear, as Dr. Unger said, what are the
14	most important considerations for you?
15	We took advantage of having discussions with
16	industry where they were considering giving additional
17	we were trying to get more money to basically cover
18	you know, increase our capacity to do these
19	meetings, and we got a little bit more resource, or at
20	least we hope to get it someday the budget situation
21	is kind of challenging these days in Washington but
22	we said we would convene at least 20 of these meetings

1	over the 5 years of 2013 to 2017, and we view that 20
2	as a way to pilot a good approach for trying to collect
3	this information, and we're open to whatever is
4	effective, whatever works well for patients, and then
5	the information that comes back can be used by FDA to
6	help give us insight about what patients are
7	experiencing. So we agreed to do these 20 and develop
8	a more systematic approach.
9	Next slide, please.
10	In trying to figure out what the 20 would be,
11	since 20 is such a small it looks like a big number,
12	I guess, when you're trying to get these meetings set
13	up. They're a lot of work, and I really appreciate my
14	staff, who have put in long hours to make these
15	meetings work well, but where should we focus that
16	first 20? And so we worked with the review divisions
17	and others in the FDA and listening to input we got
18	from patient advocates to come up with this set of
19	criteria that helped us to try to figure out where to
20	start.
21	So we looked at diseases where chronic
22	symptomatic and that affect the functioning, the

(866) 448 - DEPO www.CapitalReportingCompany.com © 2013

1	daily life, of patients, where these things may not be
2	very well captured in the clinical trials that are
3	conducted and the information that's gathered in those
4	trials today; diseases where there may not be any
5	currently approved therapies or anything that's
6	particularly effective to treat the disease; diseases
7	that reflect a range of severity across the patients
8	who experience them, and it would be valuable to hear
9	from the community to understand better that range of
10	variation; diseases that have different subpopulations
11	that may experience the disease differently or perhaps
12	more severely and understanding that better; and
13	finally, as a set of 20, we wanted it to cover a range
14	of disease areas and give us a broad range of affected
15	populations and perspectives.
16	So a lot to ask, you might say, of 20
17	diseases, but we took those criteria, and FDA
18	internally developed an initial list of almost 40 to
19	post in the Federal Register and ask for public
20	comment, and our question was more or less, "What do
21	you think? Which of these sound like the right ones?
22	Which ones should we focus on in this 5-year period?"

1	And we received about 4,500 comments in the
2	docket that we opened up for this for public comment,
3	and they addressed 90 disease areas. We sort of went
4	through very carefully and reviewed every one of these
5	comments and took it back and discussed with review
6	divisions to get more input from them about wanting to
7	know which areas they had the greatest questions that
8	were coming up now, in fact, maybe there were questions
9	coming forward to them that they needed to have
10	addressed and they would benefit from hearing from
11	patients sooner, so we tried to take into consideration
12	both the volume of interest on the part of the
13	community that gave us comments to the docket and also
14	the information needs of our reviewers.
15	I will tell you we got a very strong response
16	from the narcolepsy community, and that's one of the
17	reasons why we're having this meeting today. We got a
18	very strong of expression of desire to have a meeting,
19	and so that's why we're doing this meeting, in fact, in
20	large part. It got up to the top of the list and we
21	realized there was a really strong need for this
22	meeting.

1	So we came up with a list of 16 for the first
2	3 years and if you go to the next slide, please,
3	Pujita these are the meetings that we've covered in
4	this fiscal year, which ends next Monday, and so we had
5	a meeting on chronic fatigue syndrome in April, on
6	HIV/AIDS treatments and the future there in June; a
7	lung cancer meeting in June; and then this narcolepsy
8	meeting is our final meeting for the first year.
9	And on the next slide we show what we have
10	lined up for the coming 2 years, and it's, as you can
11	see, a fairly wide range, including some diseases that
12	are regulated by our sister center, the Center for
13	Biologics, and so some of them are related to blood
14	disorders, and you can see we have a very wide range,
15	and generally speaking, we think this does a pretty
16	good job of trying to help meet those criteria that we
17	laid out. Every one of them has a very significant
18	impact on daily life, and that's one of the things we
19	felt would be real opportunities for us to try to get
20	the patients' perspective.
21	And on the next slide, this tells you a
22	little bit how we're trying to be consistent in some

-	
1	areas across all these meetings, but we're also trying
2	to tailor the questions to address the special
3	characteristics of the disease, perhaps challenges of
4	the disease, that our reviewers are aware of and they
5	want to hear more about. They may have questions that
6	are coming up for them in the review, general
7	questions, that they also want to explore in these
8	meetings, so that's how we're tailoring them.
9	For example, in our meeting with the chronic
10	fatigue syndrome community, we focused on the impact of
11	the disease on patients' daily life, and what are they
12	doing today to treat their disease? This a condition
13	for which there are, according to patients, very few
14	effective treatments, although they are trying a range
15	of ways to deal with their disease.
16	In the HIV/AIDS meeting, we not only asked
17	patients about their experience with living with the
18	disease and current treatments, but we wanted to know
19	what their perspective would be on participating in
20	what's called cure research because that would require
21	that they stop taking treatments that they are using
22	today.

1	And in the case of lung cancer, we wanted to
2	probe not only what it's like to live with the
3	condition but what it's like to go through treatment
4	for lung cancer, and to hear and understand from
5	patients what they consider to be a meaningful benefit.
6	What is a meaningful survival benefit? Sometimes a
7	drug company will come in with an application that may
8	show that the patient survives for another week or two
9	or a little bit longer, and the question we had for
10	patients is, is that worth it to you? Do you consider
11	that to be a meaningful benefit? And you can't get an
12	answer to a question like that from anybody but the
13	people who are experiencing the disease and
14	experiencing what it's like to have been treated. So
15	it was extremely valuable for us.
16	And so we've been also looking at different
17	ways to get input. Again, we're having these meetings
18	I haven't really thought of it as an "ivory tower"
19	before, but I guess that's one way to describe our
20	location here out in the suburbs, but we are a place

22 trying to do is look at ways to maximize remote input

21 you have to travel to. So one of the things we've been

1	that we get from people who can't make it here. We
2	really appreciate so much that you made it to this
3	meeting today. We know it's not easy to travel here,
4	in some cases for some patients easy to travel at all.
5	We really appreciate your being here, and we're trying
6	to figure out how to not make getting here a barrier to
7	hearing from people, so we are looking and
8	experimenting with clickers to get questions answered
9	in some cases, and use of the webcast option to get
10	additional input.
11	And on the next slide, each of these meetings
12	will result in a report that will be shared with our
13	reviewers and will be a resource for them that will be
14	available for all future applications and development
15	programs in that disease area. We are also posting
16	this report that we will develop on our website. We've
17	recently posted the one for chronic fatigue syndrome,
18	if you're interested, to go and look at what that looks
19	like and the way that format takes place. It tries to
20	reflect what we heard from patients. We have gotten
21	some good comments back from the patients who were at
22	that meeting telling us that they thought it was a good

1	capturing of what they said. We're trying to literally
2	capture what people are telling us, not change the
3	wording or anything else to make this as faithful as
4	possible to what you have to tell us today. And this
5	will be helpful to us in conducting our future
6	assessments for treating the disease, for drugs to
7	treat the disease.
8	And with that, I will turn it over to Dr.
9	Farkas to talk about a background on narcolepsy and
10	current treatments. Thank you.
11	Background on Narcolepsy and Therapeutic Options
12	DR. FARKAS: Hello. I am Ron Farkas. I'm a
13	medical officer in the Neurology Division. And I would
14	like to explain first a few things about the FDA, and
15	then after that, there are a few slides that give kind
16	of a bird's eye view of narcolepsy, and it's really you
17	who are the experts in this, and it's really just to go
18	over some of the topics that we're going to go into
19	more as the afternoon proceeds and that we're going to
20	hear more about from the people who really know the
21	most about the disease, and that's the patients.
22	It was mentioned that this is the first

1	patient- focused meeting that's on a rare disease, and
2	the FDA has a definition of rare diseases that it uses
3	to help promote the development of safe and effective
4	treatments for rare diseases. So we often refer to
5	rare diseases as orphan diseases, and it's defined as a
6	condition that affects 200,000 people or fewer in the
7	United States. There are estimated to be 7,000
8	different rare diseases affecting 30 million Americans,
9	so that's almost 1 in 10 Americans that suffers from a
10	rare disease.
11	This slide has a few different groups at FDA
12	that work together actually as a team to develop drugs.
12 13	that work together actually as a team to develop drugs. The top office there is the FDA Office of Health and
13	The top office there is the FDA Office of Health and
13 14	The top office there is the FDA Office of Health and Constituent Affairs. And there are actually many
13 14 15 16	The top office there is the FDA Office of Health and Constituent Affairs. And there are actually many different ways to find out information about the FDA.
13 14 15 16	The top office there is the FDA Office of Health and Constituent Affairs. And there are actually many different ways to find out information about the FDA. The FDA has a website that has many different sections
13 14 15 16 17	The top office there is the FDA Office of Health and Constituent Affairs. And there are actually many different ways to find out information about the FDA. The FDA has a website that has many different sections to try to explain a lot of different aspects of what we
13 14 15 16 17 18	The top office there is the FDA Office of Health and Constituent Affairs. And there are actually many different ways to find out information about the FDA. The FDA has a website that has many different sections to try to explain a lot of different aspects of what we do, and also you can call us if there are issues or
13 14 15 16 17 18 19	The top office there is the FDA Office of Health and Constituent Affairs. And there are actually many different ways to find out information about the FDA. The FDA has a website that has many different sections to try to explain a lot of different aspects of what we do, and also you can call us if there are issues or questions, and, in truth, there are several different

1	So the Office of Health and Constituent
2	Affairs is particularly focused on being a liaison
3	between FDA and stakeholders, that's patients and
4	advocates. It also runs a variety of programs to allow
5	patients to communicate with FDA.
6	There is also the CDER, which is the Center
7	for Drug Evaluation and Research we have a lot of
8	acronyms Office of New Drugs, Rare Disease Program.
9	I think all of us at FDA are very focused on rare
10	diseases, and we have Larry Bauer, from the Office of
11	New Drugs, Rare Disease Program, here, and we work
12	closely together on applications, and that office is
13	particularly focused on getting a broad view of the
14	conditions and drug development and helping to figure
15	out what kind of policies and approaches can help us,
16	help other people really, develop drugs for rare
17	diseases.
18	And then there is also the Office of Orphan
19	Products Development, and they are involved in
20	identifying rare diseases and helping people understand
21	what they are, and they're also involved in funding
22	research into finding treatments for rare diseases.

Capital Reporting Company FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013

1	Certainly one big issue that I'm sure we'll
2	hear a lot about today is that narcolepsy is
3	underrecognized and underdiagnosed. It's estimated to
4	affect more than 1 in 2,000 people in the United
5	States. Fewer than 50,000 are diagnosed, which is
6	something like a third of the people who have the
7	condition.
8	Now, I'm just going to go and describe in
9	kind of very general terms narcolepsy. We like to talk
10	about different categories and percentages and whatnot,
11	and so I'll be saying that. I'll just kind of say
12	before that that we understand there is a lot of
13	subtlety and there is a lot of variety, variation, in
14	what people experience, but this is again, in the most
15	broad sense, kind of an overview of what we'll go into
16	more in the afternoon.
17	So narcolepsy has been categorized as two
18	different kinds: narcolepsy without cataplexy and
19	narcolepsy with cataplexy, with narcolepsy with
20	cataplexy affecting about 1 in every 3,000 Americans.
21	The symptoms often start in childhood around the age of
22	7, but it's variable. Symptoms can also start later in

1	life. Patients can experience symptoms, including
2	excessive daytime sleepiness, which is more than
3	ordinary sleepiness, it's a permanent, steady
4	sleepiness, well, waxing and waning, I think, but it
5	doesn't go away ever completely during the daytime.
6	Also, symptoms of decreased alertness, and in a
7	majority of cases, for most people with narcolepsy,
8	excessive daytime sleepiness is the first symptom to
9	appear.
10	Cataplexy is a loss of muscle tone that can
11	cause physical changes like slurred speech or muscle
12	weakness. It's uncontrollable. Here it lists triggers
13	that are common: intense emotions, excitement, fear,
14	sometimes it can come when none of these are present,
15	and that occurs in about 60 to 90 percent of patients
16	with narcolepsy.
17	Hallucinations that occur near sleep onset,
18	called hypnagogic hallucinations, or near awakening,
19	hypnopompic hallucinations, also occur in about 40 to
20	80 percent of patients. Sleep paralysis is another
21	symptom, a temporary inability to move or even to

asleep or waking up from sleep, and this occurs in 20 1 2 to 50 percent of patients. Disrupted nighttime sleep is really very 3 common in narcolepsy. Patients can have a very easy 4 time falling asleep but have difficulty maintaining 5 sleep, and actually the condition is not only a problem 6 of being too sleepy during the day, but it's a problem 7 8 of sleep consolidation at night. Other symptoms can accompany those that were 9 just described, including restless leg symptom or 10 periodic limb movement, which is this urge, a very 11 12 difficult to describe urge, to move one's legs when 13 trying to sleep, and this occurs in about half of patients with narcolepsy. 14 There are other types of problems that a 15 smaller group of patients with narcolepsy have. 16 There are automatic behaviors, continuing to perform an 17 18 activity in a semiconscious way without remembering 19 what it was, something like sleepwalking. There is REM sleep behavior disorder in about a third of patients 20 with narcolepsy where the normal kind of way that 21 people are supposed to be inactive during dreaming 22

1	doesn't work right, and so people can act out their
2	dreams, other problems like obstructive sleep apnea,
3	and then really especially as we learn more about the
4	molecular basis of narcolepsy, we understand that it's
5	connected to other fundamental biological controls like
6	those that are related to obesity, type 2 diabetes, and
7	depression.
8	Narcolepsy can be treated with drugs and also
9	lifestyle changes. Drug treatments include stimulants,
10	and on that list there is modafinil, armodafinil,
11	methylphenidate and amphetamines. Antidepressant drugs
12	are not approved for narcolepsy or cataplexy, but they
13	are used for that, some of them are used for that. And
14	then I mentioned that narcolepsy is also a condition
15	involving sleep consolidation, and so sodium oxybate is
16	approved for nighttime use to improve sleep.
17	Lifestyle or behavior changes that patients
18	sometimes find effective are scheduled naps, diet and
19	exercise, and counseling and support groups.
20	The treatments that are available have side
21	effects. Stimulants can cause irritability and
22	nervousness, shakiness; people worry about disturbances

Capital Reporting Company FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013

1	in heart rhythm, rightly so; there are GI problems,
2	upset stomach, nausea; nighttime sleep disruption from
3	stimulants; and stimulants can also cause anorexia or
4	affect your appetite.
5	Antidepressants can be associated with
6	impotence, high blood pressure, heart rhythm
7	irregularities, GI problems, headache and insomnia, and
8	the presence can in themselves cause drowsiness and
9	sleepiness, breathing problems, depression,
10	hallucinations, and sleepwalking.
11	(Laughter.)
12	DR. FARKAS: It didn't seem to end quite that
13	way when I was reading over the slides, but I think
14	with that, thank you.
15	(Applause.)
16	Overview of Discussion Format
17	MS. GIAMBONE: Great. So very quickly I'm
18	going to ask our FDA panel to do a little bit of
19	musical chairs here. So if you could just move down to
20	these side tables, and we'll have our Topic 1 panelists
21	come on up and have a seat. Thank you.
22	And thank you to Ellis, Theresa, and Ron for

1 your remarks.

2	Okay. Great. And for those of you standing
3	in the back, there are a few empty chairs sort of
4	scattered around in the room. If you would like to
5	have a seat, please feel free to do so.
6	Thank you so much, everyone.
7	So once again, my name is Soujanya Giambone,
8	and I am the facilitator for today's meeting. And I
9	want to take this time to go over the discussion topics
10	and the discussion format. So this meeting might
11	actually be a little bit different than other public
12	meetings that you've attended in that the main purpose
13	of today's meeting is to engage patients and patient
14	representatives in dialogue. And so just to set the
15	definition quickly, by "patient," I mean anybody living
16	with narcolepsy, and by "patient representative," I
17	mean anyone, a caretaker, a loved one, who is here
18	speaking on behalf of somebody who is unable to speak
19	for themselves today.
20	So let's first go over the discussion format.
21	Again, we have two topics: Topic 1, on the
22	most significant symptoms of narcolepsy and their

impact on daily life; and Topic 2, on current treatment 1 2 options and patients' perspectives to treatment options. 3 So first we're going to hear from our first 4 set of patients and patient representative panelists, 5 and they're going to really set a strong foundation for 6 the bigger dialogue, and I'm going to have you all 7 8 introduce yourselves in just a minute. 9 So we have five panelists per topic, and they reflect a range of experience with narcolepsy. They 10 have each prepared 3 to 4 minutes of remarks in 11 12 response to the topic questions, and after we hear from 13 them, we're going to follow up with some questions from -- we'll see if the FDA panel has some questions for 14 15 you. 16 After our panelists speak, we are going to turn it over to patients and patient representatives in 17 18 our audience and invite you to share your perspectives 19 and your experiences and contribute to the dialogue. 20 So here is where we want to hear what is generally 21 similar, what's slightly different, from what you've 22 heard on the panel in response to the topic questions.

1	And I'll ask some follow-up questions. And
2	we do have some microphone runners in the room, they'll
3	go around. If you're comfortable to do so, raise your
4	hand, and one of our microphone runners will run over
5	to you, and if you could state your first name before
6	you speak and you can provide your comments then.
7	And actually I did forget to mention earlier
8	on that this meeting is being recorded and transcribed,
9	so everything that we share here today and for those of
10	you joining us on the web, it will all be part of the
11	public record.
12	All right. And we're also going to do
	All right. And we're also going to do something today that has worked really well in our last
12	
12 13	something today that has worked really well in our last
12 13 14	something today that has worked really well in our last several patient-focused meetings. We're going to have
12 13 14 15	something today that has worked really well in our last several patient-focused meetings. We're going to have some polling questions, and the purpose of the polling
12 13 14 15 16	something today that has worked really well in our last several patient-focused meetings. We're going to have some polling questions, and the purpose of the polling questions is to aid the discussion and really gain a
12 13 14 15 16 17	something today that has worked really well in our last several patient-focused meetings. We're going to have some polling questions, and the purpose of the polling questions is to aid the discussion and really gain a better understanding and perspective of what's in the
12 13 14 15 16 17 18	something today that has worked really well in our last several patient-focused meetings. We're going to have some polling questions, and the purpose of the polling questions is to aid the discussion and really gain a better understanding and perspective of what's in the audience, your experiences, and your perspectives.
12 13 14 15 16 17 18 19	something today that has worked really well in our last several patient-focused meetings. We're going to have some polling questions, and the purpose of the polling questions is to aid the discussion and really gain a better understanding and perspective of what's in the audience, your experiences, and your perspectives. It's just another way to gain that information.

1 to answer the polling questions.

2	And web participants can also respond to the
3	poll through your webcast comment box, actually through
4	the polling questions that you can see on the webcast.
5	And I would like to say for the polling questions we do
6	want to make sure that it's patient and patient
7	representatives responding to the polling questions.
8	Okay? And we'll try out some of these in just a few
9	minutes.
10	And a special welcome to those of you joining
11	us remotely. It's actually an incredible response that
12	we've had for this meeting. We have close to 700
13	people, I believe, joining us on the web, so that is
14	just amazing. And so a special welcome to you all.
15	And I urge all of you on the web to contribute to the
16	dialogue. You can submit comments through your webcast
17	comment box, and although we may not be able to
18	summarize all of them today, we're listening, and
19	you're part of this dialogue. We're going to check in
20	periodically with my FDA colleagues to read off some of
21	the comments, and it is considered part of the public
22	record.

1	And last but not least, we do have this
2	public docket which is basically it's online space that
3	we have where it will be open for 2 months after this
4	meeting ends, and it's another place where you can go
5	and submit your comments, any other thoughts that come
6	to mind, you can feel free over the 2 months to
7	contribute your comments via the public docket. And
8	again that's part of the public record. Okay?
9	And we're actually going to do something new
10	today, and we're very excited about it. In addition to
11	those of you joining us remotely, we're going to invite
12	some of our remote participants to join in the
13	discussion via the phone. So towards the later part of
14	our group discussion, I am going to check in with my
15	FDA colleagues, and they'll bring in some web
16	participants to speak over the phone.
17	So for those of you on the web, I do want to
18	say that check your webcast, check on the webinar,
19	you'll see a prompt come up towards halfway through the
20	group discussion, and it will provide the number that
21	you'll dial into if you would like to contribute to the
22	dialogue over the phone, and we'll get to you towards

1 the later part of the discussion.

2	Great. So let's go ahead and go through the
3	discussion ground rules, and these are just some ground
4	rules that we have that apply to all of us so that this
5	discussion is the most fair to all of us.
6	First and foremost, we are here to listen to
7	the patients' experience with narcolepsy and patient
8	representatives here. So it's very valuable and we're
9	much looking forward to hearing that. We're also very
10	happy to see that we have representation from industry
11	and government agencies and research, and we're so
12	thankful that you're here. We just ask that you stay
13	in listening mode so that we can hear from our patients
14	and patient representatives.
15	Next, the FDA panel is here to listen, and
16	I'm going to make a disclaimer here. I am not a
17	medical expert, so I am going to rely on my FDA
18	colleagues to help me out with any questions. If you
19	have any questions, please feel to ask, and my goal is
20	to get through today's meeting without messing up any
21	of the drug names or anything, so I'm going to be
22	relying on them for that.

1	Common ground. So as I mentioned before,
2	this is a large-group facilitated discussion, and we
3	want to stay on topic, we want to generally stay on
4	topic, but we will stray a bit from that, and I just
5	want to make sure that if we we don't want to spend
6	too much time on one specific thing, we want to
7	continue to broaden and build the dialogue. Okay?
8	Next, feedback. So your feedback is very
9	important to our meeting. We have evaluation forms out
10	on the registration desk. It's completely voluntary,
11	but it would be really beneficial for the FDA to hear
12	your feedback on how you think the meeting went today
13	and what we can do better for our future meetings.
14	And last but not least, respect and courtesy
15	for each other is paramount. So today is a meeting
16	where we are going to hear a lot of personal opinions,
17	personal experiences, and so we want to make sure we
18	respect that. And so on that note, let's keep side
19	conversations to a minimum. If you need to take a
20	phone call, please do so out in the hallway. And as I
21	mentioned before, if you have any questions or if you
22	need anything, please feel free to ask us, feel free to

Capital Reporting Company FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013

39

go out to the restrooms or the breakout rooms. And I'm 1 2 looking forward to an excellent and great conversation 3 today. So with that, let's start with some of our 4 polling questions to practice here. And is that one 5 up? 6 7 Okay. So everybody have your clickers? All 8 right. Great. So the first one is: Where do you live within the Washington, D.C., metro area or outside of 9 the Washington, D.C., metro area? So you'll press 1 10 for within metro area and 2 for outside the metro area. 11 12 (Pressing clickers.) 13 MS. GIAMBONE: Okay. So can we advance to the next slide? 14 15 Great. Wow. Okay. So we have quite a bit of local neighbors here, but it's also great to see how 16 many of you have come from outside the D.C. metro area. 17 18 We thank you so much for making the trip out here. So 19 thank you. 20 Okay. So let's move on to Question 2. Have 21 you ever been diagnosed as having narcolepsy? Again, 1 for yes, or 2 for no. 22

1	(Pressing clickers.)
2	MS. GIAMBONE: Okay. Great. Wow. So it
3	looks like we have about two-thirds of our audience
4	here today has been diagnosed as having narcolepsy. So
5	we are very much looking forward to hearing from you
6	during today's dialogue. Thank you.
7	Okay. Next, let's do the next one.
8	MR. VALENTINE: And can I chime in from the
9	webcast just to compare to what we have in the room?
10	So for the first question, we actually have, as might
11	be expected, a very large proportion, about 90 percent
12	of participants, being from outside the D.C. area. And
13	for the second question, we have about 85 percent of
14	participants having been diagnosed with narcolepsy.
15	MS. GIAMBONE: Great. Great. I'm so happy
16	to hear that we have so much representation here in the
17	room and also joining us on the web, so that's really
18	going to be an excellent conversation.
19	All right. Let's move to the next question.
20	Are you male or female? 1 for male, 2 for female.
21	(Pressing clickers.)
22	MS. GIAMBONE: Okay. So we have about over

(866) 448 - DEPO www.CapitalReportingCompany.com © 2013

Capital Reporting Company FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013

1	two- thirds of our audience here is female, and we also
2	have just about a third male. So looking forward to
3	hearing conversation from both, from both males and
4	females, so thank you.
5	MR. VALENTINE: And the breakdown for the web
6	is about the same.
7	MS. GIAMBONE: It's about the same? Okay.
8	Thank you.
9	And the next question. Okay, age. And I
10	know the print is a little small, so I'm going to go
11	through all of them. So A, younger than 10; B, 11
12	through 20; C, 21 to 30; D, 31 to 40; E, 41 to 50; F,
13	51 to 60; or G, 61 or greater.
14	(Pressing clickers.)
15	MS. GIAMBONE: Okay. So let me try to see
16	this here. Okay. So we actually have a pretty good
17	spread of age representation here. I am also so happy
18	to see that we actually do have some representation
19	from the pediatric population. We were so excited to
20	see that. Thank you so much for being here.
21	And generally, let's see, we have age group
22	here between 41 to 50 is the largest representation

here, so great. And any updates from the web for that 1 2 question? MR. VALENTINE: The largest age group for the 3 web is 31 to 40, with about a quarter of the 4 participants, and about a fifth of the participants are 5 in the 21 to 30 range, as well as another fifth in the 6 7 41 to 50. 8 MS. GIAMBONE: Great. Okav. Good. All 9 right. 10 And the last question. What is the length of time since your diagnosis? A, less than 5 years ago; 11 12 B, 5 years to 10 years ago; C, 10 to 20 years ago; D, 13 more than 20 years ago; or E, I'm not sure. 14 (Pressing clickers.) 15 MS. GIAMBONE: Okay. All right. So let's see here. So we actually -- you know, this is great. 16 So based on the results, it looks like we have a good 17 bit of our audience members who this is a recent 18 19 diagnosis, so it will be really great to hear your perspectives on this recent diagnosis. And then it's 20 21 also good to see that we have some representation from 22 those that have been living with narcolepsy for quite

Capital Reporting Company FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013

43

some time. So you'll have some really great 1 2 perspectives to offer there, too. Thank you. MR. VALENTINE: And on the web, we have about 3 45 percent with the less than 5 year ago diagnosis, and 4 then about a fifth for the next two, B and C. 5 MS. GIAMBONE: Okay. Great. Thank you. 6 7 Okay. So that wraps up the first set of 8 polling questions. And I'm done talking now. What I'm going to do is I'm going to have our patient and 9 patient representatives on the panel for Topic 1 10 11 introduce themselves. 12 MS. LENZI: Hi, everyone. I'm Kerry. And I 13 am talking about Discussion Topic 1. 14 Do you want to do it person-by-person? MS. GIAMBONE: Yeah, we'll do introductions 15 first and then we'll go ahead and get started. 16 MR. COONROD: Hi. I'm Brandon Coonrod. I'm 17 18 also a panelist on Discussion 1. 19 MS. ROSEN: Hi. I'm Fran Rosen. 20 MS. BOLLINO: I'm Carrie Bollino. 21 MR. POPLAWSKI: I'm Joe Poplawski. I'm a narcoleptic. 22

1	MS. GIAMBONE: Great. All right. So once
2	again the panelists have prepared 3 to 4 minutes of
3	remarks in response to Topic Question 1. And we
4	actually will okay, there you go. So you see the
5	Topic 1 questions. But really it's what symptoms you
6	experience because of your condition and what symptoms
7	have the most significant impact on your life. Are
8	there specific activities that are important to you but
9	you can't do at all or as fully as you would like
10	because of your condition? And how have your symptoms
11	changed over time?
12	So with that, let's get started. So, Kerry?
13	Panel #1 Comments on Topic 1
13 14	Panel #1 Comments on Topic 1 MS. LENZI: Thank you. Hi, everyone. Like I
14	MS. LENZI: Thank you. Hi, everyone. Like I
14 15 16	MS. LENZI: Thank you. Hi, everyone. Like I said, my name is Kerry, and I was very recently
14 15 16	MS. LENZI: Thank you. Hi, everyone. Like I said, my name is Kerry, and I was very recently diagnosed with narcolepsy. I just found out in July
14 15 16 17	MS. LENZI: Thank you. Hi, everyone. Like I said, my name is Kerry, and I was very recently diagnosed with narcolepsy. I just found out in July that I have it. I had severe symptom onset about 2
14 15 16 17 18	MS. LENZI: Thank you. Hi, everyone. Like I said, my name is Kerry, and I was very recently diagnosed with narcolepsy. I just found out in July that I have it. I had severe symptom onset about 2 years ago, and it's been just repeated misdiagnosis for
14 15 16 17 18 19	MS. LENZI: Thank you. Hi, everyone. Like I said, my name is Kerry, and I was very recently diagnosed with narcolepsy. I just found out in July that I have it. I had severe symptom onset about 2 years ago, and it's been just repeated misdiagnosis for the past about year and a half until July, when I was

1	So to highlight some of the symptoms that I
2	feel are most severe in my life, the disturbed
3	nighttime sleep is one of them. I go through cycles in
4	my ability to sleep, so I can have a stretch of time
5	where I can sleep very easily, fall asleep for any
6	amount of time at any time, and then I'll go through
7	stretches of time where I can't sleep at all. So it
8	will be several nights with no sleep, 45 minutes is a
9	good night's sleep, 2 hours is fantastic, and that will
10	go on for months and months, and then it will turn into
11	now I can sleep at all times. So that's kind of a
12	cycle that I'm noticing.
13	And then obviously not sleeping very well

during the night would increase the excessive daytime 14 sleepiness that I experience as well as the other 15 symptoms would increase in severity. And as I said, 16 excessive daytime sleepiness is another one of the top 17 three that I experience. I'm currently an undergrad 18 19 student, so the excessive daytime sleepiness definitely 20 impacts that. I have noticed that my -- I've always 21 been a decent student, but with the onset of symptoms, 22 it's definitely gone down a little bit from I was on

1	the Dean's List, I was doing great, Honor Society, and
2	then a little decline, so it's just been a hard time
3	being in class and staying focused and being awake. If
4	I have a class that's longer than 50 minutes or after a
5	meal, I probably won't stay awake. If I am awake, I'm
6	not alert, I'm not really retaining much or
7	understanding much. So it's a lot of catch-up work
8	trying to go back and look at what I was not really
9	alert for in class and so reading ahead.
10	And so it's been a struggle to stay in
11	school, especially with my doctors have been urging me
12	to leave. So I think that is definitely impacted a lot,
13	especially with the third symptom that I think is
14	probably the most severe. I'm not really sure how to
15	classify it or what category. Like I said, I'm not
16	really too familiar with what I have yet, but I have
17	episodes when I don't sleep very frequently, it's like
18	a state of like loopiness where it will go from one
19	extreme of hyperactivity to another extreme of not
20	really being like mentally present. So it will start
21	out that I'm talking a lot and not really making a lot
22	of sense and repeating some of the same phrases and not

1	a whole lot of control of especially like my head and
2	neck, I'll just start like drooping over, I can't hold
3	onto things, and I'll just keep talking and talking and
4	talking, and then it will switch to the other extreme
5	where I can't really respond any longer, it's just a
6	blank stare, people asking questions, and I'm just
7	like, "Huh? Huh?" and I'm not really able to
8	participate in conversation any longer. And that was
9	happening like four times a day at the least, and it
10	would last either like 10 minutes or a couple hours,
11	and that ranges in severity, so it could be like a 2-
12	minute thing in the grocery store. So that happens
13	very frequently, and I think that's the hardest thing
14	to deal with, with being in public and trying to carry
15	on with daily activities.
16	And then to again talk about I kind of
17	already highlighted, it asked in the discussion some
18	specific activities that are important to you but that
19	you cannot do as fully as you would like. Again, going
20	back to school, that's definitely been difficult. I
21	have seen 20 like 20 to 25 different specialists in

22 the last 2 years, and most of them have encouraged me

1	to leave school. And then when I didn't leave school,
2	"You shouldn't go back. You should get a handle on
3	your health." And school is really important to me, so
4	trying to stick through that has been hard, especially
5	in the beginning when I didn't have a diagnosis, and my
6	professors were kind of assuming that with my grades
7	not being consistent, if there was a week where I was
8	really not feeling well, and that grade wasn't great
9	compared to like a really good grade, they kind of just
10	assumed that I wasn't trying or I was putting school
11	last, and that was kind of a struggle when I didn't
12	know the reason for that either with my professors. So
12 13	know the reason for that either with my professors. So school I think definitely is the most affected.
13	school I think definitely is the most affected.
13 14	school I think definitely is the most affected. And I also have a hard time exercising, which
13 14 15 16	school I think definitely is the most affected. And I also have a hard time exercising, which is another thing. I was running 5K every day before
13 14 15 16	school I think definitely is the most affected. And I also have a hard time exercising, which is another thing. I was running 5K every day before severe symptom onset, but now I like walking more
13 14 15 16 17	<pre>school I think definitely is the most affected.</pre>
13 14 15 16 17 18	<pre>school I think definitely is the most affected. And I also have a hard time exercising, which is another thing. I was running 5K every day before severe symptom onset, but now I like walking more than usual or standing more than usual will trigger those episodes like I mentioned, and just like it adds</pre>
13 14 15 16 17 18 19	<pre>school I think definitely is the most affected.</pre>

1	And the discussion also asked if symptoms
2	have changed over time. I haven't really been in the
3	narcolepsy area for too long, but the only change that
4	I really notice is obviously the different side effect
5	profiles that I've had from being diagnosed with
6	several different conditions, so that made the symptoms
7	I'm already experiencing a little more challenging.
8	But as far as the symptoms themselves, only making
9	lifestyle adjustments has really been I've seen a
10	slight change. Like making diet changes and things like
11	that helps a little bit now that I know what I do have,
12	but the medication that I'm on hasn't really improved
13	my symptoms very much. And I don't really think that
14	there has been any change in my symptoms.
15	And it also asked us if my symptoms come and
16	go and if anything makes them worse or better. I know
17	that there are several things that make them worse. So
18	stress, anxiety, being even more sleep deprived,
19	dehydrated, like in the sun, being hot, working out, or
20	any like walking, like I said. So a range of things
21	make it more severe. And like I mentioned, being more
22	anxious and stressed and sleep deprived really

aggravates this, so if I have like a big test on
Thursday, so Thursday I'm going to be extra stressed,
extra anxious, extra sleep deprived, so my narcolepsy
symptoms are going to be even more severe, which will
make that test even harder. So it's kind of a cycle in
that regard.

7 And with these flare-ups, it's been hard to 8 tell obviously with a diagnosis. Like, for example, I was treated for epilepsy for about 6 months, and I do 9 10 not have epilepsy. I had a positive EEG, so we went 11 along those lines, and my doctor said that if my 12 symptoms did improve, then that would be conclusive 13 when adding those medications. So I did start taking anticonvulsives, and my symptoms appeared to improve, 14 15 so that was conclusive in their eyes. So when my symptoms appeared to get worse, I kept increasing them 16 17 and increasing the anticonvulsives until I was on I 18 think it was 9 tablets of 200 mg Trioptal every day for 19 a condition I don't have with a side effect profile I couldn't handle. And that was only one of several 20 21 misdiagnoses which have been aided by these flare-ups. 22 And now that I do know what I have luckily, it's been

Capital Reporting Company FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013

1	hard to determine if a medication regimen is helping or
2	if it's better or worse or if my flare-ups are just
3	happening. So that's been difficult to tell if there
4	is progress being made or if it's just a good week.
5	So I think that about sums up the comments
6	that I had on Topic 1. So thank you.
7	MS. GIAMBONE: Brandon?
8	MR. COONROD: Hi. I would just like to start
9	off by saying thanks to the FDA for having us all here.
10	It's really exciting to see them taking interest in
11	this disorder, and I'm honored to be speaking in front
12	of you all today as part of this panel.
13	I am 15 years old and I'm a sophomore in high
14	school, so, as you can imagine, this has kind of
15	impacted my life profoundly. Daytime sleepiness is
16	probably my symptom that impacts me the most. It
17	causes me to be more drowsy when I'm awake, and if I'm
18	sitting down in class or just like sitting anywhere
19	pretty much, you can pretty count that I'm going to
20	fall asleep.
21	Before I was diagnosed with narcolepsy, which
22	was 2 years ago, I had always scored in like the 99th

1	percentile on standardized tests and stuff and I was a
2	pretty decent student, but like I just started falling
3	asleep in class and ended up getting kicked out of all
4	honors and getting C's and D's before I got medication.
5	So the daytime sleepiness is definitely the one that
6	impacts me the most.
7	Cataplexy, I've been blessed to not have that
8	as bad as it could be, but I definitely have a little
9	bit of that. When like one of my friends would tell a
10	joke or something like that, my facial muscles would
11	like slack up. So I definitely know what that's like
12	for those of you that have severely.
13	Hallucinations, that's a hard one to explain
14	to somebody that doesn't have it. The way I explain
15	that is since us narcoleptics are able to go into REM
16	sleep so quickly, if you like when you fall asleep or
17	if you're taking a nap, you're automatically dreaming,
18	so it's like you're just going in and out of dreams so
19	quickly that you can't handle it, it's like, "Okay, was
20	I dreaming or is that real or what?"
21	And another one of the symptoms that Dr.
22	Farkas mentioned that I didn't even think about was the

Capital Reporting Company FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013

1	automatic behavior thing. Sometimes when I get really
2	drowsy I can find myself like nodding off when I'm
3	standing up almost. And the automatic behavior thing
4	was kind of interesting for me because the only time
5	I've ever experienced that was when I was mowing, so it
6	actually worked out pretty well for me because I got
7	the lawn mowed that way.
8	(Laughter.)
9	MR. COONROD: Yeah, just the daytime
10	sleepiness is the main one for me.
11	The effect of these symptoms, like I
12	mentioned school, that's a big one for me, and I'm sure
13	for all of you that are students. It's hard to get
14	schoolwork done. Falling asleep in class is hard, you
15	miss some of the lectures. Socially also in school,
16	you know, kids, fellow classmates see another student
17	falling asleep a lot in class, their instant opinion
18	may be that that student is lazy or just doesn't care,
19	and the same with the teachers. I mean, it's not their
20	fault, they don't know what's going on, but before I
21	got diagnosed, I didn't know what was going on either,
22	so that's hard socially.

1	Driving, that's a big one for me because I'm
2	15 and I'll be thinking about driving next year, and
3	that's going to be tough for me because I've got to
4	realize that I do have something that could potentially
5	endanger others if I was to fall asleep while driving,
6	but at the same time, I definitely want to drive. So
7	that's a big thing. Hopefully with medication I'll be
8	able to drive even if there are some strings attached
9	to that.
10	Some other affects would be military. That's
11	definitely out of the picture for me, which is
12	something I kind of always wanted to do. And another
13	thing Dr. Farkas mentioned was obesity and depression.
14	And these aren't something that like narcolepsy
15	directly causes, but the symptoms of this definitely
16	can bring on these things. If you're falling asleep a
17	lot, you don't have the energy to, like she said,
18	exercise or anything like that, so you may be like
19	laying down more and sitting more, and that can
20	definitely cause obesity. I also think narcolepsy
21	causes decreased metabolism, but like that's just
22	something I've experienced. And depression goes along

1	with that. As I fell asleep in school and fell behind
2	in my grades and such, and with all the social issues
3	that that brought up, depression is definitely
4	something that can be brought along by these symptoms,
5	just like, "Why am I falling asleep?" like, "Why can't
6	I help this?" and everybody is like, "You're lazy. Get
7	it together," or something like that. And at the same
8	time, I thought that I was getting mad at myself, so,
9	yeah, that's definitely hard.
10	Another question was, "Have your symptoms
11	changed over time?" And they definitely have. Before
12	medications, like I said, I would fall asleep pretty
13	much like 5 minutes into class and miss pretty much the
14	whole class, which was tough, but I started Strattera,
15	and then I'm now on Strattera and Nuvigil, and that's
16	definitely helped me with school and the symptoms and
17	stuff, so that's changed my symptoms. Also it varies
18	on the amount of sleep that I get. If I get a good 10
19	hours of sleep, it definitely helps my symptoms
20	compared to not getting as much sleep. And diet,
21	that's a big thing for me. I've gone on a gluten-free
22	diet, and it seems to help with feeling less lethargic

1 and such.

_	
2	And so that pretty much sums up my experience
3	with narcolepsy. So, yeah, thanks for this opportunity
4	to bring my experience in front of you guys. I'm glad
5	to have had it.
6	MS. GIAMBONE: Thank you, Brandon.
7	Fran?
8	MS. ROSEN: I, too, want to thank the FDA,
9	and I, too, am super, super honored to be part of this.
10	So I think my whole thing is very different
11	from everybody else's, although maybe it isn't. But
12	this is also the first time I have ever met someone
13	else who has narcolepsy, so this is a big day for me.
14	I'm 62 years old, and I was diagnosed when I was 48,
15	and 2 years before I was diagnosed, I was hired to be a
16	pharmaceutical sales rep for a giant pharmaceutical
17	company, and you would think that working for the
18	Number 6th in the world that someone somewhere would
19	get it. Well, they didn't. And I'm driving the company
20	car, and they're oblivious to the whole thing.
21	Okay. So I'm not even sure when I started to
22	get symptoms because it was normal for me to take a nap

1	every day and it was normal for me to fall asleep in
2	the dentist's office. I was a great patient. And it
3	was normal for me to fall asleep getting my hair cut
4	because I was relaxed. So none of that really impacted
5	my life, but when I was 29, out of nowhere I got sleep
6	paralysis. Well, oh, my god, I thought I was becoming
7	mentally ill, and I would not tell anyone, and the
8	reason why I was afraid to tell anyone was because if
9	I'm going nuts, my ex-husband is going to take me to
10	court, he's going to take my son away from me, and so I
11	was going to be mentally ill by myself and no one was
12	going to know about it. Okay, but I lived with that
13	I mean, I'm joking about it, but I lived with that all
14	by myself for 19 years. Okay.
15	I also started to have hallucinations, and
16	initially I thought it was my father coming from the
17	other side because I could see him and I could smell
1 0	

18 him and I could feel him, but then when I hallucinated 19 that my sister was there, I realized, okay, this is not 20 my father coming from the other side because my sister 21 was well and whatever.

22

And then they weren't fun anymore. Then they

(866) 448 - DEPO www.CapitalReportingCompany.com © 2013

1	would be I would be in my bedroom, but not my present
2	bedroom, like another bedroom that I had like years
3	ago, and there would be men in my bedroom, but I would
4	be afraid of them and I wouldn't be able to do
5	anything, and that was that.
6	Okay, then in my thirties I developed
7	cataplexy, and it always happened when my son would
8	make me laugh, and he was the only one in the world who
9	could just get me hysterical like at the wrong time,
10	and all of a sudden I wouldn't be able to breathe and
11	everything would stop, and then my jaw would drop, and
12	to me it felt like an eternity, but I think it was only
13	a few seconds, but now I'm thinking, "Oh, my god, now
14	I'm mentally ill and now I'm going to have a stroke."
15	And again I didn't know who to tell.
16	So I lived like that and I beat myself up
17	because I wasn't the best mother in the world. I never
18	had the wherewithal to stand in the kitchen and bake,
19	and I used to beat myself up because, what's wrong with
20	me? Why can't I do more for my son? You wouldn't want
21	to come into my home and eat off the floors because I
22	didn't have the energy to clean my house. And so I had

1 a lot of guilt having to do with that.

2	Then mine I truly believe is hormonal because
3	as I started to go into perimenopause, all of a sudden
4	I would fall asleep when I'm driving, but it's not the
5	kind of sleep that you have control over, it's like an
6	invisible man comes and injects Sodium Pentothal in
7	you, and you're asleep, and that would happen, and then
8	I wouldn't be able to get up in the morning. And as I
9	got into more of perimenopause, the symptoms became
10	more.
11	And then I was hired by this pharmaceutical
12	company, the job of my dreams, and I can't get out of
13	my house in the morning because I shower, get dressed,
14	put makeup on, eat breakfast, and then I'm asleep on my
15	couch, and my manager never knew. And then I said, oh,
16	my god, I'm too comfortable at home, I'm going to have
17	breakfast out. So I would eat breakfast out, and by
18	the time I got to my first doctor's office, I had to
19	take a nap in the car. Okay, so what is wrong with me?
20	And gradually my life began to change. So I
21	used to call on pulmonologists, and all of a sudden I
22	saw a brochure, and it said, "Narcolepsy." And I said

1	oh, and there was one next to it called, "Menopause
2	and Insomnia." So I said I don't have insomnia, but
3	I'll read the "Narcolepsy," and oh, my god, oh, my god,
4	I could have written that brochure. It was like I did
5	write that brochure.
6	So now I get to go in and talk to the doctor,
7	and I said, "I have narcolepsy." He said, "What are
8	you talking about?" And actually then I had the sleep
9	studies and I was so excited that I had a label because
10	I wasn't mentally ill and I wasn't having a stroke, and
11	this is why I was sleeping, and I wasn't a bad mother,
12	it was because I had narcolepsy. But the symptoms
13	really, really got worse.
14	So for me, the worst symptom of this whole
15	thing and I put it together is the excessive
16	daytime sleepiness, but that for me is two things, that
17	could be those sudden sleep attacks where the only way
18	I can describe it is it's encompassing and it is so
19	powerful, the need, and as crazy as this sounds, the
20	desire to sleep that nothing else matters, and that's
21	why you can be driving in a car. You have no control.
22	And what happened to me was I had to give

1	narcolepsy control of my life because narcolepsy was
2	winning, and narcolepsy tells me how long I can shop in
3	a mall for, and narcolepsy tells me how long I'm going
4	to stay wide awake in a meeting, and narcolepsy tells
5	me if I'm going to be able to go to that party or that
6	show, and narcolepsy tells me if I'm going to be able
7	to drive.
8	And I'm sitting here telling you that I am so
9	proud of myself because I retired after 14 years of
10	being a wreck, and I put up with such abuse from my
11	managers. I was accused of being a liar, of trying to
12	fake it to get out of things. Oh, I was accused of
13	doing drugs, illegal drugs. I was forbidden to bring
14	up the word "narcolepsy" to any of my doctors, and
15	that's because I did a lunch with my manager and a
16	doctor, and he said to my manager, "You know, I just
17	have to tell you something, Fran is unbelievable, how
18	she can do this job and do it so well with narcolepsy."
19	Okay, so in the meantime, I'm like, oh, my god, I felt
20	like a million dollars. I go out and my manager says
21	to me, "What was that all about?" I said, "What do you
22	mean?" He said, "Now I know you use your narcolepsy so

1	that the doctors will feel sorry for you and write the
2	drugs. You are now forbidden to ever bring up that you
3	have narcolepsy." Well, talk about feeling ashamed.
4	Oh, I was so ashamed. And then he told me that nobody
5	wanted to work with me, but that really wasn't true.
6	His manager said to me, "You're so stupid," and she
7	wondered how I graduated from college. And what she
8	was referring to was because, not only would I have
9	sudden sleep attacks, but I get really drowsy, and when
10	I get drowsy, it's what you guys said, you don't think
11	right, you're half there, you're not there, you're in a
12	daze, you don't remember things. My facial expressions
13	change. I get a weird thing in my brain, and I get
14	drowsy. Sometimes it passes; other times I'm walking
15	around and I am asleep.
16	So what I wanted to say is I don't know how I
17	did it, but I did it. I retired after 14 well, they
18	got rid of me, but then I retired because I was there
19	long enough. But I am so proud of myself. I was a
20	successful wreck, but in spite of the narcolepsy and in
21	spite of life just chipping away at my self-esteem and
22	having horrible feelings of self-doubt and being

1	ashamed and embarrassed, I accomplished what I wanted
2	to accomplish, and I can't tell you the stress because
3	you all know we only have a short window that we can
4	really do what we need to do, and for me, that was so
5	much stress, but I did it. And I'm proud to say that I
6	am proud of myself. My managers may not have said that
7	about me, but I don't care. I, in spite of narcolepsy,
8	I did what I wanted to do.
9	(Applause.)
10	MS. ROSEN: Well, thank you, but you know
11	what? I'm sure you guys do it, too. I'm sure you've
12	done it because it's a fight, it's a battle. It
13	changed me life. I am half the woman I used to be, and
14	I don't say that like to be negative, but I used to be
15	super independent. Now I have to discuss with my
16	friends, "So I'll drive, I'm fine driving, but you'll
17	have to drive my car if I get a little drowsy," or
18	it's such a mishmash, but it is what it is, and I'm so
19	happy to be here because the big thing is I suffered
20	alone. So if anything I say helps someone in the
21	future, then that's what it's all about.
22	MS. GIAMBONE: Thank you so much, Fran.

1	MS. ROSEN: Thank you. Thanks.
2	MS. GIAMBONE: Thank you.
3	Carrie?
4	MS. BOLLINO: Wow. Can you hear me now? I
5	look back on the days, so many days, and simply shake
6	my head that I can even be sitting here today because
7	of the years driving behind the wheel of a car and
8	nodding off into a deep daze and lose entire chunks of
9	20, 30 minutes of time. Somehow I always ended safely
10	parked on the side of the road or at a truck stop or
11	anywhere where it was legal to park, and I would
12	suddenly snap back and rethink, "Where did that sign go
13	that was back there?" and realize how long had gone by.
14	I even drove under the edge of an 18-wheeler once and
15	looked up, and calmly pulled back into the lane, no
16	adrenaline rush, no sense of urgency at all.
17	And over time the driving to me, I learned
18	how to deal with it. I learned don't drive when you're
19	tired, always know where there is a stop ahead, always
20	stop and nap if you need to, if you start feeling that
21	like fading away feeling, always stop. And I double
22	the driving time whenever I go anywhere. You know, if

1	somebody says, "It takes about an hour to get there,"
2	and I leave 2 hours so that I know that I've got time
3	to stop. I always knew I was more tired than most
4	people and I tried not to view myself as lazy, but many
5	times that vicious circle of being a little bit
6	depressed, and dropping the proverbial ball, and being
7	a little late, and not really being in control of why,
8	it would drag me down. My social life was a huge
9	casualty in college and beyond because needing naps
10	became the priority, not going out and having fun.
11	In my freshman year in college, my sleep
12	paralysis began, and I remember one night my senior
13	year, we were all kind of gathered in a room having a
13 14	year, we were all kind of gathered in a room having a slumber party of sorts, telling ghost stories to each
14	slumber party of sorts, telling ghost stories to each
14 15 16	slumber party of sorts, telling ghost stories to each other, and I was kind of dozing off, not really
14 15 16	slumber party of sorts, telling ghost stories to each other, and I was kind of dozing off, not really involved in the conversation, but I was listening, and
14 15 16 17	slumber party of sorts, telling ghost stories to each other, and I was kind of dozing off, not really involved in the conversation, but I was listening, and apparently it appeared as though I had fallen asleep,
14 15 16 17 18	slumber party of sorts, telling ghost stories to each other, and I was kind of dozing off, not really involved in the conversation, but I was listening, and apparently it appeared as though I had fallen asleep, but I was there, and I wanted to interject something,
14 15 16 17 18 19	slumber party of sorts, telling ghost stories to each other, and I was kind of dozing off, not really involved in the conversation, but I was listening, and apparently it appeared as though I had fallen asleep, but I was there, and I wanted to interject something, so I sat up, and I looked and I said, "It won't let me

finally I woke up, and when I did, I recited back to 1 2 them everything that they had said, and they were all just amazed. 3 But the thing that amazes me about that 4 moment is how normal it felt to be in that place where 5 I was awake and very aware of everything that was going 6 on around me but unable to move. It also strikes me 7 8 how normal it felt to have "it" there. Mv hallucinations always included a dark being that was 9 always there, always there as I faded to sleep, always 10 there as I woke up, and by that point I guess he had 11 12 become normal. He is very scary, but I had gotten used 13 to him. 14 Anyway, the downward spirals of circumstances in my life and symptoms drew me into depression, 15 although I was never clinically diagnosed. 16 Once I 17 graduated from college, I went on two job interviews, 18 and I didn't get either job, and by that point, I was 19 feeling not worthy that I could have a job in the 20 design field. So I let go of that dream and went on to 21 other things. 22 During this low period of my life, my mom

1	witnessed a few times the sleep paralysis. There were
2	a couple of times when she came in the room and would
3	wake me from a nap because it was dinnertime, and I
4	would try to get up, but I couldn't move, and she
5	described it like it looked like a mild seizure because
6	I was fighting so hard to wake up. And we did go to
7	the doctor soon after that, asked him a couple
8	questions about it, brought it up, but he just kind of
9	brushed it aside, and so I brushed it aside, too, and
10	moved on.
11	My first cataplexy attack that I can remember
12	was at my graduation party in 1996. We were all
13	standing around in a circle, and we all got laughing,
13	standing around in a circle, and we all got laughing,
13 14	standing around in a circle, and we all got laughing, and it felt like the lights were flickering, my head
13 14 15 16	standing around in a circle, and we all got laughing, and it felt like the lights were flickering, my head dropped to the side a little bit, my hand dropped to
13 14 15 16	standing around in a circle, and we all got laughing, and it felt like the lights were flickering, my head dropped to the side a little bit, my hand dropped to the side, thankfully I had my drink in my other hand,
13 14 15 16 17	standing around in a circle, and we all got laughing, and it felt like the lights were flickering, my head dropped to the side a little bit, my hand dropped to the side, thankfully I had my drink in my other hand, but I looked around, and nobody reacted to it, nobody
13 14 15 16 17 18	standing around in a circle, and we all got laughing, and it felt like the lights were flickering, my head dropped to the side a little bit, my hand dropped to the side, thankfully I had my drink in my other hand, but I looked around, and nobody reacted to it, nobody seemed to have seen it, and so I moved on. And my
13 14 15 16 17 18 19	standing around in a circle, and we all got laughing, and it felt like the lights were flickering, my head dropped to the side a little bit, my hand dropped to the side, thankfully I had my drink in my other hand, but I looked around, and nobody reacted to it, nobody seemed to have seen it, and so I moved on. And my cataplexy attacks were so far apart from each other

1	point that he could pull me to where I needed to be to
2	understand what was happening to me. It was very
3	difficult to put those things into words.
4	I've been impulsive and irrational with my
5	eating habits forever. I believe, now looking back,
6	that the reason that I've always eaten the way I've
7	eaten is to survive and stay awake as much as I can,
8	carbs and sugars, carbs and sugars, and it has clearly
9	taken its toll on my body, and I'm catching up with
10	that, I don't know, I'm going to keep working at it,
11	but anyway.
12	I went 20 years with the mingling of these
13	symptoms and always that underlying excessive daytime
14	sleepiness, always with a short fuse, always with an
15	overwhelming negative attitude when someone woke me up.
16	Do you know how infuriating it is for someone to say,
17	"Good morning, Sunshine!" when all you want to do is
18	reel obscenities back at them?
19	(Laughter.)
20	MS. BOLLINO: My moods were they cost me
21	some jobs, they cost me some career things. In 2009, a
22	couple months before my 39th birthday, I was sent to a

1	neurologist by my primary care doctor because my hand
2	was falling asleep, and I was sitting in my living room
3	filling out the 12 pages of new patient forms that I
4	needed to fill out to go to a new doctor, and I came
5	across a question, and it described a loss of muscle
6	tone or temporary paralysis when struck with a strong
7	emotion, and I dropped the pen, and I said, "It's real.
8	Oh, my goodness." I couldn't even believe it. This
9	thing, this fleeting sensation that I had had and
10	experienced periodically for 20 years was real,
11	somebody knew what it was. And there were two other
12	questions that I ran across in that survey and had
13	similar reactions for me.
14	And when I went into the neurologist's
15	office, I sat down, and it became very clear within
16	about 2 minutes that my carpel tunnel was not the topic
17	of discussion for the day. He sent me home with a
18	pamphlet about narcolepsy and one about cataplexy, and
19	I got back to my car, and I sat and I read them, and it
20	was the answer to everything that had ever slipped
21	through my fingers, every dream, every sleep paralysis
22	episode, why I deeply knew that pursuing a career in

1	interior design was not just something I could do
2	because I didn't feel that I could ever stay awake for
3	a full day of work on a consistent basis, and why I
4	always avoided driving or doubled my driving time when
5	I went anywhere. I cannot describe to you the feeling
6	of relief that comes from finally knowing that the
7	labels "lazy," "antisocial," and "unmotivated" were
8	everyone else's labels on me and not in me, not part of
9	me, they were a part of narcolepsy.
10	Nowadays I prioritize my energy as much as I
11	can. I prioritize my meds as much as I can, that's a
12	roller coaster, because the tolerance levels always
13	have to be monitored, and going back and forth between
14	those things, my family is the ones that pay the price,
15	and that gets very frustrating. I try not to back down
16	from emotions for the fear of having cataplexy attacks
17	because, what is life if you're not living it?
18	Thankfully, my cataplexy attacks are rare. When
19	they're laughing, I can feel it coming, and I can calm
20	myself down, but in the case of anger, I try not to be
21	angry. That's the one emotion that I've tried to fight
22	the most because they bring on the most severe attacks.

1	I was baited into some big decisions in my
2	life by low self-esteem, lured by loneliness and
3	depression, into what I now realize is a trap, and I'm
4	somewhat limited in my tools to break out of that trap
5	because of my inability to make a full-time income,
6	support my family, and the only thing I have to say
7	about the trap is I'll find a way out, and narcolepsy
8	is a darn good trap.
9	It's stifling and frustrating to not be able
10	to use the talents I possess to give back to the world,
11	to the people around me, to those I love, and springing
12	that trap is my mission, and I hope that being here
13	today is going to lead to treatments that can help us
14	all spring that trap.
15	Thank you for inviting me here today, for
16	setting up this initiative and including narcolepsy.
17	I'm grateful to have had this opportunity to represent
18	the narcolepsy family and especially to represent those
19	people who have not been diagnosed.
20	Thank you.
21	MS. GIAMBONE: Thank you, Carrie. Thank you.
22	(Applause.)

Capital Reporting Company FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013

1	MS. GIAMBONE: Joe?
2	MR. POPLAWSKI: For me, the absolute worst
3	symptom of narcolepsy is the excessive daytime
4	sleepiness. The daytime sleepiness pervades my every
5	waking moment. It is a horrible feeling to constantly
6	have the urge to lay down and sleep no matter where I
7	am. I rarely, if ever, feel fully awake. I feel like
8	I'm in a constant battle between being asleep and being
9	awake, never really sure which realm I'm actually in.
10	In general, I sleep 12 to 18 hours a day with my
11	longest stretch of sleep being about 42 hours.
12	These sleep attacks and falling asleep in
	These steep decaeks and fatting asteep in
13	public or inappropriate times is embarrassing and quite
13 14	
	public or inappropriate times is embarrassing and quite
14	public or inappropriate times is embarrassing and quite often humiliating, so most of the time I decline
14 15	public or inappropriate times is embarrassing and quite often humiliating, so most of the time I decline invitations to do things. However, any plans that I do
14 15 16	public or inappropriate times is embarrassing and quite often humiliating, so most of the time I decline invitations to do things. However, any plans that I do make always include a way out or an escape to get away
14 15 16 17	public or inappropriate times is embarrassing and quite often humiliating, so most of the time I decline invitations to do things. However, any plans that I do make always include a way out or an escape to get away so I can sleep without people realizing it. I find
14 15 16 17 18	public or inappropriate times is embarrassing and quite often humiliating, so most of the time I decline invitations to do things. However, any plans that I do make always include a way out or an escape to get away so I can sleep without people realizing it. I find reasons to run errands or go home just so I can sleep
14 15 16 17 18 19	public or inappropriate times is embarrassing and quite often humiliating, so most of the time I decline invitations to do things. However, any plans that I do make always include a way out or an escape to get away so I can sleep without people realizing it. I find reasons to run errands or go home just so I can sleep in my car in a parking lot or sleep at home without
14 15 16 17 18 19 20	public or inappropriate times is embarrassing and quite often humiliating, so most of the time I decline invitations to do things. However, any plans that I do make always include a way out or an escape to get away so I can sleep without people realizing it. I find reasons to run errands or go home just so I can sleep in my car in a parking lot or sleep at home without people realizing it.

1	maddening. The fogginess causes me to forget
2	conversations or commitments that I have made or made.
3	This has caused me a lot of problems over the last
4	several years because people decide that I'm unreliable
5	or that I'm ignoring them or neglecting them or not
6	honoring my commitments that I've made to them or to
7	others. Imagine the horror of waking up, looking at
8	your phone, and realize that you have had several
9	lengthy phone conversations that you have absolutely no
10	recollection of. This has happened to me quite often.
11	Finding the right combination of the
12	medications is also a never-ending challenge.
13	Balancing the side effects against the effectiveness
14	and then battling the insurance companies, that is, if
15	you can find a doctor who will actually write you the
16	prescriptions in the first place, not to mention the
17	judgmental pharmacists.
18	There was one time I had a pharmacist leave
19	addiction information in one of my prescription bags.
20	When I confronted him, he said there is no need for
21	anyone to have my level of medications. Needless to
22	say, I found a new pharmacy. That pharmacy is no

1 longer in business.

2	Overall, my symptoms have changed
3	considerably since 2005. Before, naps would refresh me
4	for short periods of time, but now even on medication I
5	feel like an alert zombie. I also originally did not
6	have cataplexy, but in the last couple years I've been
7	developing cataplexy that manifests itself when I get
8	into extremes of mood or emotion. I have also found
9	that over time that my sleep paralysis is becoming
10	increasingly worse, and if you have never experienced
11	this, consider yourself lucky.
12	Just a few years ago, I was exercising,
13	walking and running 2 to 3 hours a day. I was quite
14	active, going backpacking, camping, and on other high
15	adventures with my sons. However, since things have
16	started getting worse, I am largely inactive, and as a
17	result, in less than 3 years I have gained well over
18	100 pounds. Also, as a result of years of different
19	medications, I have lost most of my teeth, and now I
20	need to go through the embarrassment of having the rest
21	of them removed.
22	Because of narcolepsy and my excessive need

1	to sleep, I have largely withdrawn and isolated myself
2	socially, and because of such, I have lost or detached
3	from most of my family and friends. I avoid
4	invitations to activities and events, my sons have
5	largely seen me sleep away the days for the last 7
6	years. I constantly feel that I have let them and my
7	wife down. I would love to be able to work, but
8	unfortunately I have not found a job that can
9	accommodate me. I was self-employed and had a
10	successful business but had to close it down and sell
11	it off in 2005 because I was no longer able to keep up
12	with the demands of being a business owner.
13	Despite all this, I do try to keep a positive
14	attitude and attempt to use my wakeful time as
15	productively as possible, especially with my sons.
16	They're awesome. I constantly hope that at some point
17	someone will come to me with something that will give
18	me true wakefulness, even if only for a few hours a
19	day.
20	Thank you.
21	(Applause.)
22	MS. GIAMBONE: Thank you, panelists. I want

(866) 448 - DEPO www.CapitalReportingCompany.com © 2013

1 to thank our panelists for so courageously sharing your 2 stories. So thank you.

3 So what we'll do now is we'll have a polling 4 question which I think will help kick off our group 5 discussion, so everybody get your clickers out again.

And again I'm going to read this out for you. 6 7 So of all the symptoms you have experienced because of 8 narcolepsy, which do you consider to have the most significant impact on your daily life? And you can 9 10 choose up to three symptoms: cataplexy, daytime 11 sleepiness, hallucinations while waking up or falling 12 asleep, sleep paralysis, difficulty sleeping, restless 13 leg syndrome, activity while sleeping, such as sleepwalking, or other symptoms not mentioned. 14 15 (Pressing clickers.)

MS. GIAMBONE: Okay. All right, so it looks MS. GIAMBONE: Okay. All right, so it looks like overwhelmingly that the daytime sleepiness is the most significant symptom followed by cataplexy and difficulty sleeping. Okay. And then it looks like we actually do have a good bit of -- we have a spread, we do see some hallucinations and also sleepwalking and other activities while sleeping, but I do see that

Capital Reporting Company FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013

		77
1	there are other symptoms not mentioned, so I definitely	
2	want to make some time during our group discussion to	
3	address those also. Okay?	
4	So let's get started with our group	
5	discussion. I'm going to	
6	MR. VALENTINE: And I'll just note that on	
7	the webcast it almost is an exact mirror of what was	
8	displayed here in the room.	
9	MS. GIAMBONE: Okay, great. Thank you.	
10	Large-Group Facilitated Discussion on Topic 1	
11	MS. GIAMBONE: All right. So does anybody	
12	want to share their experience with cataplexy to kick	
13	off our conversation?	
14	Yes.	
15	MS. FLYGARE: Hi. I'm Julie Flygare. I have	
16	severe cataplexy, so for me, it took a few years to	
17	develop from a slight drop of my muscle to being a full	
18	body attack. I would just like to describe what it	
19	feels like, the best I can describe to be in a full	
20	cataplexy attack, it feels to me like I am awake inside	
21	a corpse. I am completely conscious, and all I think is	
22	just move your toe, just move your finger, do anything,	

1	and nothing responds. And those milliseconds or
2	minutes that go by feel like the longest of my entire
3	life and makes everything else so much sunnier.
4	Anytime I can stand feels like a gift. And also you
5	feel like you can't breathe even though you can, and
6	your heart goes. All I think is I just want to breathe
7	deeper, just give me my breathe. Am I going to stop
8	breathing? Where am I? Am I awake? Is this closer to
9	not being alive? I don't know.
10	So for me, having severe cataplexy is a huge
11	part of my experience, and something that is
12	terrorizing of almost every second. Even when I have
13	my muscle tone right now, I know what it feels like to
14	not trust this because this might be this any second.
15	Thank you.
16	MS. GIAMBONE: Thank you, Julie.
17	Does anybody want to follow up on that?
18	Yes.
19	UNIDENTIFIED SPEAKER 1: Thank you. My son,
20	who is 16, has narcolepsy. When he started with his
21	symptoms at age 10, they hit hard and fast, the
22	excessive sleepiness and the cataplexy. One example

1

2

was during an Easter egg hunt that April a couple of	
months after the onset of symptoms. At that point, he	
had not been diagnosed and we were having our annual	
Easter eag hunt in my house with my three children	

had not been diagnosed and we were having 3 Easter egg hunt in my house with my three children. 4 The one with narcolepsy and cataplexy is the oldest 5 one, and he was 10 then, and my children, my younger 6 two, were running around grabbing the eggs like crazy, 7 8 so excited, but my 10-year-old couldn't move his arms and couldn't walk. So my husband and I were scurrying 9 around grabbing eggs and throwing them in his bag, and 10 11 he was crying and just it was an awful scene. And his 12 cataplexy was constant throughout the day. He missed 3 13 weeks of school straight while we tried to visit doctor from doctor trying to find an answer. 14

15 We had to videotape his cataplexy because the doctors didn't believe anything was wrong because in 16 the office he would pass every neurological exam. 17 18 Finally, he had the diagnosis of narcolepsy. But one 19 thing that he said through the beginning when things were starting to happen for him quickly is he felt a 20 21 popping feeling a lot throughout his body, and it's 22 something that we've brought up to doctors, but he said

Capital Reporting Company FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013

1	inside his body he felt things popping at the beginning
2	of the onset of the symptoms. So that's my son's
3	experience with cataplexy in the beginning.
4	It is controlled now, but he said it is
5	always there. And I think what he means by that, he
6	has to be on guard knowing that any emotion can trigger
7	it. We still see it in his facial muscles, but he
8	doesn't drop down to a full collapse anymore.
9	MS. GIAMBONE: Thank you. And I actually saw
10	quite a few heads nodding, so can we do a quick show of
11	hands to see how many others have experienced that
12	popping sensation for an oncoming cataplexy attack?
13	(Show of hands.)
14	MS. GIAMBONE: Okay. Thank you.
15	Anybody else want to follow up?
16	UNIDENTIFIED SPEAKER 2: Thank you. My son
17	was diagnosed at the age of 7 with narcolepsy and
18	cataplexy and I didn't think today would be so
19	emotional. The biggest all I can say is anyone who
20	has a child, if you look over and what you think is
21	your perfectly normal, healthy boy is laughing at
22	dinner with the rest of his family and he falls off the

1 chair in a complete puddle, your first instinct is to 2 obviously be scared to death that something is severely 3 wrong.

My older kids -- he's the oldest -- my 4 younger two, when we were living here in Virginia at 5 this time, his cataplexy was not under control, he was 6 7 at that point 9, 9 and 10. The younger two, my 8 youngest, at that point being 4, would run upstairs and say, "Mom, John is having really bad cataplexy, really 9 10 bad cataplexy. You need to come down now." The fact 11 that my 4-year-old had to see her brother, who she 12 admired and looked up to, in a complete puddle on the 13 ground, and being scared at that age is not something that a younger child should have to see. And my son 14 15 who is right below him would always warn me, "Mom, he's having really bad cataplexy, you need to come down now. 16 17 He's not moving. He's not moving." And they knew, and 18 they had seen it, so they knew what to expect, but it 19 was still so scary to see. 20 My son, now at the age of 16, is under, I

20 My son, now at the age of 10, is under, 1 21 would say, control, but he is a wrestler, and I do see 22 him when he's around the mat with his friends crouch --

1	he crouches when he feels a cataplexy attack come on,
2	and I can tell, and his friends just think he's tired.
3	But he gets into a crouching and he's on the ground so
4	that if he does fall, he doesn't have far to go. And
5	that's his experience.
6	MS. GIAMBONE: Thank you.
7	Let's take another comment. How about right
8	here in the back? Sure.
9	UNIDENTIFIED SPEAKER 3: Hi, there. I just
10	wanted to express that my worst situations for
11	cataplexy happened when I was in a medical facility
12	with people of every range of knowledge around me that
13	did not know what cataplexy was, and I think anyone
14	with cataplexy would agree, that's one of the other
15	areas we need to conquer.
16	I had a severe attack once when I was with
17	friends that didn't know I had narcolepsy or cataplexy,
18	and as it was happening I had enough time to say, "I
19	have narcolepsy. I something called cataplexy. This
20	is what's happening. Leave me alone. Don't call
21	anybody. I'll be fine. Just lay me down." In fear,
22	they called am ambulance. By the time the ambulance

1	got there, I couldn't communicate, and they told the
2	ambulance personnel, "She keeps saying she has
3	something called cataplexy, she'll be fine." In the
4	ambulance ride to the hospital I heard them saying back
5	and forth, "What is this? I've never heard of this.
6	She has to be a drug overdose. Is she drunk? What's
7	going on?" They were sticking me with needles, doing a
8	million things.
9	When I got to the hospital, I had a doctor
10	that tortured me for 6 hours. I had the knuckle rub in
11	my breastbone. He did something to my fingernails that
12	caused great pain. I had smelling salts put under my
13	nose. And the entire time the staff was being told
14	that I kept saying I had something called narcolepsy
15	and cataplexy, and I even told them before I dropped,
16	"Go Google it."
17	(Laughter.)
18	UNIDENTIFIED SPEAKER 3: On Textbook, it's right there.
19	And the only good thing that came out of that 8 hours -
20	- and I was almost put on a 3rd floor psych ward was
21	the ambulance driver came back and he came in the room
22	and he held my hand and he said he was sorry. He got

1	off his shift that day and went home and he Googled it,
2	and he came back in and told me he talked to the rest
3	of the staff, and he came to personally apologize. I
4	still was in a war with the doctor, and unfortunately,
5	because of that, I lived close enough to Johns Hopkins,
6	I won't go anywhere else again. And I think we need
7	awareness and knowledge in the medical community as
8	much as everything else.
9	MS. GIAMBONE: Thank you for that.
10	Let's switch gears a little bit and talk
11	about if anybody would like to share some comments on
12	daytime sleepiness. I know we heard yes. And like
13	I said, if you're comfortable to do so, please state
14	your first name. And we'll take a few comments on
15	daytime sleepiness, and then I would really like to
16	touch upon some of the other symptoms that haven't been
17	mentioned.
18	MICHELLE: My name is Michelle, and I was
19	initially diagnosed back in my twenties and initially
20	starting off around seven or eight, I would actually
21	pass out. So anywhere from two to three times a year
22	the paramedics would always come for me. And back

1 then, of course, my parents and everyone else, they 2 called it spells, and most people thought that I was 3 just faking, they were saying, hey, I just wanted 4 attention.

5 But getting back to excessive daytime sleepiness, I'm now in my forties, and it's been so 6 overwhelming as far as losing friends, not being able 7 8 to spend time with family and so forth, even working. I started off as a software developer, and I would 9 10 actually develop programs, and people would come in my 11 office and they would make statements later to me, 12 "Michelle, you were so rude. I was trying to hold a 13 conversation with you, and you just continued to type and design -- write scripts and so forth," and what was 14 15 actually happening was it was I was falling asleep, but I was able to still halfway perform. 16

But, again, my point is just going through it, it really has been difficult because friends and family to this day, they still do not understand. Most, they see it as a joke, they laugh and so forth. There have been times that I have been out eating, and my face would fall into the plate, and it's so

1	embarrassing at times. Meetings and so forth, just
2	dozing off, and walking, and even standing up at places
3	at times and then just passing out.
4	But, again, my biggest struggle is, again,
5	besides the excessive daytime sleepiness, is the fact
6	that I just wish people would be willing to at least
7	find out what it is because, like you said, once you
8	tell a person what it is, the least I tell people that
9	you can do is to at least look it up because it is
10	something that is serious, and just having to go
11	through life for so long and just having to manage
12	time.
12 13	time. Another example I can give everyone, too.
13	Another example I can give everyone, too.
13 14	Another example I can give everyone, too. Just for me to get dressed, I have to set timers every
13 14 15 16	Another example I can give everyone, too. Just for me to get dressed, I have to set timers every day. I have anywhere from 20 to 25 timers. So on my
13 14 15 16	Another example I can give everyone, too. Just for me to get dressed, I have to set timers every day. I have anywhere from 20 to 25 timers. So on my cell phone now I have to time myself so I don't spend
13 14 15 16 17	Another example I can give everyone, too. Just for me to get dressed, I have to set timers every day. I have anywhere from 20 to 25 timers. So on my cell phone now I have to time myself so I don't spend too much time getting dressed, I don't spend too much
13 14 15 16 17 18	Another example I can give everyone, too. Just for me to get dressed, I have to set timers every day. I have anywhere from 20 to 25 timers. So on my cell phone now I have to time myself so I don't spend too much time getting dressed, I don't spend too much time eating. I have to use my navigation system
13 14 15 16 17 18 19	Another example I can give everyone, too. Just for me to get dressed, I have to set timers every day. I have anywhere from 20 to 25 timers. So on my cell phone now I have to time myself so I don't spend too much time getting dressed, I don't spend too much time eating. I have to use my navigation system everywhere that I go, and I make it a point to put

1	But, again, I thank everyone for giving us an
2	opportunity, those people that are narcoleptic,
3	regardless whether you have cataplexy or not, for just
4	giving us an opportunity to come out today and to at
5	least express ourselves because this is a disability
6	that really needs to be taught. Thank you.
7	MS. GIAMBONE: Thank you.
8	Let me turn to my FDA panel. Does anybody
9	have any questions?
10	Yes, Dr. Farkas.
11	DR. FARKAS: Yeah. So a lot of people are
12	talking about a state of not complete awareness and
13	some kinds of forgetfulness, and I was just wondering,
14	I don't know how you want to ask people about this, if
15	that was when people were feeling sleepy or if that was
16	something that could happen when people weren't really
17	so aware of feeling sleepy.
18	MS. GIAMBONE: I see quite a few hands here.
19	Yes.
20	UNIDENTIFIED SPEAKER 4: Hi. So the question
21	was about like half awareness/half asleepness, and
22	whether or not you're aware of feeling that way? Is

(866) 448 - DEPO www.CapitalReportingCompany.com © 2013

1 that right?

DR. FARKAS: Well, I mean, if there was a 2 feeling of sleepiness that would tell you it was coming 3 or during it, if it was really something that could be 4 really like a separate symptom from sleepiness, a 5 separate event. 6 7 UNIDENTIFIED SPEAKER 4: Oh, you mean like a sleep attack versus a persistent all-day sleepiness? 8 DR. FARKAS: Well, I mean, I guess that --9 10 UNIDENTIFIED SPEAKER 4: Maybe I'm misunderstanding and I should pass this on. 11 12 DR. FARKAS: Some of the descriptions I think 13 were like finding oneself having a phone conversation and then not remembering or doing kind of automatic 14 behavior, and I just wasn't really clear if people even 15 knew they were sleepy at those times. 16 17 SARIAH (ph): My name is Sariah. My personal 18 experience is that if I am sleepy but not too sleepy, 19 then I have insight into the fact that I'm starting to 20 get more confused, make more errors, and I can say to people, "I'm sorry. I'm aware that I'm making 21 22 mistakes." But when my sleepiness, whatever you want to

1 call it, gets past a certain level, I lose insight that
2 I'm really in trouble.

And the latest, most dramatic example 3 happened in August on a Tuesday morning when I was 4 trying to figure out whether this was the recycling 5 truck or the trash truck in front of me because my 6 7 recycling wasn't out yet, and I asked the worker next 8 to the truck, not being aware to any extent that of course the truck is labeled in gigantic letters, it was 9 right there in my visual field right in front of me. 10 Ι 11 said to the worker -- I decided for some unknown reason 12 that this was the trash truck, and I said to the 13 worker, "Do you know when the recycling truck is coming?" and he said, "This is the recycling truck." 14 15 And I said, "No, this is the trash truck." 16 (Laughter.) 17 Now, I'm an intelligent woman, but SARIAH: 18 it took me 5 seconds to realize that he had just told 19 me he was the recycling guy, and I could now go get my recycling that I had forgotten to put out. 20 I have a 21 very high IQ, but there are moments when I function 22 like I am intellectually disabled. Provigil isn't

1	enough for me. The amphetamine-like stimulants don't do
2	it. I can't take Xyrem because of side effects. I am
3	a talented woman, and yet I can't hold a job because I
4	can't rely on my brain to cooperate on a reliable
5	basis. It is so deeply frustrating.
6	MS. GIAMBONE: Thank you.
7	Let me actually check in with our let's
8	see if we have any comments coming in from the web.
9	Let's see here. Do we have a microphone runner going -
10	- Kim, would you mind taking the microphone over to
11	James?
12	MR. VALENTINE: Thank you. So in terms of
13	the questions that were presented in terms of Question
14	1, all of the symptoms that you experienced that
15	because of your condition have the most significant
16	impact, a lot of those are the same that have been
17	discussed in the room, the big focus being on EDS and
18	cataplexy. We did hear some interesting comments from
19	many of the web participants, probably the largest
20	response to Question 2 about specific activities that
21	are important to you, is work, whether it be lateness

napping during work, and other effects of EDS. There 1 2 is a lot of difficulty being able to work. A lot of people also mentioned activities of 3 daily living, simple things like walking stairs, doing 4 chores, being able to exercise, and in addition to 5 other complications with weight gain, not being able to 6 7 exercise, not helping with that. 8 I would say the other biggest category discussed on the web is that there is a large stigma 9 10 and misconception about narcolepsy and people not 11 understanding that you don't necessarily just fall 12 asleep out of nowhere, that there is this overwhelming 13 fatigue. And then there is also, related to stigma, also an embarrassment for when people do fall asleep in 14 15 public. And one person also wanted to mention something 16 a little unique, that there is not really a focus on 17 the emotional health toll that relates to narcolepsy, 18 especially with children. If emotions trigger 19 cataplexy or other onsets of the disease, it could be 20 something like laughter, and so with children, they try to hold back that emotion, and that has a toll on them. 21 22 MS. GIAMBONE: Thank you. Thank you.

1	So let's take a few more comments and then we
2	do have a break coming up, so I want to make sure we
3	stay on track with that.
4	Yes, go ahead. Let's take the gentleman over
5	there. If you could state your first name if you're
6	comfortable to do so.
7	SHANNON: Yes. My name is Shannon, from
8	Indiana. My wife, Patty. I'll speak on her behalf.
9	To answer your question, Doctor, in kind of more of a
10	clinical term, it's kind of like a conscious sedation.
11	She can be completely with a conversation and
12	completely be out of it at the same time. And I can
13	speak as to there are times that even cooking dinner
14	that I'm with her almost every day almost all the time
15	because if I'm not there, she's afraid that her safety
16	net is gone because I'm there to protect her. I have
17	to protect her in many different ways, but I protect
18	her from other people and knowing that it's time to go,
19	it's time to do this, or it's time to do that, and
20	oftentimes her forgetfulness goes very deeply, almost
21	to the point where she's afraid of Alzheimer's being
22	considered something or some sort of dementia or

diminished capacity. 1 2 MS. GIAMBONE: Thank you for that. Let's do a quick show of hands here. 3 I see that a few comments brought up this forgetfulness, how 4 you describe sort of your brain not being able to --5 not having control of your brain. By a quick show of 6 hands if you're comfortable, how many can relate to 7 8 that experience? 9 (Show of hands.) MS. GIAMBONE: Okay. Thank you. 10 11 Sorry, Dr. Unger, did you have a question? 12 (No audible response.) 13 MS. GIAMBONE: Oh, yes, please. I have a question. 14 DR. BASTINGS: I heard 15 from Kerry about really a fluctuation of symptoms where you had like a cycle where at times you could not sleep 16 at all for a duration of time, but then symptoms got 17 18 better and they were not as inundating for you, and I'm 19 wondering if it's something that other patients also 20 experience, where you have that cycle at times. 21 UNIDENTIFIED FEMALE SPEAKER: We can't hear. 22 MS. GIAMBONE: Okay.

1	DR. BASTINGS: Yes. My question is related
2	to the cycle of symptoms. Kerry mentioned that she at
3	times has significant symptoms where she can hardly
4	sleep at all, and at other times she is not quite as
5	inundated by the symptoms, and I'm wondering if that
6	cycle is something that other patients experience.
7	MS. GIAMBONE: Who would like to answer?
8	UNIDENTIFIED FEMALE SPEAKER: It's
9	unpredictable for me. I never know.
10	MS. GIAMBONE: Okay. Let's hear from
11	Justin, would you like to answer that?
12	MR. GREENE: Of course, I'm sure we're all
13	experiencing it differently, but I have noticed annual
14	cycles. Seasons, especially season changes, are the
15	worst for me, especially when it goes from winter to
16	spring. So severe bouts well, I call it insomnia,
17	but I can't sleep, and therefore excessive daytime
18	sleepiness is at its best, so to speak. And it's not
19	just then, the summer months, the hotter months, are
20	always the worst. On a daily basis, it's really hard to
21	say. I think annual is the only dependable routine

answers your question. 1 2 MS. GIAMBONE: Thank you. 3 Yes. MS. BARKER: Hi. I'm Eileen Barker. I think 4 I was one of the first people diagnosed 50 years ago. 5 And I thank you all for coming and being interested in 6 this. First I wanted to say I'm like the most organized 7 8 person to handle like disorganization because there are so many changes you have to deal with. And in answer 9 10 to the question about changes, it's like daily there 11 are changes, but I don't know if anybody else has found 12 this, I found them totally affected by the moon, like 13 the moon, I have a lot of energy, I feel great, and very organized, and I don't have the problem with like 14 15 losing my brain organization, and then all of a sudden 16 after those like 6 days, I'm back to where it's totally 17 disorganized. And even though I control my everyday life, I can't work to my fullest capacity when it's not 18 19 a full moon. 20 And I just wanted to also add that you have to encourage the young people that you definitely 21 should stay in school, you just have to work out a 22

1	schedule, and I don't know whether these people have
2	scheduled to have naps, but you have to know you have
3	to take naps. So I started with Dr. Pollock, he was
4	one of the original doctors for narcolepsy, and it's so
5	important to be able to schedule your life. If you
6	schedule your life, and you know that you have to take
7	rests, you know that you have to not drink alcohol, not
8	ever take any other drugs, and I hope that other
9	people, you'll be able to handle it better.
10	MS. GIAMBONE: Thank you. Thank you very
11	much.
12	Let's actually check in oh, I'm sorry,
13	Theresa, did you have a question?
14	DR. MULLIN: I would just like to ask a quick
15	follow-up to some of the things people were just saying
16	about the things that they think affect the cycling of
17	their symptoms, and I wondered if others were
18	experiencing what you're describing, sort of a seasonal
19	fluctuation, and maybe by a show of hands, have others
20	noticed seasonal variations with it?
21	(Show of hands.)
22	DR. MULLIN: So that looks like a fair number

Capital Reporting Company FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013

 of you are seasonal. And then maybe even possibly monthly or kind of lunar kind of cycle as well? (Show of hands.) DR. MULLIN: Some of you, not as many, but 	
3 (Show of hands.)	
4 DR. MULLIN: Some of you, not as many, but	
5 have also noticed that. Okay, thank you.	
6 MS. GIAMBONE: Thank you. That's a great	
7 question. Thank you.	
8 So let's actually check in with the phone for	
9 just a few comments. Okay, so, Operator, would you	
10 mind conferencing in the first speaker?	
11 OPERATOR: Thank you. Our first question	
12 comes from Samantha. And your line is open.	
13 SAMANTHA: Hi. I'm Samantha. Hello,	
14 everybody. I'm really interested to know like how	
15 exactly it happens. I had a grand mal seizure that was	
16 caused by nothing when I was 19 years old, and just	
17 like that, I was narcoleptic. I was able to go from	
18 sleeping 4 hours a night and then going to work all the	
19 next day, and then going out with my friends the next	
20 night to all of a sudden, all of a sudden, having to	
21 sleep 18 hours a day, just out of nowhere. I mean,	
22 it's affected everything, like I can't go to school	

1	more than one semester at a time, which in turn means I
2	have tons of student loans and my credit is shot
3	because I can't work enough to pay them off. It's been
4	taking a toll on everything. My relationships,
5	everything, everything.
6	MS. GIAMBONE: Thank you so much for that.
7	Operator, can we bring in the next caller?
8	OPERATOR: Yes. The next question comes from
9	Sue.
10	SUE: Hi, everybody. I just wanted to
11	comment about whether you know that the sleepiness is
12	coming on and how it affects you. I am fortunate that
13	I am able to have a very successful career. I was
14	diagnosed 17 years ago, but it wasn't always easy, and
15	narcolepsy still affects me during the day, not so much
16	that I fall asleep during the day but that I lose a
17	sense of concentration and focus. I was once called
18	intellectually lazy by one of my previous bosses
19	because there were times that I was very much on
20	target, productive, and just very with it and this
21	was before I was diagnosed and then other times it
22	would take me a very long time to generate the simplest

1	of work because I just wasn't focused and it was a
2	struggle, and I find that even now when the medication
3	is not working well or if I haven't slept well.
4	The same kind of thing with driving, I could
5	sleep very well at night and feel like everything is
6	going fine and I get in the car to drive, and at about
7	45 minutes I might have to pull over and take a nap,
8	whereas other times I might feel fine and I could drive
9	a few hours. And I don't really know if there is a
10	specific pattern or not, I haven't noticed specifically
11	seasonal or anything like that other than menstrual
12	cycle sometimes affects the sleepiness. Thank you.
13	MS. GIAMBONE: Thank you very much.
14	And actually on that note I would like to
15	ask, because I did see some heads nodding, to Theresa's
16	question, how many women here have noticed the cycle
17	with the menstrual cycle triggering your symptoms?
18	(Show of hands.)
19	MS. GIAMBONE: Okay. Great. Thank you. And
20	we'll take one more caller over the phone, Operator.
21	OPERATOR: And next we have Kara.
22	Ma'am, your line is open.

1 MS. MILLER: Thank you. Hi, my name is Kara 2 Miller. I wanted to comment on the symptom that has the biggest impact on my life, which is brain fog. It 3 feels as if I'm floating on a cloud through life, but 4 it's not a like fluffy one --5 6 (Laughter.) 7 MS. MILLER: -- it's like a gray and rainy 8 one. My head always feels heavy, my vision is usually blurred, and I never feel clear, which affects my 9 10 education, work environment, and my social life. It 11 becomes very depressing to the point where I've been admitted to multiple psychiatric units, and after I was 12 13 finally diagnosed with narcolepsy, I failed multiple semesters at school, although I did get my bachelor's 14 degree and recently quit my job because of the onset of 15 16 losing focus. What I want to feel is being able to be 17 clear. 18 MS. GIAMBONE: Thank you so much. 19 Okay. So let's see if we have any more 20 burning questions either from the FDA panel or if there 21 is any other symptom that we haven't talked about, 22 we'll take another comment.

```
101
 1
             Yes.
 2
              DR. COMO: Oh, yeah, hi. Peter Como. I'm
   from FDA in the Center for Devices and Radiologic
 3
   Health. I just noticed that 21 percent of you
 4
   mentioned that you had other symptoms. I would just be
 5
   curious as to what those were.
 6
 7
             MS. GIAMBONE: Yes. So, let's see, why don't
 8
   we --
 9
             UNIDENTIFIED FEMALE SPEAKER: Brain fog.
10
             UNIDENTIFIED FEMALE SPEAKER: Yeah, brain
11
    fog.
12
             MS. GIAMBONE: Okay. Let's see a show of
13
   hands for brain fog.
              Okay. Oh, and, Operator, you can go ahead
14
15
   and mute the line. We'll wrap up. Okay. Thank you.
                    (Show of hands.)
16
             MS. GIAMBONE: Okay. So I see quite a bit of
17
18
   hands for the brain fog.
19
              Any other symptom that we haven't heard about
   that you would like to speak to?
20
21
             UNIDENTIFIED SPEAKER 5: I would just like to
   say that for me daytime sleepiness is not just during
22
```

1	the day, it's also waking up in the mornings. I will
2	regularly set over 38 alarms and not wake up, or turn
3	them off in my sleep, and then once I'm awake,
4	automatic behaviors kind of control my life where I'll
5	put, let's say, the remote control to the TV in the box
6	of fish sticks, and it makes total sense when you're
7	doing it because, you know, maybe the next time you
8	watch TV you're going to want to remember to eat fish
9	sticks, but when you're conscious and aware, you have
10	no idea where these things are, and so your life, you
11	constantly go around in circles trying to find, well,
12	where are my keys? They're not where I left them. Did
13	I leave the garage door open? Did I shut it? Did I
14	lock the door? Did I feed the dogs? Did I take my
15	medicine? And the two of those have made the biggest
16	impact in my life.
17	MS. GIAMBONE: Thank you. Thank you.
18	So actually let's do this, we'll take a break
19	now. We did go over into break time a little bit, so
20	let's take a 10-minute break. And remember we do have
21	the public docket open. You can continue to submit
22	your comments there. It will be open for 2 months, so

(866) 448 - DEPO www.CapitalReportingCompany.com © 2013

if we didn't get to you during the Topic 1 discussion, 1 2 please do so there. 3 (Break.) MS. GIAMBONE: Could we have everyone take 4 their seats? 5 Okav. And I think there are a few more 6 people outside, but we'll go ahead and get started so 7 8 we can stay on time. So before we move on to Discussion Topic 2, 9 we would like to summarize the comments that came in 10 via the web for Topic Number 1 and just see if anything 11 12 new has come up. 13 So, Pujita, would you mind? 14 MS. VAIDYA: Thank you, Soujanya. 15 So, so far we have received hundreds of comments coming from the web, so I won't be able to 16 summarize all of them. I would like to quickly mention 17 18 some symptoms that have been mentioned, and that 19 includes forgetfulness, a lot agreed with the seasonal fluctuations and extreme change in temperature and its 20 effect on them; memory loss; constant fatigue; 21 22 depression; this is another one, they mentioned

Capital Reporting Company FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013

		104
1	injuries from other symptoms; anger and mood changes,	
2	which put a lot of stress on their relationships;	
3	symptoms affecting intimacy; and interactions and	
4	relationships between onset of symptoms and everyday	
5	substances, such as caffeine and alcohol.	
6	Thank you.	
7	MS. GIAMBONE: Thank you, Pujita.	
8	Panel #2 Comments on Topic 2	
9	MS. GIAMBONE: Okay. So let's go ahead and	
10	get started with Discussion Topic 2. Once again, my	
11	name is Soujanya Giambone, and I am with the Center for	
12	Drug Evaluation and Research, Office of Strategic	
13	Programs, and I'm the facilitator for today's meeting.	
14	So Topic 2 is on patients' perspectives to	
15	treatment options. So here we're looking at what	
16	generally works, what are the downsides, and what are	
17	your perspectives in decision making that go into	
18	current treatment options?	
19	So can we actually advance to the next slide?	
20	Once again, we have five panelists, just as	
21	we did with Topic 1, and they reflect a range of	
22	experience with narcolepsy. We have patients and	

Capital Reporting Company FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013

		105
1	patient representatives. And again they've each	
2	prepared 3 to 4 minutes of remarks in response to the	
3	topic questions. So what I'll have them do is go ahead	
4	and introduce yourselves again and then we'll get	
5	started with the panel discussion.	
6	DR. GREENSTEIN: I'm Allison Greenstein, and	
7	I'm from Radford, Virginia.	
8	MS. RAY: LaShun Williams, LaShun Ray.	
9	MS. THOMPSON: My name is Casey Thompson, and	
10	I am from Littlestown, PA.	
11	MS. O'SHAUGHNESSY: My name is Sharon	
12	O'Shaughnessy, and I'm suburban Philadelphia.	
13	MR. GREENE: My name is Justin Green. I'm	
14	from Leesburg, Virginia. I have narcolepsy without	
15	cataplexy, and I'm pretty happy to be here.	
16	MS. GIAMBONE: Thank you so much. So let's	
17	start once again with Allison.	
18	DR. GREENSTEIN: I would like to thank	
19	everybody and the FDA for allowing us all to be here	
20	and all the fellow narcoleptics for being in the room.	
21	Tired. Tired is the only feeling that I ever	
22	knew. I had plenty of reasons of why I was tired.	

1	Medical school makes everyone tired. Working 90 hours
2	makes everyone feel tired. Overnight call in the
3	hospital makes everyone tired. I could have slept for
4	a year and I still would have been tired. Spring of
5	2012 I finally complained enough to my attending
6	physician that my tired wasn't everyone else's tired.
7	Falling asleep eating wasn't normal. A series of blood
8	work and several sleep studies, four of them to be
9	exact, came to the conclusion that I have narcolepsy
10	without cataplexy. Having an actual diagnosis was both
11	comforting and both very scary. I was immediately
12	started on Provigil, and I felt amazing. I could sit
13	through noon lectures without falling asleep, but
14	within 3 weeks of being on Provigil, I noticed I was
15	getting short of breath. I could no longer go up a
16	single flight of stairs without gasping for air at the
17	top. I was seeing patients in the hospital one morning
18	and got so short of breath, my chest was tight, and I
19	felt miserable. I thought I was having a heart attack.
20	I walked to the nurse's station, I took my vitals, my
21	heart rate was 180, my blood pressure was 150 over 90,
22	and I thought, great, I really am having a heart

1 attack.

2	More tests occurred, more blood work, EKGs,
3	echocardiograms, and several Holter monitors later, it
4	turns out I wasn't dying, my heart was just beating
5	entirely too fast. It took months to sort out my heart
6	rate. It would jump from 60 to 160 in one second with
7	any movement. I could not do my laundry without
8	sitting and resting. Six months prior to my diagnosis
9	and starting medications, I ran my first half marathon
10	with my mother, who now runs faster than I do. I
11	couldn't make my bed. I saw cardiologist after
12	cardiologist, specialist after specialist, and I
13	usually receive the same perplexed look, I call it the
14	"dog ear" one where they tilt their head to the side
15	and go, "You take what medication and it does what
16	again?"
17	We all went to the same medical school, we
18	all know the same things, but my doctors couldn't help
19	me. My pharmacist had only seen Provigil prescribed a
20	handful of times; she wasn't very helpful either. My
21	choices were take your medication so you don't fall
22	asleep or don't take your medications, but then your

1	heart rate will be so fast that you might want to pass
2	out, so there wasn't a really great option.
3	I found a new neurologist at an academic
4	center, and she changed me from Provigil to Nuvigil.
5	This was slightly better, so instead of my heart rate
6	being 170, it was 140. I considered that to be an
7	improvement because I could now do my laundry. We
8	started out in heart medications then. The first
9	medication, I didn't notice any improvement. I could
10	see my heart rate was a little slower, but I still felt
11	terrible. After several trials, we finally found a
12	medication that works. My biggest frustration still is
13	any sort of incline, whether it be a stair, a mountain,
14	or a hill; they completely and absolutely wind me.
15	I'm a runner, and I'm a runner who lives in
16	Southwest Virginia. We don't have flat roads. There
17	is no flat road near my house. I have adjusted my
18	methods for running to accommodate my heart rate. I
19	use a Jeff Galloway run-walk method. Previously I
20	could run 4 minutes (sic) straight without having to
21	stop at an 11- minute pace, which I thought was pretty
22	good for someone who never considered themselves a

1	runner. Now I can barely get two, and then I have to
2	walk. Any sort of big hill I have to take an extra
3	walk break and hope that my running partner doesn't get
4	too far ahead of me.
5	In the middle of starting out my medications
6	and doses, I finished residency and started my real
7	doctor job as an outpatient internist. My insurance
8	didn't kick in for a month. My former hospital was
9	less than stellar with their paperwork, and my COBRA
10	coverage didn't happen, so I had no insurance for 2
11	months. My medications cost \$500 a month, and I had no
12	income.
12 13	income. During that time I was also taking my
13	During that time I was also taking my
13 14	During that time I was also taking my internal medicine boards, so it was about medicine,
13 14 15 16	During that time I was also taking my internal medicine boards, so it was about medicine, getting ready to study for the biggest test of my
13 14 15 16	During that time I was also taking my internal medicine boards, so it was about medicine, getting ready to study for the biggest test of my entire life. Thankfully, my insurance finally kicked
13 14 15 16 17	During that time I was also taking my internal medicine boards, so it was about medicine, getting ready to study for the biggest test of my entire life. Thankfully, my insurance finally kicked in, my copay is now \$160 for 3 months, and I realized
13 14 15 16 17 18	During that time I was also taking my internal medicine boards, so it was about medicine, getting ready to study for the biggest test of my entire life. Thankfully, my insurance finally kicked in, my copay is now \$160 for 3 months, and I realized why my patients don't take their medications: \$500 is
13 14 15 16 17 18 19	During that time I was also taking my internal medicine boards, so it was about medicine, getting ready to study for the biggest test of my entire life. Thankfully, my insurance finally kicked in, my copay is now \$160 for 3 months, and I realized why my patients don't take their medications: \$500 is the difference between keeping their electricity on or

1	are metabolized. Frustrated, I have sought out
2	alternative methods for my symptoms. I have also
3	switched to a gluten-free diet. I know a couple of
4	people have also mentioned that. This has helped me
5	feel like I have not been hit by a Mack truck when I
6	wake up. While I do not have celiac, I was tested for
7	antibodies, and I do have them, indicating I have a
8	sensitivity to gluten.
9	I have been to an acupuncturist. One of my
10	worst physical symptoms I think is muscle tension and
11	overwhelming fatigue. The more tired I am, the more my
12	shoulders and back muscles hurt. My acupuncturist had
13	never treated anyone with narcolepsy, but he had good
14	results with a similar patient who had MS and her
15	fatigue. I have not been many times yet, as I just
16	recently started it, but it does seem to appear to be
17	helping. I try to stick to a regular sleep schedule,
18	and I made sure that when I bought my bed that it's the
19	most amazing bed that has ever existed.
20	(Laughter.)
21	DR. GREENSTEIN: It cost a ridiculous amount
22	of money, but I love it. We call it the magical bed.

		111
1	I exercise 3 to 4 days a week. I try to avoid	
2	caffeine. And while I realize my medication isn't	
3	perfect, I remember 2 years ago when I would have to	
4	take a nap after taking a shower in the morning because	
5	I was already too exhausted to continue with my day.	
6	MS. GIAMBONE: Thank you, Allison.	
7	LaShun?	
8	MS. RAY: Hello. My name is LaShun Ray. I'm	
9	a single mother. It's important to know that I'm	
10	representing my 9-year-old daughter, LaShun Williams,	
11	and her first concern was, would she be able to take a	
12	nap? LaShun's symptoms started at the age of 5.	
13	When I pick my daughter up from aftercare,	
14	her body is in a battle to sleep and eat. Her will is	
15	to eat first and then sleep, but her body will is to	
16	sleep first. By the time we reach the front door, she	
17	is crying and I have to help her to bed because she can	
18	barely walk, and still she needs to eat. When she does	
19	wake up, her body is now battling hunger and a	
20	headache. This is a hostile battle of the body's needs.	
21	Currently, LaShun is taking two medications,	
22	and we're trying to find a third medication that will	

1	help control her narcolepsy symptoms. This means at
2	the age of 9 she will be taking two medications to stay
3	awake and one medication to sleep at night. LaShun
4	would like to play with friends at school without
5	needing a scheduled nap. Her naps take priority over
6	playing with classmates because missing a nap means she
7	will sleep for more the next day, sometimes 18 to 20
8	hours. I have been called home because she slept the
9	whole day in school, or I have missed work because she
10	doesn't wake up. LaShun feels like she is missing out
11	with class activities, which has created an issue for
12	socializing with classmates.

LaShun is taking the highest dose available 13 for one medication and the highest dose allowed for a 14 child for another medication, and she has scheduled 15 naps, but there is no relief, and her narcolepsy 16 symptoms are starting to change. The downside from my 17 daughter's viewpoint is taking large pills that 18 19 sometimes get stuck in her throat, and this is with 20 them being cut in half. And every day she keeps asking, 21 why does she have to take them? Her nighttime medication is salty (sic), and she has to be woken up 22

1	at the second dosage between 12:00 a.m. and 2:00 a.m.
2	The side effects that she has experienced
3	with her medications are headaches, making it difficult
4	for her to function or go to school; sleepiness, making
5	her arrival to school 2 hours late or missing a school
6	day; dizziness, making it difficult for her to stand or
7	walk or sometimes she can't even sit up; extreme
8	swelling of the face. Other symptoms that she has
9	experienced with the medication that she is currently
10	taking is appetite:
11	it depresses her appetite. So while we are
12	battling weight gain because of narcolepsy, we are also
13	battling the fact that she doesn't eat.
14	The downside from my viewpoint is the long-
15	term effects from taking these medications at the
16	highest doses, as the medications can become
17	ineffective quickly, and the effect these medications
18	are having on the liver and other organs.
19	As the sole caregiver, inconvenient dosing at
20	midnight, from 12:00 to 2:00 a.m., is taking a toll on
21	me, which has led me to being sleep deprived. I am now
22	

1	While trying to maintain LaShun's health, my
2	health is deteriorating. My daughter would like
3	smaller pills, and just one. As a parent, I would like
4	to see medications approved for children and teenagers.
5	The medication she is taking now is approved for adults
6	only. I tell LaShun the medications are to improve her
7	quality of life. No medication should decrease the
8	quality of life because of adverse side effects.
9	We would both like to thank you and thank FDA
10	for allowing us to speak.
11	MS. GIAMBONE: Thank you so much, LaShun.
12	Casey?
13	MS. THOMPSON: Hi, there. Just for a little
14	background, I'm going to be 44 next month, and I was
15	diagnosed when I was 27, but my earliest symptoms I can
16	remember were probably middle school. I was always the
17	girl that got in trouble for having her head on the
18	desk. And in high school I was always the one driving
19	into the school parking lot putting on my mascara at
20	the same time because of course I was out the door at
21	the last minute.
22	When I was first diagnosed, the first

1	prescription I was given was Ritalin. Previous to my
2	narcolepsy diagnosis, I had been diagnosed with an
3	essential tremor when I was 21, so Ritalin being my
4	first stimulant, we did not get along well at all. At
5	the time, I worked in the beauty business, and you can
6	all imagine what someone is thinking in a chair when
7	you're coming up there with scissors or clippers and
8	your hands are shaking like this.
9	So stimulants were out of the question, but I
10	did have a doctor ask me if I would like to try
11	Provigil, and of course I did because I wanted anything
12	to be able to function and be normal. Provigil made me
13	feel like I had toothpicks holding my eyelids open 24
14	hours a day, 7 days a week. I think it was the third
15	or the fourth day I had to quit because there was one
16	moment, I will never forget that day, that I was
17	looking this way and turned my head, and I felt like my
18	head was still over here, and it was moving across, but
19	I was like I literally thought people were looking
20	at me and seeing my eyes bulging and bugging out of my
21	head.
22	I went years without any medication and tried

1	to find ways to survive. I myself was also a single
2	mom with four kids, and when that occurred, I wound up
3	going into self-employment. It allowed me to sleep in
4	my business. At that time, I had a sofa in a back
5	room. Today I actually have a bed in my basement in my
6	business. Years went by. I could not lose weight. I
7	only gained weight when I was pregnant, but when you
8	come home from giving birth to twins, and you've gained
9	2 (sic) pounds, depression is beyond the word to use
10	for that. I did not know until maybe about 3 years ago
11	that the weight gain and inability to lose weight was a
12	component of narcolepsy, but before that, I tried
13	everything to lose weight. I had gone to doctors, I
14	had gone to weight loss specialists. I had somebody at
15	Weight Watchers once tell me that I wasn't going to get
16	anywhere if I was lying on my logs, and that was a real
17	struggle for me because I felt like I was an active
18	person, and I wanted to move around, but I just
19	couldn't lose weight no matter what I did.
20	When I finally reached the medical facility
21	where I'm at now and was offered Xyrem, I jumped at the
22	opportunity. For me personally it's been my miracle.

(866) 448 - DEPO www.CapitalReportingCompany.com © 2013

1	I hesitate to say that because I said that once to
2	someone and they said, "Well, then what's your
3	problem?" So I say it's a miracle to an extent, but I
4	still battle. My cataplexy has I don't want to say
5	it's completely gone, real stressful moments, I feel
6	the weight hit my thighs, and I tell myself to keep
7	standing, I have not gone down, I have not had full-
8	blown cataplexy since about 6 months into taking Xyrem.
9	I will say even though with taking Xyrem I
10	struggled in the beginning because the first doctor
11	that actually prescribed it to me, I was not aware that
12	I was the first person he had prescribed it to, and he
13	prescribed it at the full 4.5 dose for me to start. By
14	some miracle, I tolerated it well. I dealt with
15	incredible, incredible muscle cramps the first 3
16	months, but I was doing so well I was determined I was
17	going to get through those muscle pains. I've learned
18	now that I must eat a banana every day. I think it
19	helps with everything, from what I understand, with the
20	magnesium and the sodium and the potassium. If I go a
21	couple days without having that banana, I'm back with
22	leg cramps.

1	I haven't had a lot of the other side effects
2	that many people I have connected with on the internet
3	have had with Xyrem, but I do have a problem with the
4	seasonal situation. I feel like my body is controlled
5	by the sun. When the fall comes and the darkness
6	comes, my body wants to sleep when it gets dark, and my
7	body wants to awake with the sun. My doctor last year
8	suggested I try Philips goLITE. I did purchase that in
9	the spring. I can't really make a comment on it yet,
10	how it's working. I figure that when I begin using it
11	this fall as we're starting to change with the lighting
12	now that maybe I'll see some type of difference, but my
13	greatest struggle that still remains is, of course, the
14	daytime sleepiness and the seasonal battle. I really
15	go through a war in the winter and fall months until
16	April/May comes along.
17	I felt like the worst mom in the world
18	because I used to get up and get my kids off to school
19	and come home and lay back down again. It's really
20	hard to feel like you can't do something you should be
21	able to do. If I didn't have the ability to be self-
22	employed, I don't know where I would be.

1	And my greatest challenge, and I think this
2	is a really big component of the medication factor, is
3	I want a job. I want a job that's Monday through
4	Friday. I've worked my entire life more than all of
5	it, including weekends. I would love to know what a
6	9:00-to-5:00 Monday through Friday job is, and I'm
7	terrified of going back to school. I used to love
8	reading books, and I'll get four pages into it and be
9	done. It's like somebody injected me with something,
10	and, whew, gone. Even now with the Xyrem, I mean,
11	that's still a problem, that I think, my god, how could
12	I go back to school? But yet at the same time, if I
13	had had Xyrem when I was in high school, I think, wow,
14	where could I be? I really could be somewhere else if
15	I had had this opportunity and this advancement back
16	then.
17	But right now I look towards what I consider
18	the next half of my life, and what can I do and where
19	will I be? And I don't want narcolepsy to control me,
20	I want to control it, and I'm hoping at some point I

22 understand that it's real, it's not the joke in the

21 get that power, and also that the people around me can

(866) 448 - DEPO www.CapitalReportingCompany.com © 2013

movies, and that it's just not a joke in any way, 1 2 shape, or form. And that's all I have to say. Thank you for 3 allowing me to be here and share this. Thank you. 4 5 MS. GIAMBONE: Thank you so much, Casey. Sharon? 6 7 MS. O'SHAUGHNESSY: Thank you very much for 8 giving us the opportunity to share our stories. Part of what makes this disorder so difficult is that you 9 really can't talk about it to people because everybody 10 11 has been tired, this is just a different level that 12 people don't understand. Since my earliest memories, 13 I've had extreme sleepiness, fractured sleep, and hypnagogic hallucinations. I was finally diagnosed 14 15 with narcolepsy at 42, and I've been under treatment 16 for 6 years. 17 You asked in your questions about other 18 conditions? I also have fibromyalgia, Raynaud's, 19 eosinophilic esophagitis and other digestive issues, allergies and asthma, high blood pressure, and short-20 term memory issues, and a lot of these disorders are 21 22 often seen with long-term nonrestorative sleep, and

1	many people complain of multiple autoimmune disorders.
2	In the 35 years it took me to get a
3	diagnosis, my doctors and I muddled through a lot of
4	well-worn but ineffective options, mostly in the
5	sedation family. When I got the narcolepsy diagnosis,
6	I tried Xyrem. The morning after the second night I
7	bounded out of bed awake and joyful, but my husband
8	said, "You don't remember last night, do you?" It
9	turns out I was having seizure-like movements for over
10	an hour that wouldn't subside even when my distressed
11	husband tried to physically stop them from happening.
12	So I called Jazz hoping for a dosage tweak, and they
13	told me to stop taking Xyrem immediately. I was
14	crestfallen. Even with that hour of flailing, it was
15	still the best I've ever felt waking up.
16	So for me and other people who can't take
17	Xyrem, we really need a pharmaceutical option for
18	fixing sleep architecture rather than mere sedation.
19	Having experienced both, I can tell you there is a huge
20	difference in how the patient understands the feeling
21	of being the sleep architecture improved rather than
22	just being sedated and out cold for a couple of hours,

1 not to mention a monetary option.

2	I administer a website of over 500 diagnosed
3	narcoleptics, and people are documenting that they are
4	being charged over \$10,000 a month for Xyrem. That's
5	the dark side of orphan drug status. Yeah. I've got
6	documentation. And it varies all over the country, so
7	that's interesting, too. But that's the dark side of
8	orphan drug status, a \$6,000-a-month increase, just
9	since I became aware of this drug, per month. We need
10	a pharmaceutical alternative that competes with Xyrem.
11	It's a wonder drug for many, and we are really grateful
12	that it's on the market, but the market needs an
13	option.
14	Lacking something like Xyrem that I can take,
15	my treatment consists of frequent naps, Lunesta,
16	Nexium, Norvasc, Lyrica, Claritin, and asthma
17	medications when needed. I think a lot of this is just
18	the sleep part of it, all these other systems go awry.
19	Supplements I've found to be helpful are multivitamin,
20	magnesium, B complex, EPA/DHA, Vitamin D, and broad
21	spectrum pre- and probiotics. Exercise is always
22	helpful, but it's really hard when you're always

1	exhausted, and everybody knows that, but it does help
2	if you can just make yourself do it. Good nutrition
3	helps my energy level. I eat almost no processed food,
4	the majority fruit and vegetables, some meat, and a
5	very small amount of whole grains.
6	I take Lunesta. It's mildly sedating. I
7	feel mostly awake when I'm supposed to be asleep. If
8	someone moves in the house, I hear them. My kids say I
9	never sleep, and in the morning it feels like I didn't
10	sleep. I set multiple alarms in different places in my
11	room to wake up in the morning.
12	Digestive issues, I have pared down to a very
12 13	Digestive issues, I have pared down to a very basic diet. I have immediate gastric symptoms if I
13	basic diet. I have immediate gastric symptoms if I
13 14	basic diet. I have immediate gastric symptoms if I ingest something that's in natural flavors, but since
13 14 15	basic diet. I have immediate gastric symptoms if I ingest something that's in natural flavors, but since companies won't tell me what those ingredients are even
13 14 15 16	basic diet. I have immediate gastric symptoms if I ingest something that's in natural flavors, but since companies won't tell me what those ingredients are even when I write to them, I can't isolate it, so I'm left
13 14 15 16 17	basic diet. I have immediate gastric symptoms if I ingest something that's in natural flavors, but since companies won't tell me what those ingredients are even when I write to them, I can't isolate it, so I'm left rarely eating out. I cook at home from scratch.
13 14 15 16 17 18	<pre>basic diet. I have immediate gastric symptoms if I ingest something that's in natural flavors, but since companies won't tell me what those ingredients are even when I write to them, I can't isolate it, so I'm left rarely eating out. I cook at home from scratch. B complex helps with memory and cognition.</pre>
13 14 15 16 17 18 19	<pre>basic diet. I have immediate gastric symptoms if I ingest something that's in natural flavors, but since companies won't tell me what those ingredients are even when I write to them, I can't isolate it, so I'm left rarely eating out. I cook at home from scratch. B complex helps with memory and cognition. Pre- and probiotics are supposed to help digestive</pre>
13 14 15 16 17 18 19 20	<pre>basic diet. I have immediate gastric symptoms if I ingest something that's in natural flavors, but since companies won't tell me what those ingredients are even when I write to them, I can't isolate it, so I'm left rarely eating out. I cook at home from scratch. B complex helps with memory and cognition. Pre- and probiotics are supposed to help digestive health, but I haven't seen any difference with the</pre>

		124
1	maybe during college and exams, report an uneasy creepy	
2	feeling in your stomach, like if you eat something, it	
3	may not go well, and I live with this feeling all the	
4	time, and I wonder if that's also related to sleep	
5	deprivation.	
6	How well has this therapy worked? It hasn't.	
7	I have a master's degree in a scientific field. I	
8	have, on my own schedule, without deadlines, written	
9	legislation that got passed, and raised several million	
10	dollars for causes I support, but my productivity just	
11	cannot be predicted. This obviously makes it	
12	impossible to support a family. Employers won't put up	
13	with chronic lateness and perpetual missed	
14	appointments. I only volunteer so that when I	
15	inevitably hit a few days or even a week at a time of	
16	forced sleep, no one can be mad because they're not	
17	paying me.	
18	A few years ago I had a friend who wanted to	
19	hire me for a six-figure position doing something I	
20	really wanted to do. I was excited, but I said, "Give	
21	me 2 weeks to see if I can live on a human schedule."	
22	So I woke up at 8:00 a.m., took my Provigil, and tried	

		125
1	to stay awake for 10 hours, and then wound down at	
2	night and went to bed early, and by Thursday I had such	
3	bad hypnagogic hallucinations during the day that I	
4	couldn't even read a newspaper. I also discovered at	
5	that time that a couple of days of a full dose of	
6	Provigil caused auditory hallucinations that were	
7	gravely concerning, so I stopped taking Provigil as	
8	well.	
9	So I am here to convey to you the frustration	
10	of having intelligence and a solid educational	
11	background but not being able to contribute	
12	productively on the awake schedule that society	
13	demands. I look forward to hearing that our organized	
14	cohesive patient base and willingness to participate in	
15	research yield treatment alternatives for narcolepsy.	
16	Thank you.	
17	(Applause.)	
18	MS. GIAMBONE: Thank you, Sharon.	
19	And, Justin?	
20	MR. GREENE: Hello. First of all, I talk	
21	loud, I'll back up. These are some awesome comments,	
22	and I thank every one of you and everyone in the	

1	audience for your attention to this, and certainly
2	thank you to everyone here at the FDA. It's a
3	fantastic session and a fantastic opportunity.
4	I'm really glad that someone else has a
5	tremor. I'm not alone.
6	My strategy for living with narcolepsy
7	depends on many things like stress, tolerance to
8	medication, and the season of the year, as I mentioned
9	earlier, and yet success is only guaranteed if I follow
10	a very strict weekly regimen that includes a stimulant
11	for my daily awareness, depressant for sleep at night,
12	and a weekly drug holiday to continually fight the need
13	or rather fight the problem of tolerance, and a
14	faultless determination to avoid interruptions to my
15	schedule. It sounds like a tall order. It is. It
16	doesn't happen.
17	My chief concern with treatment, albeit there
18	are many discouraging symptoms and side effects, is the
19	increased physiological tolerance to the medication.
20	Prior to using narcolepsy-approved medication, I was
21	incapable of participating in my life. I cannot stress
22	that enough. I was incapable of participating in my

1	life. Nevertheless, the benefits have diminished and a
2	standard of living is now harder to maintain when the
3	short hours of the day are further limited by the
4	combined threat of excessive daytime sleepiness, sleep
5	deprivation, medicinal side effects, physical and
6	psychological stress, and societal expectations, which
7	can and have rendered my treatment completely void.
8	Undoubtedly, I believe that early detection
9	and efforts to improve the social awareness of the
10	condition should be required aspects to a holistic
11	approach to treatment. I am confident that there is
12	not a single solution; rather, there are many.
13	Tailored strategies based on the differing needs of at
14	least three groups of people that I can identify:
15	those without cataplexy; those with; and those with
16	additional comorbid afflictions, like myself and as you
17	mentioned. I suggest that it's from these three groups
18	that requirements be collected and independently used
19	to develop new medicinal solutions.
20	Additionally, I believe that there are device
21	innovations that can beln but the short- and long-term

21 innovations that can help, but the short- and long-term 22 consequences of introducing things like normal life,

1	normal people do, like drinking caffeine, drinking
2	alcohol, experiencing stress, and just downright
3	ineffectual medication should be evaluated during the
4	drug development process. It's not just, "Does it
5	work?"; it's, "Does it work under these circumstances?"
6	It is this information that will assist a patient in
7	developing a careful balance between managing what it
8	is that engages them and also avoiding the triggers of
9	the condition.
10	So now here is my story. At age 9, I was
11	evaluated to have a 153 IQ. For those of you who don't
12	know, that's pretty high. At age 11, the night terrors
13	started. By 12, I couldn't sleep and I couldn't stay
14	awake. Ten years later, by age 22, I was finally
15	diagnosed. Two years after dropping out of college
16	because I slept through it, and I could not maintain
17	the GPA that I needed in order to maintain the
18	financial aid that many institutions were so grateful
19	to give me.
20	Now I'm 27, and as my meds start to fade, I
21	am losing more than just a few hours of sleep; I am
22	losing my ability to help others. I'm pretty good at

(866) 448 - DEPO www.CapitalReportingCompany.com © 2013

1	it. I'm losing my ability to care for my children.
2	And I'm losing the ability to care for myself.
3	So I have a few requests. I want us to go
4	back to the drawing board. I want us to start over.
5	This time I want us to include all the demographics,
6	not just a blanket approach, "We think this might
7	work." And I would really like to be the last of the
8	children that had no choice but to sleep through a
9	bright future.
10	(Applause.)
11	MR. GREENE: That is the most important.
12	Thank you.
13	MS. GIAMBONE: Thank you so much, Justin.
14	And let's give all of our panelists a round
15	of applause for sharing their stories.
16	(Applause.)
17	MS. GIAMBONE: And one thing I do want to do
18	before we go to our polling question and begin our
19	group discussion is to, if you're comfortable to do so,
20	by a show of hands, how many of you heard something
21	that's similar to your experience in what the panelists
22	have shared?

1 (Show of hands.) 2 MS. GIAMBONE: Great. Okay. 3 So let's do our next polling question, which we'll go through that one and then -- okay. So once 4 again let's get your clickers out. Okay. 5 Have you ever used any of the following drug therapies to help 6 reduce your symptoms of narcolepsy? And you can check 7 8 all that apply. A, modafinil, armodafinil, methylphenidate, or amphetamine; B, antidepressant 9 10 drugs, off-label use; C, Xyrem, or sodium oxybate; D, 11 other drug therapies not mentioned; or, E, I'm not 12 sure. 13 (Pressing clickers.) 14 MS. GIAMBONE: Okay. Wow. So we do see that 15 for answer A, modafinil, armodafinil, methylphenidate, 16 and amphetamine, that 100 percent of those of you in 17 the room today responding to this question have used 18 these drug therapies, followed by Xyrem. And then we 19 see antidepressant drugs, and then other drug therapies not mentioned, which we'll certainly talk about. And 20 we also see a little bit of other treatments that 21 22 you've used that you're not sure of.

1	Okay. So let's touch upon those. And
2	another thing I want to do again before we dive into
3	the group discussion is let's do another show of hands.
4	We heard quite a few downsides to treatments in our
5	panel discussion. We heard dizziness, headaches,
6	appetite issues. It was even brought to my attention
7	that downsides to treatment were also dental, dental
8	issues. So let's do a show of hands here. Let's start
9	with the dental issues. Show of hands, how many have
10	also experienced that?
11	(Show of hands.)
12	UNIDENTIFIED SPEAKER 6: Can I say something?
12 13	UNIDENTIFIED SPEAKER 6: Can I say something? MS. GIAMBONE: Sure.
13	MS. GIAMBONE: Sure.
13 14	MS. GIAMBONE: Sure. UNIDENTIFIED SPEAKER 6: I have been taking
13 14 15	MS. GIAMBONE: Sure. UNIDENTIFIED SPEAKER 6: I have been taking Ritalin and all the amphetamines for like 30 years, and
13 14 15 16	MS. GIAMBONE: Sure. UNIDENTIFIED SPEAKER 6: I have been taking Ritalin and all the amphetamines for like 30 years, and then my teeth were really bad, and then I had
13 14 15 16 17	MS. GIAMBONE: Sure. UNIDENTIFIED SPEAKER 6: I have been taking Ritalin and all the amphetamines for like 30 years, and then my teeth were really bad, and then I had infections, and then I spoke to my girlfriend, who is a
13 14 15 16 17 18	MS. GIAMBONE: Sure. UNIDENTIFIED SPEAKER 6: I have been taking Ritalin and all the amphetamines for like 30 years, and then my teeth were really bad, and then I had infections, and then I spoke to my girlfriend, who is a doctor, and she said that the medication is what makes
13 14 15 16 17 18 19	MS. GIAMBONE: Sure. UNIDENTIFIED SPEAKER 6: I have been taking Ritalin and all the amphetamines for like 30 years, and then my teeth were really bad, and then I had infections, and then I spoke to my girlfriend, who is a doctor, and she said that the medication is what makes you have dry mouth, which makes you have disease. So I

132 MS. GIAMBONE: Thank you. And I did see a 1 2 lot of heads nodding when she mentioned the dry mouth. All right. And how about dizziness and 3 headaches? 4 (Show of hands.) 5 MS. GIAMBONE: Okay. All right. Dizziness 6 and headaches, I wanted to see by show of hands because 7 8 that was another symptom, but, okay, great. So let's go ahead, and let's do the next 9 polling question if that's all right. Okay. 10 11 Besides your drug therapies, what therapies 12 have you used to help reduce your symptoms of 13 narcolepsy? A, naps; B, dietary modifications; C, exercise; D, counseling and support groups; E, other 14 15 therapies not mentioned; and, F, I'm not using any additional therapies. So we'll take a minute to answer 16 17 that polling question. 18 (Pressing clickers.) 19 MS. GIAMBONE: Okay. So naps definitely 20 seems to be the most prevalent therapy used other than 21 drug therapy. We also seem to have dietary 22 modifications and exercise have an equal standing,

1	followed by counseling and support groups, other
2	therapies not mentioned, which we'll talk about, and
3	I'm not using any additional therapies, which is also
4	very interesting to see.
5	So let's check in with the web and see what
6	the polling results look like there.
7	MS. VAIDYA: On the web, we actually have a
8	pretty similar distribution, so it's quite identical.
9	Thank you.
10	MS. GIAMBONE: Okay. Great. And I do want
11	to mention before we start with the group discussion
12	that if we're not able to get to all of your comments -
13	- and I know that in Topic 1 we weren't able to get to
14	everyone's comments just a reminder that we do have
15	the public docket open, available. It's just as
16	important as our group discussion here today. It's all
17	part of the public record, and we very, very much value
18	all of the comments that come in through the public
19	record.
20	Large-Group Facilitated Discussion: Topic 2
21	MS. GIAMBONE: So let's go ahead and start
22	with: What therapies have you used to help reduce your

		134
1	symptoms of narcolepsy? Does anybody want to talk	
2	about how let's start with naps and see, how are the	
3	naps a significant part of your therapy? Does anybody	
4	want to	
5	UNIDENTIFIED SPEAKER 7: It's not something	
6	voluntary. It's necessary. And a couple a day.	
7	MS. GIAMBONE: Okay. Thank you. And again	
8	if you could please state your name if you're	
9	comfortable to do so.	
10	MS. GRADY: I'm Kim Grady. But with that	
11	being said, our society is not very nap-friendly, and I	
12	have a child who is trying to take naps during school,	
13	but the school doesn't accommodate it because of the	
14	schedule. And I had a glimpse into how well he could do	
15	in school if he did not have narcolepsy, which was	
16	pretty I mean, he's a bright kid, and like you, has	
17	a high IQ, but he was able to take the PSAT and he was	
18	able to take it with a nap after we fought to get this	
19	where he didn't need more time. I mean, the worst	
20	thing for a person with narcolepsy is more time. I	
21	mean, you don't need more time, you need time to take a	
22	nap. So he would take a section of the test and then	

		135
1	he would nap, he would take a section and nap, take a	
2	section and nap, and he did phenomenal. But our	
3	schools and our society does not revolve around that,	
4	they cannot accommodate that, and that's a fact, but	
5	it's very upsetting as a parent to see what the	
6	potential of your child is and know that they can't	
7	reach that because of, A, medication, and, B, our	
8	world.	
9	MS. GIAMBONE: Right. So from what I	
10	understand, on one hand it's something necessary, but	
11	from hearing what you just described and also hearing	
12	from our panel, that naps are not well received	
13	sometimes in school or in the workplace, so I see	
14	UNIDENTIFIED MALE SPEAKER: It's based on the	
15	school system.	
16	MS. GIAMBONE: Okay.	
17	UNIDENTIFIED FEMALE SPEAKER: Yeah, it's the	
18	school.	
19	UNIDENTIFIED SPEAKER 8: There is a law. You	
20	do have to go to a public school, but if you go to a	
21	public school, Section 504 of the Americans with	
22	Disabilities Act is your friend, and it does guarantee	

1	equivalency and you work with teachers individually
2	into the classroom, and you should look into that.
3	My actual comment is about naps. People have
4	called me a high-functioning narcoleptic. I guess that
5	means that the medications work halfway decent for me,
6	and I've been through high school, college, and now
7	I've just completed my master's work. So I have gotten
8	through school. I did really well on the SATs without
9	having the additional time. I got 5s and 4s on AP
10	exams without additional time. But I couldn't have
11	done that if they were at a bad time of the day. So
12	the thing with naps is that if your workplace or your
13	school says, "We can schedule you a nap, but it has to
14	be between the hours of 10:00 and 10:30," that doesn't
15	work because you have this thing, the excessive daytime
16	sleepiness, it's affected by what you've eaten, it's
17	affected by your mood, it's affected by, I don't know,
18	if the moon looked green one night. There are all
19	sorts of things that affect it, it's a complex
20	interaction, and so just having a set time to take a
21	nap doesn't always work. You might need a nap after
22	lunch one day and the next day you don't, but you could

1 really use one mid-morning.

2	There are times of day I think that tend to
3	be worse for people with narcolepsy. Like I've been to
4	the conferences, and right after lunch, they just
5	really ought to just schedule everybody takes a nap
6	because people aren't terribly functional, but it does
7	differ from person to person. It's very individual,
8	and I think that's something that a lot of people lose
9	sight of when they're talking, "Well, just have a
10	scheduled nap." Well, a scheduled nap doesn't always
11	work.
12	While I have the microphone, I am going to
13	comment that Xyrem is a wonder drug, but the price is
14	exorbitant. If I had not had insurance, I would have
15	paid \$9,382 for the shipment I got last week. I have
16	insurance, but insurance also means that I just
17	finished my master's work. I would love to go do
18	something for a nonprofit and like, say, kids with AIDS
19	in Africa, but, A, I can't travel, Xyrem is only here
20	in the States and I think maybe Great Britain if you're
21	not depending on National Health Service. So that
22	complicates my life: it makes it so I can't do what I

		138
1	want to do. And I have to find a job with health	
2	insurance, I have to, and I have to do that before it	
3	runs out, and without the extension given by so-called	
4	Obamacare, I would not have been able to complete	
5	school because I wouldn't have had insurance, I	
6	couldn't have paid for Xyrem, and without Xyrem, I'm	
7	not functional. I hate the side effects of Xyrem, and	
8	somebody needs to come up with a time-released version.	
9	MS. GIAMBONE: Thank you.	
10	Let me actually turn to the FDA panel and see	
11	if there are any specific questions on treatment	
12	options and downsides and so forth.	
13	Yes.	
14	DR. YASUDA: I was wondering for the	
15	antidepressants that people take, is that for the	
16	symptom of depression or is that to help you sleep at	
17	night or for some other reason?	
18	MS. GIAMBONE: Okay, so let's see, did	
19	everybody hear the question?	
20	UNIDENTIFIED FEMALE SPEAKER: No.	
21	MS. GIAMBONE: Okay. Would you mind	
22	repeating, Dr. Yasuda?	

139 DR. YASUDA: For the antidepressants that 1 2 people take, I was wondering if that's for the symptom of depression or to help you sleep at night or for some 3 other reason. 4 5 MS. GIAMBONE: Okay. So, let's see, by a show of hands -- why don't we do that? -- for a show of 6 hands, antidepressants for depression? 7 8 (Show of hands.) 9 MS. GIAMBONE: And what was -- for sleeping? (Chorus of "cataplexy.") 10 11 MS. GIAMBONE: Oh, cataplexy. Okay. Okay. So let's see, okay, for cataplexy, let's see a show of 12 13 hands. 14 (Show of hands.) 15 MS. GIAMBONE: Okay. To help fall asleep -oh, to depress the REM sleep? 16 17 (Show of hands.) 18 MS. GIAMBONE: Okay. And is there some other 19 reason perhaps? 20 UNIDENTIFIED SPEAKER 9: Antidepressants, SSRIs and SNRIs can be very effective in depressing REM 21 intrusions during the day and decreasing the amount of 22

		140
1	REM sleep during the night. They can be effective to	
2	some degree. Tricyclics are very useful in treating	
3	cataplexy, but there is certainly no panacea.	
4	And they have side effects that can be bad	
5	for dental health.	
6	MS. GIAMBONE: Okay. So the comment was and	
7	there are also side effects that are bad for your	
8	dental health.	
9	UNIDENTIFIED SPEAKER 9: Among others.	
10	MS. GIAMBONE: Mental or I'm sorry. Did	
11	you say dental?	
12	UNIDENTIFIED SPEAKER 9: Dental.	
13	MS. GIAMBONE: Dental. Okay. Yep. Okay.	
14	Yes. Can we have the microphone over here,	
15	please?	
16	UNIDENTIFIED SPEAKER 10: Would you please	
17	leave just a few minutes for the future research and	
18	treatment?	
19	MS. GIAMBONE: Sure. Yeah. And also, yeah,	
20	thank you. And I also want to encourage once again, we	
21	do have the public comment, which I believe at this	
22	point we've already it's closed at this point.	

		141
1	Okay. So we might hear something there, too. Okay.	
2	And public docket also. We will save some time for	
3	that, but just a reminder that we also have the public	
4	docket to contribute comments there.	
5	UNIDENTIFIED SPEAKER 11: Can you please	
6	share the URL for the public docket so people can	
7	contribute?	
8	MS. GIAMBONE: Okay. It's on the website.	
9	And is it also on the agenda or no? Okay. It's on the	
10	website. Okay. Thank you.	
11	Sorry?	
12	UNIDENTIFIED SPEAKER 12: I just wanted to	
13	bring to the FDA's attention that if you talk to people	
14	with narcolepsy, they are using many, many, many	
15	different medications, OTC, prescriptions, in a	
16	tremendous attempt to deal with the symptoms. It's not	
17	just the approved medications. And people will be	
18	using them in multiple layers. So some people will	
19	take a Ritalin before they drive home from work just to	
20	get home on top of other stimulants that they're taking	
21	at the beginning of the day, and Xyrem at night. And	
22	so it's just really a pharmacopeia of options, and you	
1		

1	really need to be aware of that. They're trying
2	everything, everything, and the behavioral, and
3	vitamins and anything that anybody suggests to them.
4	So please be aware that's what's going on.
5	MS. GIAMBONE: Thank you for that comment.
6	Yes. I see a hand here.
7	UNIDENTIFIED SPEAKER 13: This will be my
8	last comment for a while. But the Xyrem my son was
9	the 9th child in the country on Xyrem, and he is 16,
10	and he was diagnosed at 9. I want you to know, as
11	Richard said, it is a pharmacopeia of drugs that our
12	kids and our adults are on. John goes from three drugs
13	to four drugs to sometimes five drugs, depending on
14	what he's doing and where he's going. He's currently a
15	16-year-old boy who takes Xyrem at night, that does not
16	take away his cataplexy, he takes Effexor for
17	cataplexy, he takes Ritalin in the morning, he takes
18	the highest dose of Nuvigil, and he still cannot make
19	it through a day without falling asleep three to four
20	times and having a nap at night before he goes to try
21	and get his homework done, and that's the reality of
22	many people with narcolepsy.

1 Thank you. MS. GIAMBONE: 2 UNIDENTIFIED SPEAKER 1: Can I just add to 3 that as well? My son is 16, and he is on the highest dose of Xyrem. That does control his cataplexy for the 4 5 most part; however, we see it in his face. He is on the highest dose of Nuvigil. He's on Ritalin in the 6 7 morning, and if he needs Ritalin at lunch, that's there 8 for him as well. He needs to nap at school. He sleeps on the way to school. He sleeps on the way home from 9 He sleeps when he gets home after he has a 10 school. snack. And he has to have his homework done by 10:30 11 12 to start the Xyrem dose in order to get up by 6:30 in 13 the morning. So if his homework is not done, then he has to close the books and go to school. He does play 14 15 a sport, so to squeeze that in as well. And I would never have him give the sport up because I think having 16 that addition to his life helps socially and also helps 17 18 him stay physically fit. He is a junior now. He has 19 big plans for college. But to squeeze everything in 20 and function and get the good grades, it's very 21 difficult. Thank you. 22 MS. GIAMBONE: Thank you.

1	So we'll take one more comment and then we'll
2	also check in with the web. And I'm glad that you
3	brought up that the exercise is something that you're
4	keeping important for your son.
5	Would anybody like to build on that and talk
6	about since that is I do see that that was one of
7	the therapies that helps reduce your symptoms. Anybody
8	want to share some thoughts on that?
9	Why don't we take this gentleman right here?
10	GARY: Thank you very much. My name is Gary.
11	I'm speaking on behalf of my wife, Nancy. We just want
12	to point out that "nap" is a very relative term. Some
13	people, 15- to 20-minute naps might work. In our case,
14	it's a 2- to 3-hour, quote/unquote, nap. So if you
15	have to take two or three of those a day, that's
16	already a large chunk out of whatever time you had of
17	your waking time. So at what point does a nap stop
18	being a therapy and start being just part of the
19	problem?
20	MS. GIAMBONE: Sure. Thank you for that
21	comment.
22	Let me check in with the web with my

1 colleagues here. Any new comments coming up on the 2 web?

3 MR. VALENTINE: Yes. So I'll just run through some of the, I guess, high-level comments that 4 a lot of people are saying. One, first, a lot of 5 people are raising issues with therapies needed for 6 comorbidities. Some examples include beta blockers, 7 8 other opioids, and allergy medications. There are several comments about still not -- even though the 9 10 medications are helpful, they still can't drive and 11 they're still afraid to get a job, so there are still 12 those impacts on their lifestyle. While many of the 13 medications help decrease the daytime sleepiness, the 14 alternative is that it makes it harder to sleep at 15 night, and it also does not help with, minimize, the 16 brain fog or forgetfulness. There are a lot of 17 comments about everything with this treatment regimen, 18 everything has to be planned, so you can't have 19 spontaneity in your life. And related to that, it 20 makes it difficult because when you're raising 21 children, you don't often have control over spontaneity 22 in your life.

1	There are issues with the stimulants with a
2	buildup of tolerance as well as addiction and abuse,
3	and that although there is a reduction in the symptoms,
4	it does not eliminate them, and they agreed with a lot
5	of the conversation in the room that therapies need to
6	address sleep structure.
7	MS. GIAMBONE: Thank you.
8	Pujita?
9	MS. VAIDYA: In addition to that, some web
10	participants have mentioned that they appear to be
11	awake when they take the medications, but they're more
12	like in a zombie-like state. And one web participant
13	also mentioned that keeping the room cold actually
14	helped with their symptoms.
15	Just to mention a few treatments that were
16	mentioned, a web participant mentioned that a gluten-
17	free diet has helped them, caffeine, and taking Vitamin
18	B supplements, and blue light-blocking eyewear.
19	Thank you.
20	MS. GIAMBONE: Thank you.
21	So I do see that people have brought up
22	different downsides to treatment, some of the brain fog

and so forth. Would anybody like to talk about your 1 2 experience with some of the downsides of the treatment that you're taking? 3 Let's see. Let's hear from back there, the -4 5 - yeah, there is a lady back in the third row. Exactly. 6 7 LIZ: I'm Liz. And there are people that have these symptoms that are very enormous to describe, 8 but then there is a large percentage of people that 9 10 either don't get diagnosed or have the diagnosis but 11 have a lot more simple versions of a lot more like 12 sedate comments to give a doctor, where you don't have 13 giant comments. Then you have things like the amphetamines, which recently we've discovered might be 14 creating at times in my day pressed speech is what a 15 16 therapist in family therapy had said, and I just get 17 maybe more energized in that point in the day, but to 18 my parents, it really pisses them off to hear the way 19 that I'm talking to them, and I can't control it, and 20 they don't realize that it's not within my control, but 21 it's one of those things that's a very more subtle concept, it's not a huge deal, and I think there are a 22

	14
1	lot of other things that over time after you've had the
2	diagnosis and after you're on the drugs, you begin to
3	compensate. Someone asked like, "What's it like? Are
4	you sleepy?" I would say I don't even really know what
5	the differences are anymore because you've just like
6	ameliorated everything, and not to say that I don't
7	still have ups and downs of your day, it's just you
8	begin to forget what it ever felt like before you had
9	narcolepsy.
10	So in describing, it's good to talk to other
11	people because like the word "brain fog," I wouldn't
12	have come up with that on my own, but as you talk to
13	others and have the support groups, then you realize,
14	yeah, yeah, that's it, or things like the
15	hallucinations and stuff. To me, I said it wasn't
16	seeing pink elephants, it was I knew my housemate was
17	talking about me, or my dreams are very real, and until
18	I had someone discuss it similarly in a setting like
19	that, you wouldn't have ever told anyone because it was
20	just paranoia on your part or something like that.
21	So more of the commenting on the simple
22	things to understand what it is that is aggravating

		149
1	your life because otherwise it's just things that, you	
2	know, someone else was saying they woke up in the	
3	morning and was always really nasty to their mother.	
4	Well, you could say that was a teenage thing or you	
5	could later realize that that was a sleep-related	
6	thing.	
7	So it's kind of having doctors listen to	
8	narcolepsy, listen to the symptoms, and maybe use	
9	narcolepsy as more quick of a possible than just	
10	treating all these other things separately.	
11	MS. GIAMBONE: Sure. Thank you. And that's	
12	actually a great place to see I did see some heads	
13	nodding when she was speaking. So in terms of the	
14	impact on speech and how you I believe we heard on	
15	the web the zombie-like state where you're sort of out	
16	of control of what it is you're experiencing. Does	
17	anybody else experience that, by a show of hands,	
18	impact on speech and	
19	(Show of hands.)	
20	MS. GIAMBONE: Okay. Okay. So let's move on	
21	to one of the questions for this particular topic is	
22	also: What is your perspective on the ideal treatment?	

150 So who would like to offer some thoughts on that? 1 Yes, 2 this gentleman right here. UNIDENTIFIED SPEAKER 14: Orexin. It's all 3 about orexin. We need orexin replacement therapy 4 somehow. That's the whole business right there. 5 MS. GIAMBONE: Okay. I'm sorry? 6 7 (Off mic comments.) MS. GIAMBONE: Okay. In the back, let's give 8 them --9 10 VIRGINIA: Hi. I'm Virginia. I have bipolar disorder and narcolepsy, and Xyrem is pretty 11 12 much the only thing that doesn't interact with my 13 bipolar meds. And I would really like to see if there is something else out there that could -- or if there 14 would be something else out there in the future that 15 could not interact because it's nice to have other 16 options because although it's really great, Xyrem is 17 18 inconvenient sometimes because you have to plan ahead 19 your schedule, but that's what I wanted to say. 20 MS. GIAMBONE: Okay. Thank you. 21 So I have heard from our panelists and also a 22 few other comments that the planning ahead with the

1	Xyrem and the dosing schedule is challenging. Would
2	anybody else like to follow up on that? Let's see.
3	Oh, okay, here, yeah, right here.
4	UNIDENTIFIED SPEAKER 15: Hi. I have
5	something really important to say about Xyrem. It is a
6	miracle drug, and I would not be functional, I would be
7	in a wheelchair, without it. And it's also an issue
8	because I am 24, I will be under my dad's insurance
9	until I'm 26, and I cannot pay \$8,000 a month for
10	Xyrem. Currently I pay a \$35 copay under the
11	insurance, and even though it's a wonder drug, it's not
12	accessible, it's not realistic, and, I mean, some
13	people, like one of the panelists said she's so
14	thankful she's self-employed, and, I mean, I just have
15	such a hard time, I make maybe \$5,000 a year at a part-
16	time job, I can't afford my own health insurance, so
17	that was one issue.
18	But the biggest issue with Xyrem is I have
19	severe like sleep eating, kind of a zombie-like state,
20	that's what I call it. I've gained a significant
21	amount of weight. Every night I end up walking
22	downstairs and I'm half aware of it sometimes, I will

1	eat like a frozen loaf of bread out of the freezer, I
2	will eat things that I would normally never eat. I
3	will wake up feeling positively ill, like a family size
4	bag of potato chips, like just any and everything. And
5	for the past I want to say like 6 weeks I haven't, and
6	that is because we have been barricading me in my
7	bedroom, which is both dangerous and very concerning.
8	The other thing with Xyrem is and I have talked to
9	other people I know, this is a concern if there was
10	a fire, if anything were to happen to you, I mean,
11	especially for those who live alone, I live with my
12	family, I mean, what would you do? How would you be
13	roused in the event of that happening, especially now
14	that I am barricaded in my room?
15	So Xyrem, you know, on the one hand, it
16	allows me to function at a much higher rate than I was
17	functioning, but it is not you know, it's almost
18	causing more problems it's at the point where you're
19	at one end or the other. Do you go with just keep
20	getting late, just keep eating this food, making
21	yourself feel sick, having all kinds of problems, or
22	where you're pretty much wheelchair-bound and

1	cataplectic and having hallucinations all the time?
2	So my idea of an ideal treatment would be
3	something that's, first of all, not like \$10,000 a
4	month, and second of all, almost, like they were
5	saying, treats like the cause, like treats the
6	hypocretin loss, you know, whatever the problem is to
7	begin with that it would kind of more address that
8	without the extreme side effects.
9	And I know everything has side effects, but
10	some of these side effects are really scary. And I've
11	had narcolepsy since I was 11, so when you're a child,
12	to give your child that kind of medicine, I mean, it's
13	scary. Like she said, her son is on the highest dose,
14	I'm on the highest dose, I take a million other drugs.
15	I mean, at what point you know, I'm 24 now. I mean,
16	how is this going to affect me, my body? It's a
17	concern. So that's all.
18	MS. GIAMBONE: So may I ask a follow-up
19	question, and this could be for the greater group, too,
20	is I think you described it as irrational eating, is
21	that how you described
22	UNIDENTIFIED SPEAKER 15: I'm in a zombie-

		154
1	like almost like they say, what everyone has said,	
2	where they're in that fog, it's almost like a fog. So	
3	I might have a vague recollection of going into the	
4	kitchen and having this intense need for popcorn. And	
5	my mom I mean, it is disruptive at our household	
6	she will find me rummaging through and sometimes	
7	I'll be mean, I'll say I just need a little bit of this	
8	or a little bit of that, and I won't remember it.	
9	They'll tell me this in the morning, or I'll wake up	
10	covered in chocolate, and my bed is covered, you know,	
11	with it is and I have no memory of it. So it's	
12	not really irrational, it's that I have no control over	
13	it. I have no control over it.	
14	MS. GIAMBONE: Yep. I do remember that	
15	somebody had also described something very similar and	
16	had called it irrational eating or this uncontrolled	
17	eating.	
18	(Off mic comment.)	
19	MS. GIAMBONE: Okay. Automatic behavior.	
20	Okay.	
21	UNIDENTIFIED FEMALE SPEAKER: Like just go	
22	and do.	

1 MS. GIAMBONE: Sleep eating. Okay. 2 Yes, Theresa. 3 DR. MULLIN: Can I just ask a question? Ι mean, we talked earlier in the day about the symptoms 4 and the things that were most bothersome, and if there 5 were a therapy, and since you have it, you all probably 6 7 know what you mean when you say it's a miracle drug or 8 it's great, but what are the things that you would most like the drug to get rid or take care of or reduce? 9 10 The things that you talked about earlier, what's your 11 list, short list, maybe of things you would like the drug to deal with that you're experiencing? 12 13 MS. GIAMBONE: Let's take right over here. 14 Yes. 15 UNIDENTIFIED SPEAKER 16: Good afternoon. Thank you for the opportunity to answer this question. 16 If I could name two things, it would be, one, keep me 17 18 awake; two, get rid of the brain fog. I don't have 19 some of these multiple medications that a lot of the 20 brave people in this room have, but let me just very 21 quickly tell you about my last 24 hours. I stopped at 22 my mom's house. I was supposed to go back to my

1	boyfriend's house after that and be there to help get
2	his daughters ready for school in the morning. I ended
3	up falling asleep at my mom's, where I spent the whole
4	night, the next day, woke up after it was too late to
5	get the girls off to school, even though I went over
6	there anyway, thought, gee, I better get my act
7	together, had a few family questions come up that I
8	needed to address, which really were not rocket
9	science, but by the time I was able to address those
10	issues that naturally come up in a family, try to shift
11	gears, I was so dopey and brain foggy that for me to
12	organize everything I wanted to pack up in my car, get
13	dressed, and come here, I showed up here today at 3:15
14	in the afternoon when all I wanted to do was be here at
15	1:00.
16	I live in Falls Church, Virginia. I didn't
4 🗖	

16 1 live in Falls Church, Virginia. I didn't 17 have to buy a plane ticket or anything to come here, 18 but anything that would help not only keep my eyes 19 open, because sometimes people see you standing up, 20 sitting there out of bed, and assume that you are fully 21 wide awake and functional, and that is not always the 22 case.

1	One more comment, this list here, first of
2	all, thank you to whoever came up with the questions
3	for being willing to listen to people who live with
4	what we live with on a daily basis. That having been
5	said, for me to think of a nap as therapy sounds
6	absurd. I don't mean to be disrespectful, but a nap is
7	not therapeutic, a nap is a symptom. It happens
8	whether we want it to or not
9	(Applause.)
10	UNIDENTIFIED SPEAKER 16: and we can't organize it
11	around anything else. It will hit at my office, it
12	will hit in my car in the parking lot before I go into
13	the office. I was caught dozing off plenty of times by
14	coworkers at that office where I am unfortunately no
15	longer working.
16	So thank you very much for listening to that,
17	but it's not just keeping your eyes open, although that
18	would be a great start.
19	Thank you very much.
20	MS. GIAMBONE: Okay. So we'll take one more
21	comment addressing Theresa's question: For the ideal
22	therapy, what is it that you would want to address? So

		158
1	we hear keeping awake and addressing the brain fog.	
2	And anybody else want to let's go ahead and take a	
3	comment in the back.	
4	UNIDENTIFIED SPEAKER 17: This gentleman is	
5	right, it is all about orexin. And I just want to say	
6	that being on a no sugar and gluten-free diet has	
7	improved everything for me.	
8	MS. GIAMBONE: Okay. Thank you very much.	
9	UNIDENTIFIED FEMALE SPEAKER: Soujanya?	
10	MS. GIAMBONE: Yes.	
11	UNIDENTIFIED FEMALE SPEAKER: This lady asked	
12	if she	
13	MS. GIAMBONE: Oh, okay. Yes.	
14	UNIDENTIFIED SPEAKER 18: I have not slept	
15	longer than about $2-1/4$ hours since I was in my	
16	twenties. To me a miracle drug would be something that	
17	would allow me to sleep through the night.	
18	MS. GIAMBONE: Thank you very much for that	
19	comment. And, yes, we'll take one more.	
20	Kim, if you don't mind.	
21	UNIDENTIFIED SPEAKER 19: Thank you. Thank	
22	you very much for having this opportunity. I've worked	

1	with people with narcolepsy for 20 years, and it's not
2	just the symptoms that we see over there. It affects
3	their lives in every way, their social lives, their
4	relationships with school, with kids, with coworkers.
5	And it's kind of, as we discussed at the break, an
6	invisible disorder. A lot of people will say, "Well,
7	you look okay. You're not in a wheelchair. You're not
8	going to die from it."
9	I don't have narcolepsy, my family doesn't
10	have it, but it's very devastating, it affects every
11	part of life, and as you could see here today, many
12	people are crying and getting very emotional. There is
13	just not enough choice of medications, of options, of
14	understanding. I'm so glad that you hear this. I'm
15	very passionate about it. I think we need to
16	understand it's a very serious devastating disorder,
17	and people need to really focus and I hope you will
18	on more options so that there will be better
19	management for this sleep disorder.
20	MS. GIAMBONE: Thank you. So it is almost
21	time for our public comment period, but I just want to
22	see if there are any more burning questions from the

FDA panel or anything else that somebody would like to 1 2 bring up. 3 (No audible response.) MS. GIAMBONE: Okay. Sir, I know you did 4 have a comment earlier, and I did say we'll take a few 5 minutes for it. Do you want to repeat your question? 6 7 UNIDENTIFIED SPEAKER 20: Thank you. I have 8 a question for the FDA people here. My experience in the past 10 years or so in on again and off again 9 10 support groups in this area is that people with 11 narcolepsy with cataplexy, a lot of them have been 12 greatly helped by Xyrem. Those who are not helped by 13 Xyrem and people with narcolepsy but without cataplexy -- well, some of them may get some help from Xyrem --14 but that whole other category, those with cataplexy who 15 are not helped, and the great majority of people 16 17 without cataplexy who are not helped, use a whole bunch 18 of different kinds of naps and medications and 19 trazodone to fall asleep or try and get a slow wave 20 sleep, you just try this, that, and the other thing. 21 And so far as I know, there is only one real 22 approach, there is a basic genetic approach largely

1	centered with Dr. Mignot at Stanford University.
2	People at Emory have come up with a treatment perhaps
3	for idiopathic hypersomnia. And I'm a real outsider, I
4	have not heard of any research on trying to promote
5	slow a good night's sleep. Of course, everybody
6	with narcolepsy that I've ever met has said you don't
7	get restorative sleep.
8	So my question is, do you people know of what
9	research is being done where outside of these obvious
10	areas that we hear about every year at narcolepsy
11	network conventions?
12	Thank you.
13	DR. BASTINGS: Unfortunately, we are not
14	allowed to discuss that. You know, there are trade
14 15	allowed to discuss that. You know, there are trade secrets issues and we are never to tell you what
15	secrets issues and we are never to tell you what
15 16	secrets issues and we are never to tell you what research is going on or what we are reviewing at the
15 16 17	secrets issues and we are never to tell you what research is going on or what we are reviewing at the agency, so what I said is that there are trade
15 16 17 18	secrets issues and we are never to tell you what research is going on or what we are reviewing at the agency, so what I said is that there are trade secret issues, and we are unable to discuss with you
15 16 17 18 19	secrets issues and we are never to tell you what research is going on or what we are reviewing at the agency, so what I said is that there are trade secret issues, and we are unable to discuss with you any application or drugs that we are reviewing at the
15 16 17 18 19 20 21	secrets issues and we are never to tell you what research is going on or what we are reviewing at the agency, so what I said is that there are trade secret issues, and we are unable to discuss with you any application or drugs that we are reviewing at the agency. The law does not allow us to discuss

1	DR. UNGER: Yeah, I mean, if a company has a
2	great idea and they have patents on a drug or drugs
3	that they are developing and they discuss those with
4	us, we go out of our way to have those discussions with
5	the drug companies because we want to facilitate drug
6	development, but those are trade secrets, so therefore
7	we're bound and unable to discuss those with you. So
8	we're not stonewalling, we're just doing what we need
9	to do.
10	MS. GIAMBONE: Okay. So oh.
11	UNIDENTIFIED SPEAKER 21: That's okay. I'm
12	going to refer to Dr. Mignot like in 2004 said that he
13	was close to finding the cause of narcolepsy. So could
14	you give us an idea whether you're funding any research
15	to find the cause so that
16	DR. UNGER: We can say we're not funding any
17	research because in general we don't fund research for
18	drug development. We're very much involved, for
19	reasons we've talked about, but we don't actually fund
20	it. I mean, NIH funds the research. Yeah.
21	And the other source I mean, you are a
22	very bright and articulate group. I suspect you all

(866) 448 - DEPO www.CapitalReportingCompany.com © 2013

1	know about the NIH has a there is a website,
2	Clinicaltrials.gov, where you can see what's being
3	studied for narcolepsy. So, you know, even though we
4	can't divulge much, it is pretty much an open society
5	now. You guys are probably very well connected and
6	when somebody gets wind of an idea, it spreads around
7	pretty quickly. But if we knew of something you don't
8	know about, we wouldn't be able to tell you
9	unfortunately.
10	MS. GIAMBONE: Thank you.
11	Okay. So we're going to get started with our
12	open public comment period. And just one last note,
13	once again as a reminder, we do have the evaluation
14	forms. They're still either out on the yeah, I
15	believe they're still out on the registration desk, so
16	again it's voluntary but very beneficial for us to know
17	how the meeting went today.
18	So let's get started with the Open Public
19	Comment period.
20	Open Public Comment
21	MS. TAN: Hi, everyone. Again I would
22	like to reiterate that I know there have been a lot of

1	hands up and we haven't been able to get to everyone,
2	but there is always the public docket available. If
3	you're not familiar with how to get to that docket and
4	what that web link is, then we would be happy to post
5	that and send that out via e-mail.
6	So we are now going to move into the Open
7	Public Comment session, and for those of you that
8	aren't aware, the purpose of this session is to allow
9	an opportunity for those who haven't had a chance to
10	speak on issues that are not related to our two main
11	discussion topics. This is also an opportunity for
12	folks who are not patients or patient representatives
13	to comment.
14	Please keep in mind that we will not be
15	responding to your comments, but they will be
16	transcribed and will be part of the public record.
17	Since we would like this to be a transparent process,
18	we encourage you to note any financial interests that
19	you have that are related to your comment. If you
20	don't have such interests, you can feel free to state
21	that. And if you don't want to discuss this, that's
22	fine, and you can still provide your comment.

1	So we've collected sign-ups before the
2	meeting and during the break. We have 10 people signed
3	up and about 20 minutes to do this, so please be
4	respectful of your other colleagues here and other
5	patients and please try to stick to the 2-minute limit.
6	We won't have a timer system or anything, but I will be
7	keeping track of time here, so if you approach the 2
8	minutes, then I'll let you know to start wrapping up.
9	So the order of speakers, I will just briefly
10	run through them, and I apologize if I mispronounce
11	your name. We have Nancy Ackerman, Julie Flygare,
12	Monica Gow, Kim Grady, Meaghan Doyle, Jed Black, Mark
13	Patterson, Moshe Turner, LaShun Ray, and then Patricia
14	Higgins. So if our first speaker, Nancy Ackerman,
15	could we get her a mic?
16	MS. ACKERMAN: I mark my age of onset as 17
17	because that is the first time I can remember walking
18	into a public restroom, locking the door, and lying
19	with my face on the floor just to get a bit of respite.
20	Years passed before I considered that I might have an
21	actual medical condition rather than just a character
22	flaw. I graduated college, was a Peace Corps

1	volunteer, obtained two graduate degrees, and worked,
2	all before diagnosis and treatment. How? Through
3	sheer self-hatred for not trying hard enough, for being
4	lazy, for lacking self- discipline, and willpower. I
5	put myself through hell in order to keep up with those
6	around me.
7	Most days I woke up stuck between wakefulness
8	and dreaming, and as my brain battled it out, the
9	dreams usually won. I would fall back asleep,
10	powerless against their pull. When professors,
11	employers, and others questioned my tardiness or
12	absences, I would lie. What was I going to say? I
13	slept in? I was tired? In today's world, tired is not
14	an acceptable excuse.
15	It was 15 years from onset to diagnosis. I
16	saw between 20 doctors, 15 to 20 doctors. When a
17	neurologist said my MRI looked perfect, I was actually
18	disappointed. When the blood work showed no
19	abnormalities, I would be referred once again to a
20	psychiatrist. When I didn't get better after taking a
21	series of medications for conditions I didn't have,
22	lithium was suggested, I balked. The psychiatrist

smiled politely and said I was in denial. 1 Since receiving the first-line treatments for 2 3 narcolepsy, I still have EDS, but I no longer have the feeling that if I don't go to sleep at this very 4 moment, I will die. And truth be told, without 5 diagnosis and treatment, I believe I would have died. 6 I am ashamed to say it in such a public forum, but I 7 8 feel it must be said. I wonder how many people have been misdiagnosed with a psychiatric illness and ended 9 10 up taking their own lives in order to escape the utter 11 misery and desperation of what was actually narcolepsy. 12 I am now married with two children. Even 13 after treatment, my symptoms continue to worsen, and 14 narcolepsy still takes a serious toll on my life. I am 15 only able to work part-time now, and I am considering 16 disability. After work, I should look forward to seeing 17 my kids, but instead I am either too exhausted from the 18 narcolepsy or too high strung and agitated from the 19 meds to enjoy that time. Seemingly simple tasks like packing their lunches or choosing their clothes for the 20 21 next day leave me feeling as if I have run a marathon. 22 My relationship with my husband is strained. I am

(866) 448 - DEPO www.CapitalReportingCompany.com © 2013

		168
1	unable to go for a night out, I don't want to sit and	
2	chat after dinner, I am too tired. We go to bed in	
3	separate rooms so that I receive optimal sleep.	
4	Suffering from narcolepsy has forced me to	
5	confront the reality that my life will never be the one	
6	that I imagined for myself, be it as a professional, a	
7	companion, or a mother. And of the countless pills	
8	I've taken, that is the hardest one to swallow.	
9	Thank you.	
10	(Applause.)	
11	MS. GIAMBONE: Thank you.	
12	Next we have Julie Flygare. And if you would	
13	like, we can just provide the mics to you instead.	
14	MS. FLYGARE: Thank you. I'm just going to	
15	sit because I do have cataplexy, and communicating is	
16	one of the harder symptoms triggers for my	
17	cataplexy.	
18	I just want to talk about a few things that I	
19	feel could be stressed a little bit more after today's	
20	discussion, including hypnagogic hallucinations and	
21	sleep paralysis. For me, these come together. The	
22	experience is that someone has come into my room and I	

		169
1	want to move usually because I think someone is	
2	attacking me, and I can feel someone touch my neck and	
3	try to strangle me, and I want to move, and I can't,	
4	and that's the sleep paralysis part, and the	
5	hallucination is that I actually see that and feel	
6	touch and hear things as if they're real.	
7	The best way I can explain this is to say	
8	that I can't distinguish what's real and what's not to	
9	the point where a kid was screaming in my apartment	
10	building hallway on a Sunday morning around 10:00, and	
11	I was in and out of sleep, and so when I eventually	
12	woke up later, I assumed that didn't happen because	
13	nothing around my sleep I can trust to be reality, and	
14	it wasn't until that evening when my roommate said to	
15	me, "Oh, my god, did you hear that kid screaming this	
16	morning in the hallway?" and I said, "Oh, that actually	
17	happened?" So it's the realness, it's not like a dream	
18	you think of, this is just as real as reality to me. I	
19	just wanted to stress that. And when you have someone	
20	attacking you and you wake up from that, I feel fully	
21	like adrenalin, it feels very chemical, and sometimes I	
22	have to take a 20-minute walk around my neighborhood	

just to walk off that experience because it was
 completely real to me.

I just wanted to mention that exercise has 3 been a big part of my life actually since I was 4 diagnosed. The first 2 years I stopped exercising 5 completely, and I went back to running to run the 6 Boston Marathon with narcolepsy with cataplexy. 7 8 However, I can say that running and exercise and yoga does not actually improve my symptoms. For me, I feel 9 10 it improves my life. I feel stronger and happier, but 11 it didn't really have any actual effect on my actual 12 symptoms, so I still have to take two naps a day and 13 deal with my cataplexy and all that. So I just wanted 14 to mention that.

And also that mood regulation around 15 sleepiness is a huge issue for me. I wake up from a 16 nap and I don't feel rested, and my boyfriend said, 17 18 "How was your nap?" I want to just scream at him. It's 19 not restful to me. It's like spending 30 minutes with 20 my brain racing in a dreamlike state, and I have a lot 21 of mood regulation issues. When I wake up, for the next 1/2 hour I usually just don't speak to my 22

		171
1	boyfriend for that time, and then I come back to me,	
2	which is actually usually a pretty nice person.	
3	So I just wanted to mention some of those	
4	issues as well. Thank you so much.	
5	MS. TAN: Thank you, Julie.	
6	And next we have Monica Gow.	
7	MS. GOW: Thank you. My name is Monica Gow,	
8	and I'm a cofounder of Wake Up Narcolepsy. My son, his	
9	symptoms started at age 10, and he was diagnosed 3	
10	months later, was way too long for us. In those 3	
11	months, he saw approximately 15 doctors and underwent	
12	multiple expensive, sometimes painful, tests to be	
13	diagnosed with narcolepsy. At the beginning when he	
14	was sleeping a lot, I asked one of my ER doctor friends	
15	if she thought it could have been narcolepsy because	
16	growing up there was a family friend with narcolepsy,	
17	so I was familiar with it, and she said, "Absolutely	
18	not. He is having growing pains and that's why he is	
19	so tired." And I had also never heard of cataplexy,	
20	which he was experiencing terribly, so I put the	
21	narcolepsy out of my mind. And the first pediatric	
22	neurologist who specialized in sleep accused my son of	

1	avoiding school when he had missed 3 weeks of school
2	straight because he was sleeping up to 18 hours a day.
3	She thought he possibly had depression and was avoiding
4	school, and this was somebody who could have helped us.
5	So we immediately left her and just forgot about
6	insurance and just went on our way to Boston
7	Children's, and he was diagnosed with another incorrect
8	diagnosis, and then finally we got to narcolepsy with
9	cataplexy. But what we learned about narcolepsy after
10	he was diagnosed, like I said, I knew somebody growing
11	up with it, and I thought it was this man was a
12	dentist, my dentist, and I thought he just took a nap
13	in the back room and was able to continue with his
14	dentistry all day, but it is so complex and affects
15	every single part of a person's life. So taking that
16	and learning that. And then also experiencing how we
17	were treated and how he was treated by doctors and the
18	waste of money with all of these medical exams was
19	something that drove us, my husband and I and another
20	adult we met with narcolepsy, drove us to start Wake Up
21	Narcolepsy, which is a nonprofit organization dedicated
22	to raising funds through fundraisers to support

1 research.

2	And we founded this in November of 2008, and
3	since then we have donated over \$200,000 to research at
4	Stanford University, Beth Israel Hospital, Toronto, to
5	sick kids in Toronto, and also a study going on at
6	Vanderbilt in Tennessee. And we also have a lot of
7	activities that promote increased awareness. So
8	through Wake Up Narcolepsy and looking at this FDA
9	invitation, which we thought was an amazing
10	opportunity, we joined forces with other community
11	leaders, Julie Flygare, and we created Unite
12	Narcolepsy, and through Unite Narcolepsy, we produced a
13	survey and collected over at this point, we have
14	interim results we collected over 1,300 responses of
15	people in the country, which is so huge because most
16	people with narcolepsy don't want to talk about it,
17	they're embarrassed. It's politically okay to make fun
18	of narcolepsy. And we're thrilled with the results.
19	It's shown the medical world and it will show the rest
20	of the world how serious this disorder is. And with
21	that, just outside on the table out there I left some
22	brochures about Wake Up Narcolepsy and what we do and

1	some school programs we have to educate teachers and
2	school nurses. And we just have some awareness like
3	paraphernalia, the bracelets, pencils, whatnot, and
4	also after today's meeting back over at the Courtyard
5	Marriott, we're having a reception over there, if
6	anybody would like to join us and meet and talk more
7	about this. And the instructions are out there as well.
8	And also the results of our survey are on this table,
9	and it's a very interesting read. And it's just a
10	wonderful opportunity now for the narcolepsy community
11	to have voices heard.
12	Thank you.
13	(Applause.)
14	
14	MS. TAN: Thank you. Next we have Kim
15	MS. TAN: Thank you. Next we have Kim Grady. And I would just like to remind everyone to try
	-
15	Grady. And I would just like to remind everyone to try
15 16	Grady. And I would just like to remind everyone to try to please stick to the 2-minute limit just because
15 16 17	Grady. And I would just like to remind everyone to try to please stick to the 2-minute limit just because we're short on time unfortunately.
15 16 17 18	Grady. And I would just like to remind everyone to try to please stick to the 2-minute limit just because we're short on time unfortunately. MS. GRADY: I will stick to the 2 minutes,
15 16 17 18 19	Grady. And I would just like to remind everyone to try to please stick to the 2-minute limit just because we're short on time unfortunately. MS. GRADY: I will stick to the 2 minutes, you can raise your hand. I just wanted to share on
15 16 17 18 19 20	Grady. And I would just like to remind everyone to try to please stick to the 2-minute limit just because we're short on time unfortunately. MS. GRADY: I will stick to the 2 minutes, you can raise your hand. I just wanted to share on what Monica said about the Unite Narcolepsy initiative.

1	diagnosed with narcolepsy by a physician and 12 percent
2	were received from close family members, spouses,
3	parents, and children of people with narcolepsy.
4	And I just wanted to highlight because there
5	have been studies done and surveys done, but they've
6	been from the doctors' standpoint or the pharmaceutical
7	standpoint, not from the patients' standpoint. So I
8	think not only the FDA bringing us here today has been
9	phenomenal for all of us, but some of these statistics
10	I think were very shocking to me, who as somebody that
11	has been dealing with this for 9 years, one of the more
12	shocking statistics I read was that 40 percent of
13	people diagnosed 40 percent were between the ages of
14	11 and 17 when symptoms first began.
15	It's worthwhile to note that there are no
16	FDA- approved treatments for children. There is a high
17	rate of comorbid conditions; two-thirds of respondents
18	have one or more other conditions. Cataplexy was
19	reported by 65 percent of respondents, and that's much
20	higher than some clinic-based studies indicate. 84 of
21	respondents reported not being able to perform at work
22	or school as they would like.

1	The thousands of comments submitted, some of
2	which were quite lengthy and detailed, tell a
3	heartbreaking story of dreams deferred, career and
4	educational plans put on hold, self-image and
5	confidence eroded, independence lost, and families torn
6	apart. The simplest pleasures, things that make us
7	human, like laughing with friends or holding an infant
8	child, are abandoned out of incapacity or fear of
9	sudden loss of muscle control and wakefulness. 82
10	percent described their untreated condition as severe,
11	meaning it significantly impacts daily activity. And
12	with treatment, 22 still consider themselves in the
13	severe group, so that tells you how effective our
14	medications are. And 61 percent are moderate with some
15	impact on daily activity. Nearly 95 percent of
16	respondents have tried one or more of the four FDA-
17	approved medications for narcolepsy, EDS, or cataplexy.
18	79 percent use one or more of the medications
19	currently.
20	Thank you.
21	MS. TAN: Thank you.
22	Next we have Meaghan Doyle.

1	MS. DOYLE: Hi. I just want to take a moment
2	to thank you guys and go into a little bit more details
3	on my symptoms. As Julie was saying, the dreams and
4	reality with hallucinations, I often have a difficult
5	time determining which is which. I will get text
6	messages from, let's say, CNN and look at my phone in
7	the morning and also get an e-mail from my professor
8	saying, "Because there was a road cop, class is
9	cancelled." Well, I go back and check my phone, the
10	CNN text message was real, the e-mail was not.
11	My medication stops working after about 2
12	months. I am on the highest dose of Xyrem, and
13	although it helps, it does not help like it did when I
14	first started. During my cycle, it does not work at
15	all. And narcolepsy in general has a big toll on my
16	relationship between the alarms, losing things, not
17	being able to come up with words that I'm looking for,
18	and having to play the, "You know, that thing that you
19	sit in to go to the grocery store, and it's blue, and
20	it has four wheels," and my husband finally has to say,
21	"Oh, the car." I'm often treated like a child because
22	of these things.

		178
1	The last thing I wanted to talk about real	
2	quickly on the obesity, I feel an insatiable desire to	
3	eat sugar and carbs. I could eat a pound of sugar	
4	literally, like straight from the bag, and want more.	
5	And it's frustrating because I don't feel good on it,	
6	but my body physically needs it, it seems like.	
7	So that's all I had to say.	
8	MS. TAN: Thank you.	
9	Next we have Jed Black. We'll bring the mic	
10	over if that's easier. Thank you.	
11	DR. BLACK: Hi. I'm Jed Black. I'm a	
12	physician and faculty at Stanford University, and I	
13	have over the past 20-plus years conducted much	
14	research on sleep disorders and narcolepsy and have	
15	seen hundreds of narcolepsy patients, and I just wanted	
16	to comment on this event. I'm impressed with what's	
17	transpired here. I think this is a remarkable process	
18	that the FDA has established and kudos to them for this	
19	effort, and especially congratulations to all of the	
20	patients and family members and others that have shown	
21	up here. And what I've seen over the past 20-plus	
22	years is exactly what has been expressed here, the	

1 profound impact of the condition on the lives of the 2 individuals and their family members. And recently I 3 have joined Jazz Pharmaceuticals in their efforts to 4 try to develop better treatments and provide greater 5 community awareness and physician education and patient 6 awareness.

7 The comments that have come up about 8 physicians not knowing about narcolepsy are a major issue, and unfortunately physicians are a dense and 9 10 arrogant group and do not recognize their lack of 11 understanding and knowledge, and in fact I am one of 12 The first real kind of rap upside the head I those. 13 had was many years ago, a woman with narcolepsy I had been treating, she would come back each time and say, 14 15 as I wrote the triplicate prescription for her 16 methylphenidate, that everything was fine, she was 17 doing well. One time her husband came back, and when 18 she said this, he looked at me and said, "Dr. Black, 19 you don't know. She is not doing well. Yes, she's 20 better, but she's far from having a normal degree of alertness and function." 21 22 And with the work that's been done in the

1	field, the amount of sleepiness and brain fog that
2	patients with narcolepsy experience is akin to what
3	someone without narcolepsy would experience with 2 to 3
4	hours of sleep a night for about 2 weeks, and so for
5	those of us that don't have narcolepsy, that kind of
6	puts in perspective how impactful and the profound
7	amount of sleep propensity that exists in narcolepsy,
8	and that's not to mention all of the other ancillary
9	features that have been so well described.
10	I have found that a lot of times patients
11	feel hesitant to tell their physician, to be aggressive
12	in telling the physicians, that they're not doing as
13	well as they should be, they're having problems with
14	the medications, it's easy to sort of just say
15	everything is going well, but I would encourage you to
16	continue to do what you've done today and to tell the
17	world and to tell your physicians and others and
18	continue to rally. I think there is a tremendous
19	amount of work that needs to be done on the research
20	side, but also on the communication to the medical
21	community, how impacted your life is by this condition.
22	Thank you.

1 Thank you. MS. TAN: 2 Next we have Mark Patterson. 3 DR. PATTERSON: Hi. My name is Mark Patterson. I have a daughter with narcolepsy. I'm a 4 pediatrician and I'm on the Board of Trustees of the 5 Narcolepsy Network. And I agree with Dr. Black, that 6 7 the biggest part is teaching physicians about 8 narcolepsy. That's become one of my missions. That's why I'm here to say I have two comments. One, with 9 10 Xyrem, the big problem that's been mentioned before, 11 which is the fact -- because it is -- I mean, it's not 12 clear what its function is, whether it's a hypnotic or 13 what it does, it definitely makes people sort of incapacitated. It's like being extraordinarily drunk. 14 15 And it is a big safety issue when it comes to that 16 because when people get up in the middle of the night 17 because you have to dose it twice a day, when people 18 get up in the middle of the night to take their second 19 dose, it's common to fall asleep in the bathroom, to fall asleep in other places, or fall off the toilet, 20 kind of wander around the house, or conditions with the 21 22 eating issue, this can be a problem just in the safety

1 once you're on medication because it's like being 2 extraordinarily intoxicated.

The other big issue is just the extreme 3 measures to which some patients go to try and find 4 medications for the treatments. One of the things I do 5 is kind of monitor things on Facebook, and there are 6 7 several narcolepsy sites that are out there, and last 8 week an issue came up, someone posted about a natural food additive or natural product called Orexinal that's 9 10 based on the orexin and the real thing, and it's sold 11 by a pharmacy or a lab out in San Francisco, and it was 12 selling for \$1,000 for a month's supply, and they sell it as an all natural product, so the FDA didn't follow 13 it because it's sort of a food additive, and it was 14 15 proprietary material, so there was no information as far as what the ingredients actually were, but people 16 were actually discussing online as far as whether they 17 18 should buy it or not. And so just to me, being a 19 physician, the fact that they were so desperate they were willing to spend \$1,000 to buy this unknown 20 21 product to spray up their nose to try and stay awake just shows again the amount of desperation in these 22

people's lives. 1 2 So I applaud you all for having this forum and actually hearing from patients because that's the 3 thing that's lacking a lot of times when we're trying 4 to come up with research ideas. So I appreciate 5 everyone's comments, and I hope this ever continues. 6 7 Thanks. 8 MS. TAN: Thank you. Next we have Moshe Turner. 9 MR. TURNER: Thank you. My name is Moshe 10 Turner, and I've been a narcoleptic without cataplexy 11 12 for 45 years or so. I didn't come here to tell my 13 personal story, and it's a good thing because everybody else has told it for me, all these other comments, it's 14 15 like listening to myself. What I would like to do is I would like the 16 FDA and the wider world also, but particularly the FDA, 17 18 to understand that what we call narcolepsy is only that 19 group of symptoms which are the most visible physical manifestations of the underlying neurological 20 condition. The Federal Register listing for this 21 22 meeting misidentifies narcolepsy as a chronic disorder

184

1	of the central nervous system caused by the brain's
2	inability to control the sleep-wake cycles. This is
3	absolutely not true. Narcolepsy is a neurological
4	disorder of the brain caused by interrupted or
5	unavailable orexinergic signaling. Orexin directly
6	regulates or is involved in the regulation of the
7	monoamines, dopamines, serotonin, adrenalin, histamine,
8	and I can never pronounce this norepinephrine,
9	something as well as the cholinergic, GABAergic, and
10	glutamatergic systems. The interruption or absence of
11	orexinergic signaling has been found to very highly
12	correlate with the dysregulation of a wide range of
13	processes throughout the body, such as breathing, blood
14	pressure, heart rate, feeding, intestinal motility,
15	olfactory perception, homeostasis, motivation, mood,
16	and, of course, the sleep-wake cycle, just to name a
17	few.
18	Giving me drugs that keep me awake during the

19 day or help me to sleep better at night is like giving 20 me a Band-Aid. These drugs merely provide symptomatic 21 relief at best. What narcoleptics need is a drug 22 which, if it can't restore orexinergic signaling, will at the very least restore the proper functioning of
 these other systems.

3 Now, with all due respect for my younger colleagues here, I have found that the effects of 4 narcolepsy, particularly in regard to homeostasis, have 5 become ever more crippling as I have progressed into 6 middle age. Where at one time EDS was my main enemy, 7 8 now it's homeostasis. While we certainly want to address the issues that are important to narcoleptics 9 of all ages, we have to keep in mind that as a person 10 gets older, the ability of the body to compensate for 11 12 the dysregulation of all these other neurotransmitters 13 diminishes.

14 I would like to see that the FDA pays close attention to the science behind this condition -- and 15 it's not a disease, it's a condition -- and that the 16 FDA not be driven off course by a lot of the things 17 18 that are said by both the patients and the 19 pharmaceutical companies. To paraphrase a saying from 20 an old political campaign from a while back, it's about 21 the orexin, stupid, and that's the truth. 22 That's all I've got to say. Thank you.

(866) 448 - DEPO www.CapitalReportingCompany.com © 2013

186 1 (Applause.) 2 MS. TAN: Thank you. Next we have LaShun Ray? 3 (No audible response.) 4 Oh, okay. Okay, and then 5 MS. TAN: finally we have Patricia Higgins. 6 7 MS. HIGGINS: I'm Patricia Higgins, a trustee 8 of the Narcolepsy Network, and we're committed to helping people diagnosed with narcolepsy or idiopathic 9 10 hypersomnia. I started falling at age 16, and at age 11 32 the falls became more frequent. The falls were 12 alarming and I was trying to figure out what was 13 happening to me. I was working in the emergency department as a registered nurse. Many were witnessed 14 15 by medical staff. If a nurse was witnessed sleeping on 16 the job or taking a nap, they were fired automatically 17 on the spot. Physicians had rooms that you could lay 18 down in and take naps. So we developed the idea of I 19 could go in the physicians room and sleep and take a 20 nap because nursing administrators would not go in 21 there, and that's how we tried to solve the problem. 22 Cataplexy is the number one symptom that

1	impacts my life. I've been referred to as a drunk on
2	several occasions where alcohol had not been consumed.
3	I do not drink alcohol today. It was during that time
4	that I lived the reality of a deep depression. I was
5	thinking about suicide and a plan was evolving. The
6	depression must be addressed; it almost killed me.
7	Depression was clouding so much of my
8	judgment. Treating the depressed individual should be
9	focused on immediately regardless of what else is going
10	on. Reckless behaviors and actions are not realized
11	when an individual is severely depressed. People
12	diagnosed with narcolepsy are chronically ill.
13	Chronically ill patients are often most vulnerable,
14	disenfranchised, underfunded, and often forgotten.
15	Thank you for not forgetting us.
16	(Applause.)
17	MS. TAN: Thank you. So before we get
18	started on our last agenda item, if I could just ask
19	everyone to pass the clickers down to the end of the
20	row, and if our FDA staff could collect them. Thank
21	you very much.
22	And I would like to call Dr. Bastings up to

(866) 448 - DEPO www.CapitalReportingCompany.com © 2013

1 the podium. Thank you.

2 Closing Remarks DR. BASTINGS: Well, I want to thank each and 3 every one of you for participating in this meeting. 4 Ιt is incredibly helpful for us to hear from you about 5 your experience with narcolepsy. I will try to briefly 6 summarize some of the highlights of what I heard from 7 8 you today. First of all, I was impressed by the lack of 9 awareness of the condition in the community and the 10 delay in diagnosis that some of you have encountered 11 12 before you really could have your condition addressed. 13 The key symptoms that most of you have reported has been daytime sleepiness with cataplexy 14 also a big issue in a significant number of you. 15 16 Another symptom that was mentioned by many is the brain fog that can be a major hassle in your daily 17 18 lives. Hallucinations are also an important symptom 19 that was mentioned. 20 And because of all of these symptoms, I heard 21 many of you talk about how scary the condition is, how 22 terrorizing it can be in terms of planning your daily

1 activities, and the fear that these various symptoms
2 provoke in your daily lives.

So I think I heard loud and clear that the 3 disease has a huge impact on your lives starting from 4 school, whether you are in high school or whether you 5 are in college. The condition can have a huge impact 6 on your choice of career, it can have a huge impact on 7 8 you getting a job, on you being able to keep your job, it has a huge impact on you being able to participate 9 10 in social activities, to go out, to dine with friends. 11 Basically it has a huge impact on your activities of 12 daily living. It causes some of you to lose your 13 friends and to lose contact with some members of your family. So we really appreciate the impact of 14 15 narcolepsy in your lives.

In terms of treatments, most of you have tried all of the FDA available drugs and many of you are also trying other drugs or other approaches. Naps has been mentioned. It's not really a treatment, but some of you use it to manage your symptoms. Some of you use diet. Exercise has been mentioned as well. There is no magic bullet unfortunately for narcolepsy,

1	and many of you continue to experience significant
2	symptoms despite the treatments, and there remains a
3	big unmet medical need for this condition, and there is
4	a lot that remains to be done. Many of you are taking
5	several drugs at the same time, and despite taking
6	these different treatments, continue to experience
7	symptoms. And you discussed the various side effects
8	that these drugs can be causing and that can be
9	limiting.
10	Another issue that has been mentioned is the
11	tolerance that can occur on some of these treatments.
12	In terms of what you would like to see in new
13	drugs being developed, the idea is that there would be
14	a drug that targets what we think is the cause of the
15	disease rather than having a less specific treatment.
16	The key symptoms that you would like the drug to
17	address is the daytime sleepiness, you want a drug to
18	let you be awake during the day. And another symptom
19	that was also mentioned is brain fog, you would like a
20	drug to really improve the brain fog that many of you
21	experience.
22	Another aspect is that you would like a drug

		191
1	that would let you sleep through the night. Many of	
2	you have spoken about your great difficulties with	
3	sleep, with sometime duration as short as 2 hours for	
4	many, many months or maybe even for most of your life.	
5	So a drug that could help to restore sleep is also	
6	something that is wanted.	
7	So again thank you, everybody, for	
8	participating to this. And the feedback is incredibly	
9	helpful to us.	
10	Thank you.	
11	(Applause.)	
12	(Whereupon, at 5:06 p.m., the	
13	Narcolepsy Public Meeting on Patient-	
14	Focused Drug Development was	
15	adjourned.)	
16		
17		
18		
19		
20		
21		
22		

		192
1	CERTIFICATE OF COURT REPORTER	
2	I, BRYAN YOUNG, the Court Reporter before	
3	whom the foregoing proceeding was taken, do hereby	
4	certify that the proceeding was recorded by me; that	
5	the proceeding was thereafter reduced to typewriting	
6	under my direction; that said transcript is a true and	
7	accurate record of the proceeding; that I am neither	
8	related to nor employed by any of the parties to this	
9	proceeding; and, further, that I have no financial	
10	interest in this proceeding.	
11		
12		
13		
14		
15	BRYAN YOUNG Digital Court Reporter	
16		
17		
18		
19		
20		
21		
22		

		193
1	CERTIFICATE OF TRANSCRIPTION	
2	I, DEBORAH ARBOGAST, hereby certify that I am	
3	not the Court Reporter who reported the following	
4	proceeding and that I have typed the transcript of this	
5	proceeding using the Court Reporter's notes and	
6	recordings. The foregoing/attached transcript is a	
7	true, correct and complete transcription of said	
8	proceeding.	
9		
10		
11		
12	Date DEBORAH ARBOGAST	
13	DEBORAN ARDOGASI	
14		
15		
16		
17		
18		
19		
20		
21		
22		

	Pag	ge 1	
\$	100 74:18 130:16	172:2	2005 74:3 75:11
\$1,000 182:12,20	103 3:12	180 106:21	2008 173:2
\$10,000 122:4	104 3:13	188 3:18	2009 68:21
153:3	10903 1:11	18-wheeler 64:14	2012 106:5
\$160 109:17	10-minute 102:20	19 57:14 97:16	2013 1:7 17:1
\$200,000 173:3	10-year-old 79:8	158:21	2017 17:1
\$35 151:10	11 41:11 108:21	1996 67:12	20993 1:12
\$5,000 151:15	128:12 141:5		20-minute 144:13
\$500 109:11,18	153:11 175:14	$\frac{2}{2}$	169:22
\$6,000-a-month	12 69:3 72:10	2 3:13,14,16 6:1,6 11:13 20:10 30:6	20-plus 178:13,21
122:8	128:13 141:12 175:1	33:1 36:3,6	21 41:12 42:6
\$8,000 151:9		39:11,20,22	101:4 115:3
\$9,382 137:15	12:00 113:1,20	40:20 44:17 45:9	162:11
	13 2:12 142:7	47:11,22 51:22 56:15 65:2 69:16	2-1/4 158:15
$\frac{1}{12222852065}$	133 3:16	74:13 80:16	22 128:14 176:12
1 3:2,3,8 5:20 6:5 25:9 27:4,20	14 61:9 62:17 150:3	90:20 102:22	24 1:7 2:16 115:13
31:20 32:21		103:9 104:8,10,14	151:8 153:15
39:10,21 40:20	140 108:6	109:10 111:3	155:21 25 47 21 86 15
43:10,13,18 44:3,5,13 51:6	15 51:13 54:2 144:13 151:4	113:5 116:9	25 47:21 86:15
77:10 78:19	153:22	123:22 124:21	26 151:9
90:14 103:1,11	166:15,16	133:20 144:14 165:7 170:5	26th 174:21
104:21 133:13	171:11	174:18 177:11	27 114:15 128:20
143:2	150 106:21	180:3,4 191:3	29 57:5
1,300 173:14	153 128:11	2,000 27:4	2-minute 165:5
1,476 174:22	16 20:1 78:20	2:00 113:1,20	174:16
1/2 170:22	81:20 142:9 143:3 155:15	20 16:22	3
1:00 156:15	157:10 186:10	17:1,7,10,11,16	3 11:13 20:2 33:11
10 25:9 41:11	160 107:6	18:13,16 29:1 41:12 42:12,13	44:2 74:13,17
42:12 47:10 55:18 78:21 79:6	16-year-old	47:21 64:9 68:12	79:12 82:9 83:18
81:7 125:1	142:15	69:10 86:15	105:2 106:14 109:17 111:1
140:16 160:9	17 98:14 158:4	112:7 159:1 160:7 161:21	116:10 117:15
165:2 171:9	165:16 175:14	165:3 166:16	171:9,10 172:1
10:00 136:14 169:10	170 108:6	200 50:18	180:3
	171 3:17	200,000 25:6	3,000 27:20
10:30 136:14 143:11	18 72:10 97:21	200,000 25:0 2004 162:12	3:15 156:13
1 12,11	112:7 158:14	2007 102.12	30 25:8 41:12 42:6

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013 Page 1

64:9 131:15 50,000 27:5 absences 166:12 9 170:19 **500** 122:2 absolute 72:2 9 50:18 81:7 112:2 **31** 2:20 41:12 42:4 **504** 135:21 absolutely 73:9 128:10 139:20 **32** 186.11 108:14 171:17 140:9,12 142:10 **51** 41:13 184:3 175:11 35 121:2 5K 48:15 absurd 157:6 9:00-to-5:00 119:6 **38** 102:2 5s 136:9 **abuse** 61:10 146:2 90 19:3 28:15 **39th** 68.22 **5-year** 18:22 40:11 106:1,21 academic 108:3 **3-hour** 144:14 **95** 176:15 acceptable 166:14 6 3rd 83:20 **99th** 51:22 **6** 50:9 83:10 95:16 accessible 151:12 117:8 120:16 4 9th 142:9 accommodate 131:12,14 152:5 **4** 2:2 33:11 44:2 75:9 108:18 9-year-old 111:10 81:8 87:20 **6:30** 143:12 134:13 135:4 88:7.10 97:18 **60** 28:15 41:13 accompany 29:9 А 105:2 108:20 107:6 **a.m** 113:1,20 accomplish 63:2 111.1124:22 **61** 41:13 176:14 accomplished 63:1 4,500 19:1 abandoned 176:8 **62** 56:14 according 21:13 4.5 117:13 ability 45:4 118:21 **65** 175:19 accurate 192:7 **40** 18·18 28·19 128:22 129:1,2 6th 56:18 41:12 42:4 accused 61:11,12 185:11 175:12,13 171:22 able 16:3 35:17 7 **41** 41:12,22 42:7 Ackerman 47:7 52:15 54:8 7 27:22 75:5 80:17 165:11,14,16 **42** 72:11 120:15 58:4,10 59:8 115:14 134:5 61:5,671:9 acronyms 26:8 44 3:2 114:14 7,000 25:7 75:7,11 85:7,16 across 18:7 21:1 **45** 43:4 45:8 99:7 91:2,5,6 93:5 700 35:12 69:5,12 115:18 183:12 96:5,9 97:17 75 174:22 act 30:1 135:22 98:13 100:16 **48** 56:14 77 3:8 103:16 111:11 156:6 4s 136:9 115:12 118:21 79 176:18 Acting 3:20 6:13 4-year-old 81:11 125:11 7:15 133:12,13 8 actions 187:10 5 134:17,18 138:4 **8** 2:7 83:19 135:19 active 74:14 156:9 163:8 5 17:1 42:11,12 8:00 124:22 164:1 167:15 116:17 43:4 55:13 89:18 172:13 175:21 94:22 101:21 80 28:20 activities 5:18 44:8 177:17 189:8,9 111:12 47:15,18 75:4 **82** 176:9 abnormalities 76:22 90:20 91:3 5:06 191:12 84 175:20 112:11 173:7 166:19 **50** 29:2 41:12,22 **85** 40:13 189:1,10,11 **absence** 184:10 42:7 46:4 95:5

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013 Page 2

activity 29:18 additive 182:9,14 advocates 9:3 ages 175:13 76:13 176:11,15 17:18 26:4 185:10 address 21:2 77:3 actual 106:10 146:6 153:7 Affairs 8:6 25:14 aggravates 50:1 156:8,9 157:22 136:3 165:21 26:2aggravating 170:11 185:9 190:17 affect 12:15 17:22 148:22 actually 6:21 9:9 addressed 19:3,10 27:4 31:4 96:16 aggressive 180:11 10:2 11:3,22 187:6 188:12 136:19 153:16 agitated 167:18 14:5 25:12,14 addressing 157:21 affected 18:14 29:6 32:11 ago 12:19 158:1 48:13 95:12 34:7,20 35:3,11 42:11,12,13 43:4 97:22 136:16.17 adds 48:18 36:9 40:10 44:18 51:22 58:3 affecting 25:8 41:16,18 42:16 adjourned 191:15 74:12 95:5 98:14 27:20 104:3 44:4 53:6 60:8 111:3 116:10 adjusted 108:17 72:9 73:15 76:20 affects 25:6 54:10 124:18 179:13 adjustments 49:9 80:9 84:20 98:12,15 99:12 agreed 17:7 85:10,15 90:7 100:9 159:2,10 administer 122:2 103:19 146:4 96:12 97:8 99:14 172:14 Administration ahead 37:2 43:16 102:18 104:19 afflictions 127:16 1:1.9 46:9 64:19 92:4 116:5 117:11 afford 151:16 101:14 103:7 administrators 133:7 138:10 104:9 105:3 186:20 146:13 149:12 afraid 57:8 58:4 109:4 132:9 162:19 166:17 92:15,21 145:11 admired 81:12 133:21 167:11 169:5.16 Africa 137:19 admit 9:19 150:18,22 158:2 170:4,9 171:2 aftercare 111:13 admitted 100:12 182:16,17 183:3 aid 34:16 128:18 afternoon 7:10 Admittedly 9:18 acupuncturist aided 50:21 8:17 24:19 27:16 110:9,12 adrenalin 169:21 AIDS 137:18 155:15 156:14 add 3:10 95:20 184:7 **air** 106:16 against 73:13 143.2adrenaline 64:16 166:10 akin 180:2 addiction 73:19 adult 172:20 age 27:21 alarming 186:12 146:2 adults 114:5 41:9.17.21 42:3 alarms 102:2 adding 50:13 142:12 78:21 80:17 123:10 177:16 addition 36:10 81:13.20 111:12 advance 13:20 albeit 126:17 91:5 143:17 112:2 39:13 104:19 146:9 128:10,12,14 alcohol 96:7 104:5 advancement 165:16 171:9 128:2 187:2,3 additional 16:16 119:15 185:7 186:10 23:10 127:16 alert 46:6.9 74:5 advantage 16:15 132:16 133:3 agencies 37:11 alertness 28:6 adventures 74:15 136:9,10 agency 161:17,20 179:21 adverse 114:8 Additionally agenda 4:21 141:9 alive 78:9 127:20 advisory 15:17 187:18 all-day 88:8

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013 Page 3 FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013

Page 4

	rag		
allergies 120:20	192:7 193:2	25:21	68:11 156:6
allergy 145:8	amazed 66:3	answers 95:1	anywhere 51:18
Allison 105:6,17	amazes 66:4	antibodies 110:7	64:11,22 70:5 84:6,21 86:15
111:6	amazing 35:14	anticonvulsives	116:16
allow 26:4 158:17	106:12 110:19	50:14,17	AP 136:9
161:20 164:8	131:21 173:9	antidepressant	apart 67:19 176:6
allowed 112:14	ambulance 82:22	30:11 130:9,19	-
116:3 161:14	83:2,4,21	antidepressants	apartment 169:9
allowing 105:19	ameliorated 148:6	31:5 138:15	apnea 30:2
114:10 120:4	Americans 25:8,9	139:1,7,20	apologize 84:3
allows 152:16	27:20 135:21	antisocial 70:7	165:10
alone 63:20 82:20	Among 140:9	anxiety 49:18	apparently 65:17
126:5 152:11	amount 45:6 55:18	anxious 49:22 50:3	appear 28:9
already 15:14 47:17 49:7 111:5	110:21 123:5 139:22 151:21	anybody 6:4 22:12	110:16 146:10
47:17 49:7 111:5 140:22 144:16	180:1,7,19	32:15 77:11	appeared 50:14,16
alternative 110:2	182:22	78:17 80:15 82:21 84:11 87:8	65:17
122:10 145:14	amphetamine	95:11 134:1,3	appetite 31:4
alternatives	130:9,16	142:3 144:5,7	113:10,11 131:6
125:15	amphetamine-like	147:1 149:17	applaud 183:2
Alzheimer's 92:21	90:1	151:2 158:2	applause 4:4,8
am 8:13 13:20	amphetamines	174:6	31:15 63:9 71:22 75:21 125:17
24:12 32:8 36:14	30:11 131:15	anymore 9:21 57:22 80:8 148:5	129:10,15,16
37:16,17 41:17	147:14		157:9 168:10
43:13 46:5 51:13	analyze 11:17	anyone 32:17 57:7,8 73:21	174:13 186:1
55:5 56:9 61:8	ancillary 180:8	80:19 82:13	187:16 191:11
62:15,19 63:6,13 72:7 74:16	Andrea 8:10	110:13 148:19	application 22:7
77:20,21 78:7,8	anger 70:20 104:1	anything 18:5 24:3	161:19
82:22 88:18	angry 70:21	37:21 38:22	applications 23:14
89:22 90:2	annual 79:3	49:16 54:18 58:5	26:12
98:12,13 104:11 105:10 106:22	94:13,21	63:20 77:22 79:16 99:11	apply 37:4 130:8
103.10 108.22	anorexia 31:3	103:11 115:11	appointments
125:9 127:11		142:3 152:10	124:14
128:21 137:12	answer 22:12 35:1 69:20 79:14 92:9	156:17,18	appreciate 17:13
151:8 152:14	94:7,11 95:9	157:11 160:1	23:2,5 183:5 189:14
157:14 167:7,12,14,15,1	130:15 132:16	165:6	approach 12:18
7,22 168:2	155:16	Anytime 78:4	17:2,8 127:11
177:12 179:11	answered 23:8	anyway 66:14	129:6 160:22

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013

Page 5

	Pag	,00	
165:7	aside 67:9	141:16	121:7 123:7 125:1,12 128:14
approaches 3:15	asleep 29:1,5 45:5	attended 32:12	146:11 155:18
26:15 189:18	51:20 52:3,16	attending 106:5	156:21 158:1
appropriate 11:10	53:14,17 54:5,16	0	130.21 138.1 182:21 184:18
	55:1,5,12 57:1,3	attention 85:4	190:18
approval 10:12	59:4,7,14 62:15	126:1 131:6 141:13 185:15	
approve 11:16	65:17 69:2		awakening 28:18
12:1	72:8,12 76:12	attitude 68:15	aware 21:4 66:6
approved 14:13	85:15 91:12,14	75:14	87:17,22 88:21
15:13 18:5	98:16 106:7,13	audible 93:12	89:8 102:9
30:12,16 114:4,5	107:22 123:7	160:3 186:4	117:11 122:9
141:17 175:16	139:15 142:19	audience 3:10 9:3	142:1,4 151:22
176:17	156:3 160:19	33:18 34:18 40:3	164:8
approximately	166:9 181:19,20	41:1 42:18 126:1	awareness 84:7
171:11	asleepness 87:21		87:12 126:11
	aspect 190:22	auditory 125:6	127:9 173:7
April 20:5 79:1	-	August 89:4	174:2 179:5,6
April/May 118:16	aspects 25:17 127:10	174:21	188:10
ARBOGAST	127:10	autoimmune	awareness/half
193:2,12	assessment 14:10	121:1	87:21
architecture	assessments 24:6	automatic 29:17	
121:18,21	assist 128:6	53:1,3 88:14	away 13:12 28:5
ŕ		102:4 154:19	57:10 62:21
area 6:16 12:11	associated 31:5		64:21 72:16 75:5
15:21 16:2 23:15	assume 156:20	automatically	142:16
39:9,10,11,17	assumed 48:10	52:17 186:16	awesome 75:16
40:12 49:3	169:12	available 14:18	125:21
160:10	assuming 48:6	15:9,12 23:14 30:20 112:13	awful 79:11
areas 18:14 19:3,7 21:1 82:15	asthma 120:20	133:15 164:2	awry 122:18
161:10	122:16	133.13 104.2 189:17	· ·
			B
aren't 54:14 137:6	attached 54:8	Avenue 1:11	bachelor's 100:14
164:8	attack 67:11	avoid 75:3 111:1	background 2:15
armodafinil 30:10	77:18,20 80:12	126:14	U
130:8,15	82:1,16 88:8	avoided 70:4	5:12 24:9,11 114:14 125:11
arms 79:8	106:19 107:1		
arrival 113:5	attacking 169:2,20	avoiding 128:8 172:1,3	backpacking 74:14
arrogant 179:10	attacks 60:17 62:9	awake 46:3,5	bad 52:8 60:11
articulate 162:22	67:19 70:1(18 22	51:17 61:4 66:6	81:9,10,16 125:3
	70:16,18,22	68:7 70:2 72:7,9	131:16 136:11
ashamed 62:3,4	72:12	77:20 78:8 102:3	140:4,7
63:1 167:7	attempt 75:14	112:3 118:7	bag 79:10 152:4
			-

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013

Page 6

	Pag		
178:4	118:14	behavioral 142:2	109:15 151:18 181:7
bags 73:19	battled 166:8	behaviors 29:17	
baited 71:1	battling 73:14	102:4 187:10	biological 30:5
bake 58:18	111:19	behind 55:1 64:7	Biologics 20:13
balance 128:7	113:12,13	185:15	Biotin 131:20
Balancing 73:13	Bauer 7:21 26:10	believe 6:8 35:13 59:2 68:5 69:8	bipolar 150:11,13
balked 166:22	beat 58:16,19	79:16 127:8,20	bird's 24:16
ball 65:6	beating 107:4	140:21 149:14	birth 116:8
banana 117:18,21	beauty 115:5	163:15 167:6	birthday 68:22
Band-Aid 184:20	became 59:9 65:10	beneficial 38:11	bit 9:18 10:1 16:19
barely 109:1	69:15 122:9 186:11	163:16	20:22 22:9 31:18
111:18	become 66:12	benefit 12:4 14:14 15:5 19:10	32:11 38:4 39:15 42:18 45:22
Barker 95:4	113:16 181:8	22:5,6,11	42.18 43.22 49:11 52:9 65:5
barricaded 152:14	185:6	benefit-risk 14:10	67:15 76:20
	becomes 100:11	benefits 12:2,6	84:10 101:17
barricading 152:6	becoming 57:6	127:1	102:19 130:21
barrier 23:6	74:9	besides 86:5	154:7,8 165:19 168:19 177:2
base 125:14	bed 107:11	132:11	
based 42:17	110:18,19,22	best 9:8 58:17	Black 165:12 178:9,11 179:18
127:13 135:14	111:17 116:5	77:19 94:18	181:6
182:10	121:7 125:2	121:15 169:7	blank 47:6
basement 116:5	154:10 156:20 168:2	184:21	blanket 129:6
basic 123:13		beta 145:7	
160:22	bedroom 58:1,2,3 152:7	Beth 173:4	blessed 52:7
basically 6:4 12:20	begin 118:10	better 9:14 12:5,12	blockers 145:7
16:17 36:2 189:11	129:18 148:2,8	15:3 16:1,12	blood 20:13 31:6
	153:7	18:9,12 34:17	106:7,21 107:2 120:20 166:18
basis 30:4 70:3 90:5 94:20 157:4	beginning 48:5	38:13 49:16 51:2	184:13
	79:19 80:1,3	93:18 96:9 108:5 156:6 159:18	blown 117:8
Bastings 3:19 6:13 7:15 93:14 94:1	117:10 141:21	166:20 179:4,20	
161:13 187:22	171:13	184:19	blue 146:18 177:19
188:3	begins 14:9	beyond 15:9 65:9	blurred 100:9
bathroom 181:19	behalf 32:18 92:8	116:9	board 129:4 181:5
bathrooms	144:11	bigger 33:7	boards 109:14
6:15,18 7:3	behavior 29:20	biggest 80:19 86:4	
battle 63:12 72:8	30:17 53:1,3 88:15 154:19	91:8 100:3	body 68:9 77:18 79:21 80:1
111:14,20 117:4	00.15 157.17	102:15 108:12	/).21 00.1

Page 7 111:14,15,19 brave 155:20 131:6 144:3 capture 24:2 146:21 118:4,6,7 153:16 bread 152:1 captured 18:2 178:6 184:13 brushed 67:9 break 3:12 5:22 capturing 24:1 185:11 6·8 7·1 71·4 92·2 **Brvan** 1:19 car 56:20 59:19 body's 111:20 102:18,19,20 192:2,14 60:21 63:17 64:7 **Bollino** 43:20 64:4 103:3 109:3 **budget** 16:20 69:19 72:19 99:6 68:20 159:5 165:2 156:12 157:12 **bugging** 115:20 **Bona** 8:1 breakdown 41:5 177:21 **build** 38:7 144:5 books 119:8 carbs 68:8 178:3 breakfast 59:14,17 **building** 169:10 143:14 breakout 6:22 cardiologist **buildup** 146:2 **bosses** 98:18 39.1 107:11,12 **bulging** 115:20 **Boston** 170:7 breastbone 83:11 care 12:18 53:18 172:6 63:7 69:1 **bullet** 189:22 breath 106:15,18 129:1,2 155:9 **bothersome** 155:5 **bunch** 160:17 breathe 28:22 career 68:21 69:22 bought 110:18 58:10 78:5,6,7 **burning** 100:20 98:13 176:3 159:22 bound 162:7 breathing 28:22 189:7 31:9 78:8 184:13 business 74:1 **bounded** 121:7 careful 128:7 75:10,12 115:5 briefly 165:9 **bouts** 94:16 116:4,6 150:5 carefully 11:18 188:6 19:4 **box** 35:3,17 102:5 **buy** 156:17 **bright** 129:9 caregiver 113:19 **boy** 80:21 142:15 182:18,20 134:16 162:22 caretaker 32:17 boyfriend 170:17 bring 36:15 54:16 С 171:1 56:4 61:13 62:2 carpel 69:16 caffeine 104:5 boyfriend's 156:1 70:22 98:7 **Carrie** 43:20 64:3 111:2 128:1 141:13 160:2 bracelets 174.3 71.21 146:17 178:9 **brain** 62:13 90:4 carry 47:14 caller 98:7 99:20 bringing 175:8 93:5,6 95:15 case 22:1 70:20 calm 70:19 Britain 137:20 100:3 144:13 156:22 calmly 64:15 101:9,10,13,18 broad 18:14 26:13 cases 23:4,9 28:7 145:16 146:22 27:15 122:20 campaign 185:20 148:11 155:18 Casey 105:9 broaden 38:7 camping 74:14 156:11 158:1 114:12 120:5 166:8 170:20 broader 15:20 Campus 1:10 casualty 65:9 180:1 184:4 brochure 59:22 cancelled 177:9 cataplectic 153:1 188:17 60:4,5 cancer 20:7 22:1,4 190:19,20 cataplexy brochures 173:22 27:18,19,20 capacity 16:18 brain's 184:1 brother 81:11 93:1 95:18 28:10 30:12 52:7 Brandon 43:17 58:7 67:11.19 brought 55:3,4 Capital 1:20 51:7 56:6 69:18 70:16,18 67:8 79:22 93:4

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013

Page 8

	Pag		
74:6,7 76:10,18 77:12,16,20 78:10,22 79:5,12,15 80:3,12,18 81:6,9,10,16 82:1,11,13,14,17 ,19 83:3,15 87:3 90:18 91:19	2:6,10,14,19,22 3:22 4:16 5:4 8:9 26:6 CDER's 8:11 celiac 110:6 cell 86:16 center 1:2 2:5 4:15	94:14 95:9,10,11 104:1 character 165:21 characteristics 21:3 charged 122:4 chat 168:2	Chorus 139:10 chronic 17:21 20:5 21:9 23:17 124:13 183:22 chronically 187:12,13 chunk 144:16
105:15 106:10 117:4,8 127:15 139:10,11,12 140:3 142:16,17 143:4	7:13 20:12 26:6 101:3 104:11 108:4 centered 161:1	check 35:19 36:14,18 90:7 96:12 97:8 130:7 133:5 144:2,22 177:9	chunks 64:8 Church 156:16 circle 65:5 67:13 circles 102:11
160:11,13,15,17 168:15,17 170:7,13 171:19 172:9 175:18 176:17 183:11 186:22 188:14	central 184:1 certain 89:1 certainly 27:1 126:1 130:20 140:3 185:8 CERTIFICATE	chemical 169:21 chest 106:18 chief 126:17 child 80:20 81:14 112:15 134:12	circumstances 66:14 128:5 Claritin 122:16 clarity 11:5 class 46:3,4,9
catching 68:9 catch-up 46:7 categories 27:10 categorized 27:17 category 46:15	192:1 193:1 certify 192:4 193:2 Chad 8:9 34:20 chair 81:1 115:6 chairs 31:19 32:3	135:6 142:9 153:11,12 176:8 177:21 childhood 27:21 children 79:4,6 91:18,20 114:4	48:19 51:18 52:3 53:14,17 55:13,14 112:11 177:8 classify 46:15 classmates 53:16
91:8 160:15 caught 157:13 cause 28:11 30:21 31:3,8 54:20	challenge 73:12 119:1 challenges 21:3 challenging 16:21	129:1,8 145:21 167:12 175:3,16 Children's 172:7 chime 40:8	112:6,12 classroom 136:2 clean 58:22 clear 69:15 88:15
109:21 153:5 162:13,15 190:14 caused 73:3 83:12 97:16 125:6	49:7 151:1 chance 164:9 change 24:2 48:21 49:3,10,14 59:20 62:13 103:20	chipping 62:21 chips 152:4 chocolate 154:10 choice 129:8	100:9,17 181:12 189:3 clearly 68:8 clickers 23:8 34:21 39:7,12 40:1,21
184:1,4 causes 51:17 54:15,21 73:1 124:10 189:12 causing 152:18 190:8 CDER 1:2	changed 44:11 49:2 55:11,17 63:13 74:2 108:4 changes 28:11 30:9,17 44:21 48:19 49:10	159:13 189:7 choices 107:21 cholinergic 184:9 choose 76:10 choosing 167:20 chores 91:5	41:14 42:14 76:5,15 130:5,13 132:18 187:19 clinical 10:9 15:3,9 18:2 92:10 clinically 66:16

	Pag	e 9	
Clinicaltrials.gov	165:22 189:6	102:22	11:14 22:7
163:2	combination 73:11	103:10,16 104:8	56:17,19 59:12
clinic-based	combined 127:4	125:21	162:1
175:20	combined 127.4	133:12,14,18	compare 40:9
	comes 11:14 17:5	141:4	-
clippers 115:7	59:6 70:6 97:12	145:1,4,9,17	compared 48:9 55:20
close 35:12 75:10	98:8 118:5,6,16	147:12,13	
84:5 143:14	181:15	150:7,22 164:15	compensate 148:3
162:13 175:2	comfortable 34:3	176:1 179:7	185:11
185:14	59:16 84:13 92:6	181:9 183:6,14	competes 122:10
closed 140:22	93:7 129:19	commitment 9:5	-
	134:9	commitments	complain 121:1
closely 26:12			complained 106:5
closer 78:8	comforting 106:11	73:2,6	complete 81:1,12
closing 3:18 6:12	coming 13:11 16:3	committed 186:8	87:12 138:4
188:2	19:8,9 20:10	committee 15:17	193:7
	21:6 57:16,20		
clothes 167:20	70:19 88:3 89:14	common 28:13	completed 11:13
cloud 100:4	90:8 92:2 95:6	29:4 38:1 181:19	136:7
clouding 187:7	98:12 103:16	communicate 26:5	completely 28:5
e e	115:7 145:1	83:1	38:10 77:21
CNN 177:6,10	comment 3:17	communicating	86:22 92:11,12
coaster 70:12	6:3,6,11 18:20	168:15	108:14 117:5
COBRA 109:9	19:2 35:3,17		127:7 170:2,6
	82:7 98:11	communication	complex 12:20
coffee 6:19	100:2,22 118:9	180:20	122:20 123:18
cofounder 171:8	136:3 137:13	community 15:21	136:19 172:14
aggnition 122.19	140:6,21 142:5,8	18:9 19:13,16	
cognition 123:18	144:1,21 154:18	21:10 84:7	complicates
cohesive 125:14	157:1,21	173:10 174:10	137:22
cold 121:22 146:13	158:3,19 159:21	179:5 180:21	complications
collapse 80:8	160:5	188:10	91:6
-	163:12,19,20	Como 101:2	component 116:12
colleagues 7:5,8	164:7,13,19,22		119:2
35:20 36:15	178:16	comorbid 127:16	
37:18 145:1		175:17	concentration
165:4 185:4	commenting 148:21	comorbidities	98:17
collect 17:2 187:20	148:21	145:7	concept 147:22
collected 127:18	comments 3:2,7,13	companies 10:16	concern 111:11
	6:4 19:1,5,13	16:6 73:14	126:17 152:9
165:1 173:13,14	23:21 34:6	123:15 162:5	153:17
college 62:7	35:16,21 36:5,7	185:19	
65:9,11 66:17	44:13 51:5		concerning 125:7
124:1 128:15	84:11,14 90:8,18	companion 168:7	152:7
136:6 143:19	92:1 93:4 97:9	company 1:20	concerns 11:20
	I I		

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013 Page 9

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013

Page 10

		İ	
conclusion 106:9	127:22	continues 183:6	corpse 77:21
conclusive	consider 14:11	continuing 29:17	correct 193:7
50:12,15	22:5,10 74:11	contribute 33:19	correlate 184:12
condition 11:7	76:8 119:17	35:15 36:7,21	cost 68:20,21
12:12 15:4 21:12	176:12	125:11 141:4,7	109:11 110:21
22:3 25:6 27:7	considerably 74:3	control 47:1 59:5	couch 59:15
29:6 30:14	consideration	60:21 61:1 65:7	
44:6,10,22 50:19	19:11	81:6,21 93:6	counseling 30:19
90:15 127:10	considerations	95:17 102:4,5	132:14 133:1
128:9 165:21 176:10 179:1	14:15 16:14	112:1 119:19,20	count 51:19
180:21 183:21	considered 35:21	143:4 145:21	countless 168:7
185:15,16	92:22 108:6,22	147:19,20	country 122:6
188:10,12,21	165:20	149:16	142:9 173:15
189:6 190:3		154:12,13 176:9 184:2	
conditions 26:14	considering 16:16 167:15		couple 9:17 47:10
49:6 120:18		controlled 80:4	67:2,7,20 68:22 74:6 79:1 110:3
166:21	consistent 20:22	118:4	117:21 121:22
175:17,18	48:7 70:3	controls 30:5	125:5 134:6
181:21	consists 122:15	convene 16:22	
conducted 18:3	consolidation 29:8	conventions	courageously 76:1
178:13	30:15	161:11	course 15:2 85:1
	constant 72:8		89:9 94:12
conducting 24:5	79:12 103:21	conversation 39:2	114:20 115:11
conferences 137:4		40:18 41:3 47:8 65:16 77:13	118:13 161:5 184:16 185:17
conferencing	constantly 72:5 75:6,16 102:11	85:13 88:13	
97:10		92:11 146:5	court 57:10
confidence 176:5	Constituent 8:6		192:1,2,15
confident 127:11	25:14 26:1	conversations 38:19 73:2,9	193:3,5
	consumed 187:2	,	courtesy 38:14
confront 168:5	contact 189:13	convey 125:9	Courtyard 174:4
confronted 73:20	Contd 3:1	cook 123:17	cover 16:17 18:13
confused 88:20	context 15:3,17,22	cooking 92:13	coverage 109:10
congratulations	16:1	Coonrod 43:17	covered 20:3
178:19	continually 126:12	51:8 53:9	154:10
connected 30:5	continue 38:7	cooperate 90:4	
118:2 163:5	102:21 111:5	cop 177:8	coworkers 157:14 159:4
conquer 82:15	167:13 172:13		
-	180:16,18	copay 109:17	cramps 117:15,22
conscious 77:21 92:10 102:9	190:1,6	151:10	crazy 60:19 79:7
	continued 85:13	copy 4:21	created 112:11
consequences		Corps 165:22	173:11
		-	

Page 11 creating 147:15 12:16 18:1 20:18 decreased 28:6 184:19 190:18 54:21 21:11 33:1 47:15 credit 98:2 days 16:21 64:5 76:9 91:4 94:20 75:5 95:16 111:1 decreasing 139:22 creepy 124:1 95:10 126:11 115:14 117:21 dedicated 172.21 157:4 176:11,15 crestfallen 121:14 123:22 124:15 188:17,22 deep 64:8 187:4 125:5 166:7 crippling 185:6 189:2,12 deeper 78:7 criteria 17:19 daytime 28:2,5,8 dangerous 152:7 45:14,17,19 18:17 20:16 deeply 69:22 90:5 dark 66:9 118:6 51:15 52:5 53:9 92:20 critical 10:8 14:15 122:5,7 60:16 68:13 deferred 176.3 **crouch** 81:22 72:3,4 76:10,17 darkness 118:5 defined 25:5 84:12,15 85:5 crouches 82.1 darn 71:8 86:5 94:17 definitely 45:19,22 crouching 82:3 101:22 118:14 data 11:2,17 46:12 47:20 crying 79:11 127:4 136:15 48:13 52:5,8,11 date 174:21 111:17 159:12 145:13 188:14 54:6,11,15,20 193:12 190:17 C's 52:4 55:3,9,11,16,19 daughter 77:1 95:21 daze 62:12 64:8 cure 9:7 21:20 111:10,13 114:2 132:19 181:13 deadlines 124:8 181:4 **curious** 101:6 definition 25:2 deal 21:15 47:14 daughters 156:2 current 3:15 32:15 64:18 95:9 5:12,19 21:18 daughter's 112:18 **degree** 14:16 15:4 141:16 147:22 24:10 33:1 100:15 124:7 day 4:18 11:1.5 155:12 170:13 104:18 29:7 47:9 48:15 140:2 179:20 dealing 175:11 currently 18:5 50:18 56:13 57:1 **degrees** 166:1 45:18 111:21 dealt 117:14 69:17 70:3 72:10 113:9 142:14 dehydrated 49:19 74:13 75:19 **Dean's** 46.1 151:10 176:19 79:12 84:1 85:19 delay 188:11 **death** 81:2 86:15 92:14 **cut** 57:3 112:20 delighted 8:18 **DEBORAH** 97:19,21 cycle 45:12 50:5 demands 75:12 98:15,16 102:1 193:2.12 93:16,20 94:2,6 125:13 111:5 112:7,9,20 decent 45:21 52:2 97:2 99:12,16,17 113:6 dementia 92:22 136:5 177:14 184:16 115:14,15,16 demographics decide 73:4 cycles 45:3 94:14 117:18 125:3 129:5 184:2 127:3 134:6 decided 89:11 denial 167:1 136:11,22 137:2 cycling 96:16 decision 12:4 139:22 141:21 dense 179:9 14:15 104:17 142:19 144:15 D dental 131:7.9 decisions 71:1 147:15,17 148:7 **D.C** 39:9,10,17 140:5.8,11,12,13 155:4 156:4 decline 46:2 72:14 40:12 dentist 172:12 167:21 170:12 decrease 114:7 dad's 151:8 172:2,14 181:17 dentistry 172:14 145:13 daily 3:4 5:17

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013

dentist's 57:2 desire 19:18 60:20 158:6 189:21 16:5 23:14 25:3 178:2 26:14.19 128:4 department dietary 132:13,21 162:6,18 191:14 186:14 desk 6:7 38:10 differ 137:7 develops 14:12 114:18 163:15 dependable 94:21 difference 109:19 desperate 182:19 device 127:20 depending 137:21 118:12 121:20 123:20 **Devices** 101:3 142:13 desperation 167:11 182:22 differences 148:5 depends 126:7 diabetes 30:6 despite 75:13 depress 139:16 diagnosed 27:5 different 12:14 190:2,5 39:21 40:4,14 18:10 22:16 depressant 126:11 detached 75:2 44:16,20 49:5 25:8,11,15,16,17 depressed 65:6 51:21 53:21 ,19 27:10,18 detailed 176:2 187:8,11 56:14,15 66:16 32:11 33:21 details 177:2 71:19 79:3 80:17 depresses 113:11 47:21 49:4.6 detection 127:8 84:19 95:5 56:10 74:18 depressing 100:11 98:14,21 100:13 92:17 120:11 139:21 deteriorating 114:15,22 115:2 123:10 141:15 114:2 depression 30:7 146:22 160:18 120:14 122:2 31:9 54:13.22 determination 128:15 142:10 190:6 126:14 55:3 66:15 71:3 147:10 170:5 differently 18:11 103:22 116:9 171:9,13 determine 51:1 94:13 138:16 139:3,7 172:7,10 determined differing 127:13 172:3 187:4,6,7 175:1.13 186:9 117:16 187:12 difficult 29:12 deprivation 124:5 determining 177:5 47:20 51:3 68:3 127:5 diagnosis 85:18 113:3.6 devastating 42:11,19,20 43:4 deprived 49:18,22 120:9 143:21 12:7,10 48:5 50:8 79:18 50:3 113:21 145:20 177:4 159:10,16 106:10 107:8 describe 22:19 115:2 121:3.5 difficulties 191:2 develop 17:7 23:16 27:8 29:12 60:18 147:10 148:2 25:12 26:16 difficulty 29:5 67:22 70:5 166:2,15 167:6 77:17 85:10 77:18,19 93:5 76:12,19 91:2 172:8 188:11 127:19 179:4 147:8 digestive 120:19 dial 36:21 developed 18:18 123:12,19 described 29:10 58:6 186:18 dialogue 3:11 67:5 69:5 135:11 **Digital** 192:15 190:13 32:14 33:7,19 153:20,21 diminished 93:1 35:16,19 36:22 154:15 176:10 developer 15:11 127:1 38:7 40:6 180:9 85:9 diminishes 185:13 die 159:8 167:5 describing 96:18 developing 16:6 148:10 dine 189:10 74:7 128:7 162:3 died 167:6 descriptions 88:12 **dinner** 80:22 development 1:5 diet 30:18 49:10 92:13 168:2 2:12 5:8 8:2 55:20,22 110:3 design 66:20 70:1 9:5,11,13 123:13 146:17 85:14 dinnertime 67:3 10:9,16 13:16,18

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013 Page 12

direction 192:6 131:3,5 documentation **Disrupted** 29:3 133:11,16,20 122:6 disruption 31:2 directly 4:19 10:15 164:11 168:20 12:13 15:7 54:15 documenting disruptive 154:5 184:5 discussions 13:6 122:3 distinguish 169:8 16:15 162:4 **Director** 2:9,14 **dog** 107:14 distressed 121:10 3:20 5:3.6 6:13 disease 3:4 9:12 dogs 102:14 7:16 8:20 10:20 12:7,11 distribution 133:8 **dollars** 61:20 14:16,19 **Disabilities** 135:22 disturbances 124:10 15:7,13,19,21 30.22disability 87:5 16:2 18:6.11.14 donated 173:3 167:16 disturbed 45:2 19:3 **done** 6:3 10:10 21:3,4,11,12,15, disabled 89:22 **dive** 131.2 43:8 53:14 63:12 18 22:13 23:15 disappointed **Division** 2:18 3:21 119:9 136:11 24:6.7.21 166:18 142:21 5:10 6:14 25:1,10 26:8,11 143:11,13 161:9 7:16,18,20 discipline 166:4 91:19 131:19 175:5 179:22 8:21,22 24:13 185:16 189:4 disclaimer 37:16 180:16,19 190:4 divisions 17:16 190:15 discouraging 19:6 door 6:16 diseases 7:22 9:15 126:18 102:13,14 divulge 163:4 12:20 17:21 111:16 114:20 discovered 125:4 18:4,6,10,17 dizziness 113:6 147.14165:18 20:11 25:2,4,5,8 131:5 132:3,6 dopamines 184:7 discuss 63:15 26:10,17,20,22 docket 19:2.13 148:18 dopey 156:11 disenfranchised 36:2,7 102:21 161:14,18,20 187:14 dosage 113:1 133:15 141:2,4,6 162:3,7 164:21 121:12 164:2.3 disorder 29:20 discussed 19:5 51:11 120:9 dose 112:13,14 doctor 50:11 60:6 90:17 91:9 159:5 150:11 117:13 125:5 61:16 67:7.22 190:7 159:6,16,19 69:1,4 73:15 142:18 discussing 65:21 173:20 183:22 143:4,6,12 79:13,14 83:9 182:17 184:4 84:4 92:9 109:7 153:13,14 discussion 2:20 177:12 115:10 117:10 disorders 20:14 181:17,19 3:7.8.16 118:7 131:18 120:21 121:1 5:14,15,21 6:1,2 147:12 171:14 178:14 doses 109:6 113:16 31:16 32:9,10,20 **doctors** 46:11 disorganization dosing 113:19 34:16 61:14 62:1 95:8 151:1 36:13,14,20 79:16,22 96:4 disorganized 37:1,3,5 38:2 double 64:21 107:18 116:13 95:17 43:13,18 47:17 121:3 149:7 doubled 70:4 49:1 69:17 76:5 displayed 77:8 166:16 171:11 downright 128:2 77:2,5,10 172:17 175:6 disrespectful 103:1,9 104:10 downs 148:7 157:6 doctor's 59:18 105:5 129:19 downside 112:17

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013 Page 13

113:14 177:3 124:1 125:3 26:7,14 30:9 37:21 83:6 128:3 134:12 downsides 104:16 dressed 59:13 104:12 139:22 140:1 131:4,7 138:12 86:14,17 156:13 122:5,8,9,11 165:2 177:14 146:22 147:2 drew 66.15 126:12 128:4 184:18 187:3 downstairs 151:22 130:6,11,18,19 190:18 drink 67:16 96:7 132:11,21 downward 66:14 187:3 dying 107:4 137:13 151:6,11 **Doyle** 165:12 drinking 128:1 dysregulation 155:7,9,12 176:22 177:1 184:12 185:12 drive 54:6,8 61:7 158:16 dozing 65:15 86:2 63:16,17 64:18 162:2,5,18 157:13 90:22 99:6,8 Е 184:21 141:19 145:10 190:14,16,17,20, ear 107:14 Dr 5:2,5,9 6:12 22 191:5,14 7:10,12,15,17,19 driven 185:17 earlier 34:7 126:9 8:1,13,17 13:19 driver 83:21 drugs 5:4 7:14,22 155:4,10 160:5 14:9 16:13 8:21 9:1,6 earliest 114:15 driving 54:1.2.5 24:8.12 31:12 10:5,11,14,15 56:19 59:4 60:21 120:12 52:21 54:13 11:22 16:4 24:6 63:16 64:7,17,22 early 48:20 125:2 87:10,11 25:12 26:8,11,16 70:4 86:20 99:4 88:2,9,12 127:8 30:8,11 61:13 114:18 93:11,14 94:1 62:2 96:8 easier 178:10 96:3,14,22 97:4 drooping 47:2 130:10,19 easily 45:5 101:2 105:6,18 142:11,12,13 drop 58:11 77:17 110:21 Easter 79:1,4 148:2 153:14 80:8 138:14,22 139:1 161:19 162:2 easy 23:3,4 29:4 dropped 67:15 155:3 161:1.13 184:18,20 98:14 180:14 69:7 83:15 162:1,12,16 189:17,18 eat 58:21 59:14,17 178:11 179:18 dropping 65:6 190:5,8,13 102:8 181:3,6 187:22 128:15 **drunk** 83:6 181:14 111:14,15,18 188:3 drove 64:14 187:1 113:13 117:18 drag 65:8 172:19,20 123:3 124:2 dry 131:19 132:2 dramatic 89:3 drowsiness 31:8 152:1,2 178:3 **D's** 52:4 drastic 48:21 eaten 68:6,7 drowsy 51:17 53:2 dual 11:21 136:16 62:9,10,14 63:17 drawing 129:4 due 185:3 eating 68:5 85:21 drug 1:1,2,5,9 dream 66:20 69:21 duration 93:17 2:5,9,11 4:15 86:18 106:7 169:17 191:3 123:17 151:19 5:3,8 7:11 8:20 dreaming 29:22 9:10,13 152:20 153:20 during 6:11 13:6 52:17,20 166:8 154:16,17 155:1 10:8,16,19 28:5 29:7.22 181:22 dreamlike 170:20 11:6,15,19 12:1 40:6 45:14 66:22 13:9,16,18 72:22 77:2 79:1 echocardiograms dreams 30:2 52:18 14:12,13 59:12 148:17 88:4 91:1 107:3 15:10,18,22 98:15,16 101:22 166:9 176:3 edge 64:14 16:3,6 22:7 103:1 109:13

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013 Page 14

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013

Page 15

	Pag		
EDS 90:17 91:1	100:20 107:20	192:8	equivalency 136:1
167:3 176:17	147:10 163:14	employers 124:12	ER 171:14
185:7	167:17	166:11	Eric 3:19 6:13
educate 174:1	EKGs 107:2	empty 32:3	7:15
education 100:10	electricity 109:19	encompassing	eroded 176:5
179:5	elephants 148:16	60:18	errands 72:18
educational 125:10 176:4	eliminate 146:4	encountered	errors 88:20
EEG 50:10	Ellis 2:8 5:2 7:10	188:11	escape 72:16
	8:13,15,19 31:22	encourage 95:21	167:10
effect 49:4 50:19 53:11 103:21	else 24:3 56:13	140:20 164:18 180:15	esophagitis 120:19
113:17 170:11	60:20 78:3 80:15 84:6,8 85:1	encouraged 47:22	especially 30:3
effective 9:6 10:5	95:11 119:14	endanger 54:5	46:11,13 47:1
11:6,16,19 17:4	126:4 149:2,17	U	48:4 71:18 75:15
18:6 21:14 25:3	150:14,15 151:2	enemy 185:7	91:18 94:14,15 152:11,13
30:18 139:21 140:1 176:13	157:11 158:2 160:1 183:14	energized 147:17	178:19
	187:9	energy 54:17	essential 115:3
effectiveness 10:11,19 73:13	else's 56:11 70:8	58:22 70:10 95:13 123:3	established 178:18
effects 30:21 73:13	106:6		
90:2 91:1 109:22	e-mail 25:22 164:5	engage 32:13	estimated 25:7 27:3
113:2,15 114:8	177:7,10	engages 128:8	eternity 58:12
118:1 126:18	embarrassed 63:1	enjoy 167:19	evaluate 10:11
127:5 138:7	173:17	enormous 147:8	
140:4,7 153:8,9,10 185:4	embarrassing	ensure 10:5,9	evaluated 128:3,11
190:7	72:13 86:1	entire 64:8 78:2	evaluation 1:2
Effexor 142:16	embarrassment	83:13 109:16	2:5,9 4:16 5:4
efficacy 10:19	74:20 91:14	119:4	7:11 8:20 26:7
effort 16:10	emergency 186:13	entirely 107:5	38:9 104:12
178:19	Emory 161:2	environment	163:13
efforts 13:15 127:9	emotion 69:7	100:10	evening 169:14
179:3	70:21 74:8 80:6	eosinophilic 120:19	event 88:6 152:13
egg 79:1,4	91:21		178:16
eggs 79:7,10	emotional 80:19	EPA/DHA 122:20	events 75:4
eight 84:20	91:17 159:12	epilepsy 50:9,10	eventually 169:11
Eileen 95:4	emotions 28:13 70:16 91:18	episode 69:22	everybody 8:17
		episodes 46:17	39:7 55:6 56:11
either 47:10 48:12 53:21 66:18	emphasis 11:10	48:18	65:21 76:5 97:14 98:10 105:19
55.21 00.10	employed 118:22	equal 132:22	70.10 103.17

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013

Page 16

	rag		
120:10 123:1	136:10 172:18	93:8,20 94:6	113:7 120:13
137:5 138:19		104:22 129:21	153:8 182:3
161:5 183:13	excellent 39:2	147:2 149:17	
191:7	40:18	160:8 168:22	extremely 11:17
191.7	excessive 28:2,8		22:15
everyday 95:17	45:14,17,19	170:1 180:2,3	extremes 74:8
104:4	60:15 68:13 72:3	188:6 190:1,6,21	
everyone 8:10	74:22 78:22 85:5	experienced 53:5	eye 24:16
32:6 43:12 44:14	86:5 94:17 127:4	54:22 69:10	eyelids 115:13
70:8 85:1 86:13	136:15	74:10 76:7 80:11	eyes 50:15 115:20
87:1 103:4		90:14 94:22	e de la companya de l
	excited 36:10	113:2,9 121:19	156:18 157:17
106:1,2,3,6	41:19 60:9 79:8	131:10	eyewear 146:18
125:22 126:2	124:20		
154:1 163:21	excitement 28:13	experiences 33:19	F
164:1 174:15		34:18 38:17	face 85:22 113:8
187:19	exciting 51:10	experiencing 17:7	143:5 165:19
everyone's 133:14	excuse 166:14	22:13,14 49:7	
183:6	exercise 30:19	94:13 96:18	Facebook 182:6
everything 34:9		128:2 149:16	faces 4:14
58:11 66:2,6	54:18 91:5,7	155:12 171:20	-
69:20 78:3 84:8	111:1 122:21	172:16	facial 52:10 62:12
	132:14,22 144:3		80:7
97:22 98:4,5	170:3,8 189:21	experimenting	facilitate 162:5
99:5 116:13	exercising 48:14	23:8	facilitated 3:8,16
117:19 142:2	74:12 170:5	expert 37:17	38:2 77:10
143:19	exhausted 111:5	experts 24:17	133:20
145:17,18 148:6	123:1 167:17	-	
152:4 153:9		explain 24:14	facilitator 4:12
156:12 158:7	ex-husband 57:9	25:17 52:13,14	32:8 104:13
179:16 180:15	existed 110:19	169:7	facility 82:11
everywhere 86:19		explore 21:7	116:20
•	exists 180:7	-	
evidence 15:10	exorbitant 137:14	express 82:10 87:5	fact 19:8,19 81:10
evolving 187:5	expect 81:18	expressed 178:22	86:5 88:19 113:13 135:4
exact 77:7 106:9	expectations 127:6	expression 19:18	179:11 181:11
exactly 97:15		expressions 62:12	182:19
147:6 178:22	expected 40:11	-	
exam 79:17	expensive 171:12	extension 138:3	factor 119:2
	experience 12:14	extent 89:8 117:3	faculty 178:12
example 13:8 21:9 50:8 78:22 86:13	14:19 18:8,11	extra 50:2,3 109:2	fade 128:20
50:8 78:22 86:13 89:3	21:17 27:14 28:1	extraordinarily	faded 66:10
	33:10 37:7 44:6	181:14 182:2	fading 64:21
examples 145:7	45:15,18 56:2,4	extreme 46:19	
exams 124:1	77:12 78:11 80:3	47:4 103:20	failed 100:13
	82:5 88:18	T, T 103.20	

	Pag	e 17	
fair 37:5 96:22	31:12 52:22	Federal 18:19	116:17 118:17
fairly 20:11	54:13 87:10,11	183:21	121:15 148:8
faithful 24:3 fake 61:12	88:2,9,12 farther 10:6 fast 78:21 107:5	feed 102:14 feedback 38:8,12 191:8	female 40:20 41:1 93:21 94:8 101:9,10 135:17
faking 65:21 85:3	108:1	feeding 184:14	138:20 154:21
fall 45:5 51:20	faster 107:10	feel 6:20 7:1,4 32:5	158:9,11
52:16 54:5 55:12 57:1,3 59:4 82:4 85:22 91:11,14	father 57:16,20 fatigue 20:5 21:10	36:6 37:19 38:22 45:2 57:18 62:1	females 41:4 fewer 25:6 27:5
98:16 107:21	23:17 91:13	70:2,19 72:7	fibromyalgia
118:5,11,15	103:21	74:5 75:6 78:2,5	120:18
139:15 160:19	110:11,15	95:13 99:5,8	field 66:20 89:10
166:9 181:19,20 fallen 65:17	fault 53:20 faultless 126:14	100:9,16 106:2 110:5 115:13 117:5 118:4,20	124:7 180:1 fifth 42:5,6 43:5
falling 28:22 29:5	FDA 1:1	123:7 152:21	fight 63:12 70:21
52:2 53:14,17	2:6,10,14,19,21,	164:20 167:8	126:12,13
54:16 55:5 69:2	22 3:22 4:15	168:19	fighting 67:6
72:12 76:11	7:5,7 8:2 9:4	169:2,5,20	figure 17:10,19
85:15 106:7,13	10:14,15 15:14	170:9,10,17	23:6 26:14 89:5
142:19 156:3	17:5,17 18:17	178:2,5 180:11	118:10 186:12
186:10 falls 80:22 156:16 186:11	24:14 25:2,11,13,15,16 26:3,5,9 31:18	feeling 48:8 55:22 62:3 64:20,21 66:19 70:5 72:5	fill 15:15 69:4 filling 69:3
familiar 46:16	33:14 35:20	79:21	final 14:5 20:8
164:3 171:17	36:15 37:15,17	87:15,17,22 88:3	finally 18:13 66:1
families 176:5	38:11 51:9 56:8	105:21 121:20	70:6 79:18
family 70:14 71:6,18 75:3 80:22 85:8,19 121:5 124:12 147:16 152:3,12	87:8 100:20 101:3 105:19 114:9 126:2 138:10 160:1,8 173:8 175:8,16 176:16 178:18	124:2,3 152:3 167:4,21 feelings 62:22 feels 77:19,20 78:4,13 82:1	100:13 106:5 108:11 109:16 116:20 120:14 128:14 172:8 177:20 186:6
147.10 132.3,12 156:7,10 159:9 171:16 175:2 178:20 179:2	182:13 183:17 185:14,17 187:20 189:17	100:4,8 112:10 123:9 169:21 fell 55:1	financial 128:18 164:18 192:9 finding 26:22
189:14	FDA's 2:11 5:7 8:5 13:17 141:13	fellow 53:16	73:11 88:13
fancy 34:22		105:20	162:13
fantastic 45:9	fear 28:13 70:16	felt 20:19 58:12	fine 63:16 82:21
126:3	82:21 176:8	61:19 66:5,8	83:3 99:6,8
Farkas 2:17 5:9	189:1	67:14 79:20 80:1	164:22 179:16
7:17 24:9,12	features 180:9	106:12,19 108:10 115:17	finger 77:22

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013 Page 17

Page 18 fingernails 83:11 flaw 165:22 152:20 182:9,14 fought 134:18 fingers 69:21 fleeting 69:9 forbidden 61:13 foundation 33:6 62:2 finished 109:6 founded 173:2 flickering 67:14 137.17forced 124.16 fourth 9:9 115:15 flight 106:16 168:4 fire 152:10 floating 100:4 fractured 120:13 forces 173:10 fired 186:16 floor 83:20 165:19 Fran 43:19 56:7 foregoing 192:3 first 5:2,16 9:11,19 61:17 63:22 floors 58:21 17:16 20:1,8 foregoing/ Francisco 182:11 fluctuation 93:15 24:14,22 28:8 attached 193:6 96:19 free 6:20 7:1.5 32:20 33:4 34:5 foremost 37:6 32:5 36:6 38:22 37:6 39:8 40:10 fluctuations forever 68:5 146:17 164:20 43:7,16 56:12 103:20 59:18 67:11 forget 34:7 73:1 freezer 152:1 **fluffy** 100:5 73:16 81:1 84:14 86:22 115:16 frequent 122:15 **Flygare** 77:15 92:5 95:5,7 148:8 186:11 165:11 97:10,11 107:9 forgetfulness 168:12,14 frequently 46:17 108:8 87:13 92:20 93:4 173:11 47:13 111:11,15,16 103:19 145:16 114:22 115:4 focus 13:4 17:15 freshman 65:11 forgetting 187:15 117:10,12,15 18:22 90:17 Friday 119:4,6 125:20 145:5 forgot 172:5 91:16 98:17 friend 124:18 153:3 157:1 100:16 159:17 forgotten 89:20 135:22 171:16 165:14,17 170:5 focused 11:1 21:10 187:14 171:21 175:14 friends 52:9 63:16 25:1 26:2,9,13 form 120:2 177:14 179:12 75:3 81:22 46:3 99:1 187:9 188:9 format 2:20 5:14 82:2,17 85:7,18 191:14 23:19 31:16 97:19 112:4 first-line 167:2 focuses 11:20 32:10,20 171:14 176:7 fiscal 14:5 20:4 fog 100:3 189:10,13 former 109:8 fish 102:6,8 101:9,11,13,18 front 51:11 56:4 forms 38:9 69:3 145:16 146:22 fit 143:18 89:6,10 111:16 163.14148:11 154:2 five 33:9 104:20 frozen 152:1 forth 70:13 83:5 155:18 158:1 142:13 180:1 188:17 85:8,14,20 86:1 **fruit** 123:4 fix 12:21,22 13:1,3 190:19,20 138:12 147:1 Frustrated 110:1 fixing 121:18 fogginess 72:21 forties 85:6 frustrating 70:15 73:1 flailing 121:14 fortunate 98:12 71:9 90:5 178:5 foggy 156:11 flare-ups 50:7,21 forum 167:7 183:2 frustration 108:12 51:2 folks 164:12 125:9 forward 19:9 37:9 flat 108:16,17 follow-up 34:1 39:2 40:5 41:2 full 28:22 70:3 96:15 153:18 125:13 167:16 77:17,19 80:8 flavors 123:14,21 95:19 117:7,13

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013

(866) 448 - DEPO www.CapitalReportingCompany.com © 2013

food 1:1,9 123:3

Page 19 125:5 138:3 **Galloway** 108:19 64:2 71:21 72:1 75:22 76:16 fullest 95:18 giving 16:16 garage 102:13 77:9,11 78:16 87:1,4 116:8 full-time 71:5 Gary 144:10 80:9,14 82:6 120:8 184:18,19 **fully** 44:9 47:19 84:9 87:7,18 gasping 106:16 glad 4:18 56:4 90:6 91:22 72:7 156:20 **gastric** 123:13 126:4 144:2 93:2,10,13,22 169:20 gathered 18:3 159:14 94:7,10 95:2 **fun** 57:22 65:10 65:13 96:10 97:6 98:6 glimpse 134:14 173:17 99:13,19 100:18 gears 84:10 156:11 glutamatergic function 89:21 101:7,12,17 184:10 gee 156:6 113:4 115:12 102:17 103:4 143:20 152:16 gluten 110:8 general 21:6 27:9 104:7,9,11 179:21 181:12 146:16 72:10 162:17 105:16 111:6 177:15 114:11 120:5 functional 137:6 gluten-free 55:21 125:18 110:3 158:6 138:7 151:6 generally 20:15 129:13,17 156:21 33:20 38:3 41:21 goal 37:19 130:2,14 131:13 104:16 functioning 17:22 **god** 57:6 58:13 132:1,6,19 152:17 185:1 generate 98:22 59:16 60:3 61:19 133:10,21 134:7 fund 162:17,19 119:11 169:15 **genetic** 160:22 135:9,16 138:9,18,21 **fundamental** 30:5 gentleman 92:4 **goLITE** 118:8 139:5,9,11,15,18 144:9 150:2 funding 26:21 gone 45:22 55:21 140:6,10,13,19 158:4 64:13 92:16 162:14,16 141:8 142:5 116:13,14 gets 70:15 82:3 fundraisers 143:1,22 144:20 117:5,7 119:10 89:1 118:6 172:22 146:7.20 143:10 163:6 goodness 69:8 149:11.20 funds 162:20 185:11 150:6,8,20 Google 83:16 172:22 getting 23:6 26:13 153:18 fuse 68.14 Googled 84:1 52:3,4 55:8,20 154:14,19 future 12:17 16:4 57:3 74:16 85:5 gotten 23:20 66:12 155:1,13 157:20 136:7 20:6 23:14 24:5 86:17 106:15 158:8,10,13,18 38:13 63:21 109:15 152:20 159:20 160:4 government 9:4 129:9 140:17 159:12 189:8 162:10 163:10 37:11 150:15 168:11 ghost 65:14 **Gow** 165:12 giant 56:16 147:13 **GI** 31:1,7 171:6.7 G gift 78:4 **GPA** 128:17 Giambone 2:3,21 GABAergic 184:9 gigantic 89:9 4:3.9.11 8:12 grabbing 79:7,10 gain 12:5 34:16,19 31:17 32:7 39:13 **girl** 114:17 91:6 113:12 grade 48:8,9 40:2,15,22 116:11 girlfriend 131:17 grades 48:6 55:2 41:7,15 42:8,15 **gained** 74:17 43:6,15 44:1 143:20 girls 156:5 116:7,8 151:20 51:7 56:6 63:22 gradually 59:20 given 11:6 115:1

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013

	Pag	e 20	
graduate 166:1 graduated 62:7 66:17 165:22	105:6,18 110:21 grocery 47:12 177:19	half-sleep 72:22 halfway 36:19 85:16 136:5	happened 58:7 60:22 73:10 82:11 89:4 169:17
graduation 67:12 Grady 134:10 165:12 174:15,18 Graham 8:3 grains 123:5 grand 97:15 grateful 71:17 122:11 128:18	ground 37:3 38:1 81:13 82:3 group 5:21 6:2 29:16 36:14,20 41:21 42:3 76:4 77:2,4 129:19 131:3 133:11,16 153:19 162:22 176:13 179:10 183:19	hallucinated 57:18 hallucination 169:5 hallucinations 28:17,18,19 31:10 52:13 57:15 66:9 76:11,21 120:14 125:3,6 148:15 153:1 168:20	169:17 happens 47:12 97:15 157:7 happier 170:10 happy 7:6 9:2 14:4 37:10 40:15 41:17 63:19 105:15 164:4 hard 46:2 48:4,14 50:7 51:1 52:13
gravely 125:7 gray 100:7 great 4:13 31:17 32:2 37:2	groups 25:11 30:19 127:14,17 132:14 133:1 148:13 160:10	177:4 188:18 hallway 6:17 38:20 169:10,16 Hampshire 1:11	53:13,14,22 55:9 67:6 78:21 94:20 118:20 122:22 151:15 166:3
39:2,8,15,16 40:2,15 42:1,8,16,19 43:1,6 44:1 46:1	growing 171:16,18 172:10 guarantee 135:22 guaranteed 126:9	hand 34:4 67:15,16 69:1 83:22 135:10 142:6 152:15 174:19	harder 50:5 127:2 145:14 168:16 hardest 47:13 168:8 hardly 94:3
48:8 57:2 77:9 83:12 95:13 97:6 99:19 106:22 108:2 130:2 132:8 133:10	guard 80:6 guess 17:12 22:19 66:11 88:9 136:4 145:4	handful 107:20 handle 48:2 50:20 52:19 95:8 96:9	hassle 188:17 hate 138:7 haven't 22:18 49:2
137:20 149:12 150:17 155:8 157:18 160:16 162:2 191:2 greater 41:13	<pre>guilt 59:1 guy 89:19 guys 56:4 62:10 63:11 163:5 177:2</pre>	hands 80:11,13 87:18 93:3,7,9 96:19,21 97:3 99:18 101:13,16,18 115:8 129:20	84:16 99:3,10 100:21 101:19 118:1 123:20 152:5 164:1,9 having 15:5 16:15
153:19 179:4 greatest 19:7 118:13 119:1 greatly 160:12	<u>Н</u> habits 68:5 hair 57:3	130:1 130:1 131:3,8,9,11 132:5,7 139:6,7,8,13,14, 17 149:17,19	19:17 22:17 39:21 40:4,14 51:9 59:1 60:10 62:22 65:10,13 70:16 74:20 78:10 70:2
green 105:13 136:18 GREENE 94:12 105:13 125:20 129:11 Greenstein	half 29:13 44:19 62:11 63:13 87:21 107:9 112:20 119:18 151:22	17 149.17,19 164:1 happen 59:7 79:20 87:16 109:10 126:16 152:10 169:12	78:10 79:3 81:9,16 86:10,11 88:13 93:6 97:20 106:10,19,22 108:20 113:18 114:17 117:21

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013 Page 20

Page 21 121:9,19 125:10 167:18 175:16 83:4,5 84:12 160:12,16,17 136:9,20 142:20 93:14 101:19 172:4 189:5 143:16 149:7 129:20 131:4,5 helpful 24:5 higher 152:16 152:21 153:1 149:14 150:21 107:20 175:20 154:4 157:4 161:4 171:19 122:19,22 highest 112:13,14 158:22 171:18 174:11 188:7.20 145:10 188:5 113:16 142:18 174:5 177:18 189:3 191:9 143:3,6 179:20 180:13 hearing 19:10 23:7 helping 26:14,20 153:13,14 183:2 190:15 37:9 40:5 41:3 51:1 91:7 110:17 177:12 head 7:13 13:6.22 125:13 135:11 186:9 high-functioning 47:1 64:6 67:14 183:3 helps 49:11 55:19 136:4 100:8 107:14 heart 31:1.6 78:6 63:20 117:19 114:17 high-level 145:4 106:19,21,22 123:3,18 143:17 115:17,18,21 107:4.5 highlight 45:1 144:7 177:13 179:12 108:1,5,8,10,18 175:4 hereby 192:3 184:14 headache 31:7 highlighted 47:17 193:2 111:20 heartbreaking highlights 188:7 he's 57:10 headaches 113:3 176:3 81:4,15,17,22 highly 184:11 131:5 132:4,7 heavy 100:8 82:2,3 134:16 hill 108:14 109:2 heads 80:10 99:15 held 83:22 142:14 143:6 132:2 149:12 hire 124:19 hell 166:5 hesitant 180:11 health 8:6 10:4 hired 56:15 59:11 Hello 24:12 97:13 hesitate 117:1 25:13 26:1 48:3 histamine 184:7 111:8 125:20 91:17 101:4 hesitation 11:6 hit 78:21 110:5 114:1,2 123:20 help 7:6 11:9 13:9 hey 85:3 117:6 124:15 137:21 138:1 14:8 15:3,16 hi 7:12,15 8:10 157:11,12 140:5,8 151:16 16:1.12 17:6 14:1 43:12,17,19 20:16 25:3 **HIV/AIDS 20:6** healthy 80:21 44:14 51:8 77:15 26:15,16 37:18 21:16 hear 4:19 5:2 82:9 87:20 95:4 55:6,22 71:13 hold 47:2 85:12 10:13 12:13 97:13 98:10 76:4 107:18 90:3 91:21 176:4 15:6,20 16:13 100:1 101:2 111:17 112:1 18:8 21:5 22:4 114:13 150:10 holding 115:13 123:1,19 127:21 24:20 27:2 151:4 163:21 176:7 128:22 130:6 33:4,12,20 37:13 177:1 178:11 132:12 133:22 holiday 126:12 38:11,16 40:16 181:3 138:16 139:3,15 **holistic** 127:10 42:19 64:4 90:18 145:13.15 **Higgins** 165:14 93:21 94:10 Holter 107:3 156:1,18 160:14 186:6,7 123:8 138:19 177:13 184:19 home 58:21 59:16 high 31:6 51:13 141:1 147:4,18 191:5 69:17 72:18.19 74:14 89:21 158:1 159:14 84:1 112:8 116:8 helped 17:19 114:18 119:13 161:10 169:6,15 118:19 123:17 55:16 110:4 120:20 128:12 188:5 141:19,20 146:14,17 134:17 136:6 heard 23:20 33:22

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013

	Pag		
143:9,10	113:5 115:14	28:19	31:17 33:7
homeostasis	121:22 125:1	hypnotic 181:12	37:16,21 39:1
184:15 185:5,8	127:3 128:21	hypocretin 153:6	40:15 41:10
homework 142:21	136:14 155:21	• •	42:13
143:11,13	158:15 172:2	hysterical 58:9	43:8,9,12,17,19,
,	180:4 191:3		20,21 44:20
Honor 46:1	house 58:22 59:13	I	45:12,18
honored 51:11	79:4 108:17	idea 86:21 102:10	46:5,6,14,15,21
56:9	123:8 155:22	153:2 162:2,14	47:6,7 49:7,12
honoring 73:6	156:1 181:21	163:6 186:18	50:2
honors 52:4	household 154:5	190:13	51:11,13,17,19 53:2,12 54:1
	housekeeping 5:1	ideal 149:22 153:2	55:15
hope 10:6 12:5	6:15	157:21	56:4,14,19,21
16:20 71:12 75:16 94:22 96:8	housemate 148:16	ideas 183:5	57:9,13 58:13,14
109:3 159:17	huge 65:8 78:10	identical 133:8	59:4,14,16 61:3,5,6,8,19
183:6	121:19 147:22	identify 127:14	62:14
Hopefully 54:7	170:16 173:15	identifying 26:20	63:5,11,16,18
hoping 119:20	189:4,6,7,9,11	idiopathic 161:3	65:22 68:9,10
121:12	Huh 47:7	186:9	71:3,17 72:8,9
Hopkins 84:5	human 124:21		73:4,5 76:6
hormonal 59:2	176:7	ignoring 73:5	77:5,15 85:6
	humiliating 72:14	ill 57:7,11 58:14	86:20,21
horrible 62:22	e	60:10 152:3	88:10,19,21 89:2,17
72:5	hundreds 103:15	187:12,13	92:14,15,16
horror 73:7	178:15	I'll 4:20,22 5:13	93:18 94:5,12
hospital 83:4,9	hunger 111:19	7:7 9:19 27:11	95:4,7,16 96:12
106:3,17 109:8	hunt 79:1,4	34:1 45:6 47:2,3	97:13,14 100:4
173:4	hurt 110:12	54:2,7 60:3	101:2 102:3
hostile 111:20		63:16 71:7 77:6	104:13
	husband 79:9	82:21 92:8 102:4	105:6,7,12,13,15
hot 49:19	121:7,11 167:22	105:3 118:12	108:15 111:8,9
hotter 94:19	172:19 177:20	119:8 125:21	114:14 116:21
hour 65:1	179:17	145:3 154:7,9 165:8	117:21 119:6,20
121:10,14	hyperactivity		123:7,16 126:4,5
170:22	46:19	illegal 61:13	128:20,22
hours 17:14 45:9	hypersomnia	illness 167:9	129:1,2 130:11
47:10 55:19 65:2	161:3 186:10	I'm 4:15,18	132:15 133:3
72:10,11,22	hypnagogic 28:18	7:7,10,11,12,15,	134:10 138:6
74:13 75:18	120:14 125:3	17,19,21	140:10 144:2,11
83:10,19	168:20	8:10,18,19	147:7,19
97:18,21 99:9	hypnopompic	13:19,21 14:1	150:6,10 151:9,22
106:1 112:8	пураоротри	24:12 27:1,8	131.7,44

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013 Page 22

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013

Page 23

	<u>1 ag</u>		
153:14,15,22	188:9	45:14,16 122:8	ingest 123:14
159:14 161:3,21	improve 16:11	increased 126:19	ingredients 123:15
162:11 168:14	30:16 50:12,14	173:7	182:16
171:8 177:17,21	114:6 127:9	increasing	initial 18:18
178:11,16 181:4,5,9 186:7	170:9 190:20	50:16,17	
	improved 49:12	increasingly 74:10	initially 57:16 84:19
imagine 51:14 73:7 115:6	121:21 158:7	0.	
	improvement	incredible 35:11 117:15	initiative 2:12
imagined 168:6	108:7,9		9:13,17 13:18 14:3 71:16
immediate 123:13	improves 170:10	incredibly 188:5 191:8	174:20
immediately	impulsive 68:4		injected 119:9
106:11 121:13	•	independence	U
172:5 187:9	inability 28:21 71:5 90:22	176:5	injects 59:6
impact 5:17 20:18	116:11 184:2	independent 63:15	injuries 104:1
21:10 33:1 44:7		independently	innovations
76:9 90:16 100:3	inactive 29:22 74:16	127:18	127:21
102:16		Indiana 92:8	input 16:2,12
149:14,18 176:15 179:1	inappropriate 72:13	indicate 175:20	17:17 19:6
189:4,6,7,9,11,1		indicating 110:7	22:17,22 23:10
4	incapable	e	insatiable 178:2
impacted 46:12	126:21,22	individual 15:16	inside 65:22 77:20
51:15 57:4	incapacitated	137:7 187:8,11	80:1
180:21	181:14	individually 136:1	insight 17:6 88:19
impactful 180:6	incapacity 176:8	individuals 179:2	89:1
-	incline 108:13	industry 16:16	insomnia 31:7
impacts 3:4 45:20 51:16 52:6	include 30:9 72:16	37:10	60:2 94:16
145:12 176:11	129:5 145:7	ineffective 113:17	instant 53:17
187:1	included 66:9	121:4	
important 10:1,3	includes 103:19	ineffectual 128:3	instead 108:5 167:17 168:13
11:9 12:13	126:10	inevitably 124:15	
13:4,7 16:14		č	instinct 81:1
38:9 44:8 47:18	including 20:11 28:1 29:10 71:16	infant 176:7	institutions 128:18
48:3 90:21 96:5	119:5 168:20	infections 131:17	instructions 174:7
111:9 129:11	income 71:5	information 14:11	insurance 73:14
133:16 144:4	109:12	15:1 17:3,5 18:3	109:7,10,16
151:5 185:9 188:18		19:14 25:15	137:14,16
	inconvenient	34:19 73:19	138:2,5
-			151:8,11,16
impotence 31:6		informing 16:4	172:6
impressed 178:16	increase 16:18	infuriating 68:16	integral 12:4
impossible 124:12 impotence 31:6	113:19 150:18 incorrect 172:7	128:6 182:15 informing 16:4	151:8,11,16 172:6

intellectually introduce 7:8 33:8 170:16 179:9 122:11,12,22 89:22 98:18 43:11 105:4 181:15.22 123:6 126:2 182:3,8 188:15 127:17 128:4,5 intelligence 125:10 introducing 190:10 131:21 127:22 intelligent 89:17 133:8,15,16 issues 25:18 55:2 introductions 134:5.6 intense 28:13 120:19.21 43:15 135:5,10,14,17 154:4 123:12 131:6,8,9 136:16,17,19 intrusions 139:22 145:6 146:1 interact 150:12,16 137:7 140:22 inundated 94:5 156:10 interaction 136:20 141:8,9,16,22 161:15,18 inundating 93:18 143:20 144:14 interactions 104.3 164:10 170:21 147:20,21,22 invisible 59:6 171:4 185:9 interest 19:12 148:7,10 149:1,7 159:6 51:10 192:10 item 187:18 150:3,16,17 invitation 173:9 interested 16:6 151:7,11,12 items 5:1 6:15,20 invitations 72:15 23:18 95:6 97:14 152:17,18 it's 4:13 6:5 9:21 75:4 153:12,16 interesting 53:4 11:7,18,21 154:2,11,12 90:18 122:7 **invite** 33:18 36:11 12:9,10,11 14:20 155:7,8 157:17 133.4 174.9 20:10 22:2,3,14 invited 3:10 159:1,5,10,16 23:3 24:16,17 interests inviting 71:15 163:16 169:17 25:5 27:3,22 164:18,20 170:18,19 involved 10:16 28:3,12 29:7 interferes 109:22 173:17.19 174:9 26:19,21 65:16 30:4 34:19 175:15 177:19 interim 173:14 162:18 184:6 35:6,11 36:2,4 178:5 180:14 37:8 38:10 39:16 interior 70:1 involves 9:13 181:11,12,14,19 41:7 42:20 interject 65:18 involving 30:15 182:1,10,14 44:5,18 45:22 183:13,14 internal 109:14 IQ 89:21 128:11 46:2,7,10,17 185:8,16,20 134:17 47:5 50:5,7,22 internally 18:18 189:19 51:2,4,10 irrational 68:4 internet 118:2 I've 4:12,14 45:20 52:18,19 153:20 49:5,9 52:7 53:5 internist 109:7 53:13,19 59:4,5 154:12,16 54:3,22 55:21 60:18 62:10 interpret 11:3 irregularities 31:7 65:2 68:4,6 63:12,18,21 69:7 interrupted 184:4 70:21 73:6 74:6 irritability 30:21 71:9 79:21 83:18 83:5 94:22 interruption 85:6.22 86:22 isn't 56:11 89:22 100:11 117:17 92:10,18,19 184:10 111.2119:4 120:13,15 93:19 94:8,18,20 interruptions isolate 123:16 95:10,16,18 96:4 121:15 122:5,19 126:14 97:22 98:3 136:6,7 137:3 isolated 9:21 75:1 interviews 66:17 151:20 153:10 100:5,7 102:1 Israel 173:4 158:22 161:6 110:18 111:9 intestinal 184:14 issue 27:1 112:11 116:22 117:3,5 168:8 178:21 intimacy 104:3 123:21 118:10,19 183:11 185:22 151:7,17,18 intoxicated 182:2 119:9,22 120:1 187:1

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013 Page 24

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013

Page 25

	i ug		
ivory 9:19 22:18	177:3	knew 59:15 65:3	LaShun's 111:12
	July 44:16,19	69:11,22	114:1
J	jump 107:6	81:17,18 88:16 105:22 148:16	last 34:13 36:1
James 8:5 90:11	jumped 116:21	163:7 172:10	38:14 42:10
jaw 58:11	• I		47:10,22 48:11
Jazz 121:12 179:3	June 20:6,7	knowledge 82:12 84:7 179:11	73:3 74:6 75:5 114:21 118:7
Jed 165:12	junior 143:18		121:8 129:7
178:9,11	Justin 94:11	knuckle 83:10	137:15 142:8
Jeff 108:19	105:13 125:19	kudos 178:18	155:21 163:12
	129:13		178:1 182:7
Jim 8:1		L	187:18
job 20:16 59:12	<u> </u>	lab 182:11	late 65:7 113:5
61:18	Kara 99:21 100:1	label 60:9	152:20 156:4
66:17,18,19 75:8 90:3 100:15	Kerry 43:12	labeled 89:9	lateness 90:21
109:7 119:3,6	44:12,15 93:15 94:2	labels 70:7,8	124:13
138:1 145:11		lack 90:22 179:10	later 11:13 27:22
151:16 186:16	key 10:9 188:13 190:16	188:9	36:13 37:1 85:11
189:8		lacking 122:14	107:3 128:14 149:5 169:12
jobs 68:21	keys 102:12	166:4 183:4	171:10
Joe 43:21 72:1	kick 76:4 77:12 109:8	lady 147:5 158:11	latest 89:3
John 81:9 142:12	kicked 52:3	laid 20:17 65:20	laugh 58:8 85:20
Johns 84:5	109:16	lane 64:15	0
join 4:5 36:12	kid 134:16	large 12:3 19:20	laughing 65:22 67:13 70:19
174:6	169:9,15	40:11 91:9	80:21 176:7
joined 173:10		112:18 144:16	
179:3	kids 53:16 81:4 116:2 118:18	147:9	laughter 31:11 53:8 68:19 83:17
joining 4:6 34:10	123:8 137:18	large-group 3:8,16	89:16 91:20
35:10,13 36:11	142:12 159:4	38:2 77:10	100:6 110:20
40:17	167:17 173:5	133:20	laundry 107:7
joke 52:10 85:20	killed 187:6	largely 74:16	108:7
119:22 120:1	Kineu 187:0 Kim 90:10 134:10	75:1,5 160:22	law 135:19 161:20
joking 57:13	158:20 165:12	largest 41:22 42:3	lawn 53:7
joyful 121:7	174:14	90:19	lay 72:6 82:21
judgment 187:8	kinds 27:18 87:13	Larry 7:21 26:10	118:19 186:17
judgmental 73:17	152:21 160:18	LaShun 105:8	layers 141:18
Julie 77:15 78:16	kiosk 6:19	111:7,8,10,21 112:3,10,13	laying 54:19
165:11 168:12	kitchen 58:18	112.5,10,15	lazy 53:18 55:6
171:5 173:11	154:4	186:3	65:4 70:7 98:18

166:4	02 7 04 10		
	82:7 84:10	44:21 48:19 49:9	86:20 91:16
lead 2:18 71:13	90:7,9 92:1,4	145:12	102:19 108:10
	93:3 94:10 96:12	light-blocking	114:13 130:21
leader 7:20	97:8 100:19	146:18	154:7,8 168:19
leaders 173:11	101:7,12	lighting 118:11	177:2
learn 30:3	102:5,18,20	0 0	Littlestown
learned 64:17,18	104:9 105:16	lights 67:14	105:10
117:17 172:9	129:14 130:3,5 131:1,3,8 132:9	limb 29:11	live 15:7 22:2 39:8
learning 172:16	133:5,21 134:2	limit 165:5 174:16	124:3,21 152:11
0	138:18 139:5,12	limited 71:4 72:22	156:16 157:3,4
least 16:20,22 36:1	147:4 149:20	127:3	lived 57:12,13
38:14 47:9 86:6,8,9 87:5	150:8 151:2	limiting 190:9	58:16 84:5 187:4
127:14 185:1	155:13 158:2	_	liver 113:18
	163:18 177:6	line 97:12 99:22	
leave 46:12	letters 89:9	101:15	lives 12:16 108:15 159:3 167:10
48:1,19 65:2 73:18 82:20	level 73:21 89:1	lined 20:10	179:1 183:1
90:22 102:13	120:11 123:3	lines 50:11 161:22	188:18
140:17 167:21	levels 70:12	link 164:4	189:2,4,15
lectures 53:15	liaison 26:2	list 18:18 19:20	living 21:17 32:15
106:13		20:1 30:10 46:1	42:22 69:2 70:17
led 113:21	liar 61:11	155:11 157:1	81:5 91:4 126:6
	lie 166:12	listen 37:6,15	127:2 189:12
Leesburg 105:14	life 13:8 18:1	149:7,8 157:3	Liz 147:7
leg 29:10 76:13	20:18 21:11 28:1	listened 65:20	loaf 152:1
117:22	33:1 44:7 45:2		loans 98:2
legal 64:11	51:15 57:5 59:20	listening 17:17 35:18 37:13	
legislation 124:9	61:1 62:21 63:13 65:8 66:15,22	65:16 157:16	lobby 6:16
legs 29:12	70:17 71:2 76:9	183:15	local 39:16
length 42:10	78:3 86:11 95:18	listing 183:21	located 6:16
0	96:5,6	lists 28:12	location 22:20
lengthy 73:9 176:2	100:3,4,10		lock 102:14
LENZI 43:12	102:4,10,16	literally 24:1	
44:14	109:16 114:7,8	115:19 178:4	locking 165:18
less 18:20 42:11	119:4,18 126:21 127:1,22 137:22	lithium 166:22	logs 116:16
43:4 55:22 74:17	143:17	little 9:17,18 10:6	loneliness 71:2
109:9 190:15	145:19,22 149:1	16:19 20:22 22:9	long 4:18 12:19
lethargic 55:22	159:11 167:14	31:18 32:11	17:14 49:3
let's 32:20 37:2	168:5 170:4,10	41:10 45:22 46:2	61:2,3 62:19
38:18 39:4,20	172:15 180:21	49:7,11 52:8	64:13 86:11
40:7,19 41:21	187:1 191:4	63:17 65:5,7 67:15 84:10	98:22 113:14
42:15 44:12 77:4	lifestyle 30:9,17	07.13 84.10	171:10

longer 22:9 46:4 190:4 188:17 matter 3:5 11:2 47:5,8 48:22 72:6 116:19 loud 125:21 189:3 majority 28:7 74:1 75:11 123:4 160:16 matters 60:20 love 71:11 75:7 106:15 157:15 110:22 119:5.7 makeup 59:14 maximize 22.22 158:15 167:3 137:17 mal 97:15 may 16:3,5 longest 72:11 78:2 loved 32:17 18:1,4,11 21:5 male 40:20 41:2 **long-term** 120:22 22:7 35:17 53:18 **low** 66:22 71:2 135:14 127:21 54:18 63:6 124:3 luckily 50:22 **males** 41:3 loopiness 46:18 153:18 160:14 lucky 74:11 mall 61:3 lose 64:8 89:1 maybe 13:5 19:8 98:16 **lunar** 97:2 56:11 88:10 man 59:6 172:11 116:6,11,13,19 96:19 97:1 102:7 lunch 61:15 manage 86:11 137:8 189:12,13 116:10 118:12 136:22 137:4 189:20 124:1 137:20 losing 85:7 95:15 143:7 management 147:17 149:8 100:16 lunches 167:20 159:19 151:15 155:11 128:21,22 191.4Lunesta 122:15 manager 59:15 129:1,2 177:16 123:6 61:15,16,20 62:6 **MBA** 2:3 loss 28:10 69:5 lung 20:7 22:1,4 managers 61:11 103:21 116:14 **MD** 1:12 2:8,17 63:6 153:6 176:9 3:19 lured 71:2 managing 128:7 lost 74:19 75:2 Meaghan 165:12 lving 116:16 176:5 176:22 manifestations 165:18 183:20 lot 17:13 18:16 meal 46:5 Lyrica 122:16 25:17 26:7 manifests 74:7 mean 32:15.17 27:2,12,13 38:16 Μ 53:19 57:13 marathon 107:9 46:7,12,21 47:1 61:22 88:2,7,9 **Ma'am** 99:22 167:21 170:7 53:17 54:17 59:1 97:21 119:10 Mack 110:5 mark 165:12,16 72:19 73:3 79:21 134:16,19,21 181:2.3 87:11 90:16 mad 55:8 124:16 151:12,14 91:2,3 95:13 **market** 122:12 152:10,12 maddening 73:1 103:19 104:2 153:12,15 marketing 10:12 magic 189:22 114:19 118:1 154:5,7 155:4,7 11:16 14:13 120:21 121:3 magical 110:22 157:6 **married** 167:12 122:17 132:2 162:1,20,21 magnesium 137:8 145:5,16 Marriott 174:5 181:11 117:20 122:20 146:4 147:11 **mascara** 114:19 meaning 176:11 main 32:12 53:10 148:1 155:19 164:10 185:7 master's 124:7 157:12 159:6 meaningful 136:7 137:17 160:11 163:22 22:5,6,11 maintain 114:1 170:20 171:14 127:2 128:16,17 mat 81:22 means 80:5 98:1 173:6 180:10 112:1,6 136:5 maintaining 29:5 material 182:15 183:4 185:17 137:16 major 179:8

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013 Page 27

	Pag	e 28	
meantime 61:19	medicine 102:15	60:10	mg 50:18
measures 182:4	109:14 153:12	mention 34:7	mic 150:7 154:18
meat 123:4	meds 70:11 109:20	73:16 91:15	165:15 178:9
	128:20 150:13	103:17 122:1	Michelle 84:18
mechanisms 15:14	167:19	133:11 146:15	85:12
medical 2:18 5:10	meet 20:16 174:6	170:3,14 171:3	
7:17 14:17 24:13	meeting 1:4	180:8	microphone 34:2,4 90:9,10
37:17 82:11 84:7	4:12,17 9:9	mentioned 8:19	137:12 140:14
106:1 107:17	14:3,5,22 15:18	24:22 30:14	
116:20 165:21	19:17,18,19,22	38:1,21 48:18	mics 168:13
172:18 173:19	20:5,7,8 21:9,16	49:21 52:22	middle 109:5
180:20 186:15	23:3,22 25:1	53:12 54:13	114:16
190:3	32:8,10,13 34:8	76:14 77:1 84:17	181:16,18 185:7
medication 44:20	35:12 36:4 37:20	91:3 94:2 101:5	mid-morning
49:12 51:1 52:4	38:9,12,15 61:4	103:18,22 110:4	137:1
54:7 74:4 99:2	104:13 163:17	126:8 127:17	midnight 113:20
107:15,21	165:2 174:4	130:11,20	e
108:9,12 109:21	183:22 188:4	132:2,15 133:2	Mignot 161:1
111:2,22	191:13	146:10,13,16	162:12
112:3,14,15,22	meetings	181:10	Milburn 8:9
113:9 114:5,7	9:10,11,12 14:4	188:16,19 189:19,21	mild 67:5
115:22 119:2	16:11,19,22	190:10,19	
126:8,19,20 128:3 131:18	17:12,15 20:3	,	mildly 123:6
135:7 177:11	21:1,8 22:17	mere 121:18	military 54:10
182:1	23:11 32:12	merely 184:20	Miller 100:1,2,7
	34:14 38:13 86:1	message 177:10	
medications 50:13	meets 14:17	U	million 25:8 61:20 83:8 124:9
55:12 73:12,21		messages 177:6	153:14
74:19 107:9,22	members 42:18	messing 37:20	
108:8	175:2 178:20 179:2 189:13	met 56:12 161:6	milliseconds 78:1
109:5,11,18,22 111:21 112:2		172:20	mind 34:20 36:6
111.21 112.2	memories 120:12	metabolism 54:21	90:10 97:10
114:4,6 122:17	memory 103:21		103:13 138:21
136:5 141:15,17	120:21 123:18	metabolized 110:1	158:20 164:14
145:8,10,13	154:11	method 108:19	171:21 185:10
146:11 155:19	men 58:3	methods 108:18	mine 59:2
159:13 160:18		110:2	
166:21	Menopause 60:1		mingling 68:12
176:14,17,18	menstrual	methylphenidate	minimize 145:15
180:14 182:5	99:11,17	30:11 130:9,15	minimum 38:19
medicinal	Mental 140:10	179:16	minute 14:2 33:8
127:5,19	mentally 46:20	metro	47:12 108:21
127.3,17	57:7,11 58:14	39:9,10,11,17	114:21 132:16
	57.7,11 50.14		11.21 152.10

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013

Page 29

	Pag		
minutes 9:17	88:11	109:11,17	116:18 149:20
33:11 35:9 44:2	modafinil 30:10	117:8,16 118:15	164:6 169:1,3
45:8 46:4 47:10	130:8,15	171:10,11	moved 67:10,18
55:13 64:9 69:16	ŕ	177:12 191:4	,
78:2 99:7 105:2	mode 37:13	month's 182:12	movement 29:11
108:20 140:17	moderate 176:14		107:7
160:6 165:3,8	modifications	mood 74:8 104:1	movements 121:9
170:19 174:18	132:13,22	136:17	moves 123:8
miracle 116:22	molecular 30:4	170:15,21 184:15	movies 120:1
117:3,14 151:6			
155:7 158:16	mom 66:22	moods 68:20	moving 65:22
mirror 77:7	81:9,15 116:2	moon 95:12,13,19	81:17 115:18
	118:17 154:5	136:18	mowed 53:7
misconception	moment 66:5 72:5	morning 59:8,13	mowing 53:5
91:10	115:16 167:5	68:17 89:4	8
misdiagnosed	177:1	106:17 111:4	MRI 166:17
167:9	moments 89:21	121:6 123:9,11	muddled 121:3
misdiagnoses	117:5	142:17 143:7,13	Mullin 2:13 5:5
50:21	mom's 155:22	149:3 154:9	7:12 9:16
misdiagnosis	156:3	156:2 169:10,16	13:15,19 14:1
44:18		177:7	96:14,22 97:4
miserable 106:19	Monday 20:4	mornings 102:1	155:3
	119:3,6	Moshe 165:13	multiple 100:12,13
misery 167:11	monetary 122:1	183:9,10	121:1 123:10
mishmash 63:18	money 16:17	ŕ	141:18 155:19
misidentifies	110:22 172:18	mostly 9:20 121:4	171:12
183:22	Monica 165:12	123:7	multivitamin
	171:6,7 174:20	mother 58:17	122:19
misperception 10:13	monitor 182:6	60:11 107:10	muscle 28:10,11
		111:9 149:3	69:5 77:17 78:13
mispronounce	monitored 70:13	168:7	110:10
165:10	monitors 107:3	motility 184:14	117:15,17 176:9
miss 53:15 55:13	monoamines	motivation 184:15	,
missed 79:12	184:7	mountain 108:13	muscles 28:22 52:10 80:7
112:9 124:13	month 109:8,11		110:12
172:1	114:14 122:4,9	mouth 131:19	
missing 112:6,10	151:9 153:4	132:2	musical 31:19
113:5		mouthwash	mute 101:15
mission 71:12	monthly 97:2	131:22	myself 53:2 55:8
	months 36:3,6	move 28:21 29:12	57:11,14
missions 181:8	45:10 50:9 68:22	31:19 39:20	58:16,19 61:9
mistakes 88:22	79:2 94:19	40:19 66:7 67:4	62:19 63:6 65:4
misunderstanding	102:22 107:5,8	77:22 79:8 103:9	70:20 75:1 86:16
mounderstanding			

Capital Reporting Company FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013

	Pag	e 30	1
113:22 116:1	30:4,8,12,14	183:18,22 184:3	net 92:16
117:6 127:16	32:16,22 33:10	185:5 186:8,9	network 161:11
129:2 166:5	37:7 39:21	187:12 188:6	181:6 186:8
168:6 183:15	40:4,14 42:22	189:15,22	
	44:16 49:3 50:3	191:13	neurological 79:17
N	51:21 54:14,20	narcolepsy-	183:20 184:3
Nancy 144:11	56:3,13 59:22	approved	neurologist 69:1
165:11,14	60:3,7,12	126:20	108:3 166:17
,	61:1,2,3,4,6,14,1		171:22
nap 52:17 56:22	8,22 62:3,20	narcoleptic 43:22	nounalogistia
59:19 64:20 67:3	63:7 69:18 70:9	87:2 97:17 136:4	neurologist's 69:14
99:7 111:4,12	71:7,16,18 72:3	183:11	09.14
112:5,6	74:22 76:8 78:20	narcoleptics 52:15	Neurology 2:19
134:18,22	79:5,18 80:17	105:20 122:3	3:21 5:11 6:14
135:1,2	82:17,19 83:14	184:21 185:9	7:16,18,20 8:22
136:13,21	91:10,17 96:4		24:13
137:5,10 142:20	98:15 100:13	nasty 149:3	neurotransmitters
143:8	104:22 105:14	National 137:21	185:12
144:12,14,17	106:9 110:13	natural 123:14,21	
157:5,6,7	112:1,16 113:12	182:8,9,13	never-ending
170:17,18	115:2 116:12	, ,	73:12
172:12	119:19 120:15	naturally 156:10	Nevertheless
186:16,20	121:5 123:22	nausea 31:2	127:1
nap-friendly	125:15 126:6	navigation 86:18	newspaper 125:4
134:11	130:7 132:13	-	
napping 91:1	134:1,15,20	Nearly 176:15	Nexium 122:16
	137:3 141:14	necessarily 91:11	nice 150:16 171:2
naps 30:18 65:9	142:22 148:9	necessary 134:6	night 29:8 45:14
74:3 96:2,3	149:8,9 150:11	135:10	65:12 97:18,20
112:5,16 122:15	153:11 159:1,9		99:5 112:3
132:13,19	160:11,13	neck 47:2 169:2	121:6,8 125:2
134:2,3,12	161:6,10 162:13	needles 83:7	126:11 128:12
135:12 136:3,12	163:3	Needless 73:21	136:18 138:17
144:13 160:18	167:3,11,14,18		139:3 140:1
170:12 186:18	168:4 170:7	negative 63:14	141:21
189:18	171:8,13,15,16,2	68:15	142:15,20
narcolepsy 1:4	1 172:8,9,20,21	neglecting 73:5	145:15 151:21
2:15 3:15	173:8,12,16,18,2	0 0	156:4 158:17
5:12,17 9:1,6	2 174:10,20	neighborhood	168:1 180:4
12:9,15 16:4,7	175:1,3 176:17	169:22	181:16,18
19:16 20:7	177:15	neighbors 39:16	184:19 191:1
24:9,11,16	178:14,15	neither 192:7	
27:2,9,17,18,19	179:8,13	nervous 184:1	nights 45:8
28:7,16	180:2,3,5,7		night's 45:9 161:5
29:4,14,16,21	181:4,6,8 182:7	nervousness 30:22	nighttime 29:3
			8

Page 31 30:16 31:2 45:3 noticing 45:12 131:1 offer 43:2 150:1 132:6,8,10,19 112:21 November 173:2 offered 116:21 133:10 134:7 NIH 162:20 163:1 Nowadays 70:10 135:16 office 2:4,9 4:16 **nobody** 62:4 67:17 138:18,21 nowhere 57:5 5:3,4,6 139:5,11,12,15,1 **nod** 13:22 91:12 97:21 7:9,11,13,21 8 140:6,13 8:1,3,5,7,11,20,2 nodding 53:2 64:8 nurse 186:14,15 141:1,8,9,10 1 25:13 80:10 99:15 nurses 174:2 149:20 26:1,8,10,12,18 132:2 149:13 150:6,8,20 151:3 57:2 59:18 69:15 nurse's 106:20 none 28:14 57:4 79:17 85:11 154:19,20 155:1 nursing 186:20 157:20 158:8.13 nonprofit 137:18 104:12 nutrition 123:2 159:7 160:4 157:11,13,14 172:21 162:10,11 nuts 57:9 officer 2:18 5:10 nonrestorative 163:11 173:17 7:18 24:13 120:22 Nuvigil 55:15 186:5 108:4 142:18 off-label 130:10 noon 106:13 old 51:13 56:14 143:6 nor 192:8 oftentimes 92:20 97:16 185:20 norepinephrine **oh** 57:6 58:13 older 81:4 185:11 0 184:8 59:15 60:1.3 Oak 1:10 9:18 oldest 79:5 81:4 61:12,19 62:4 **normal** 29:21 **Obamacare** 138:4 olfactory 184:15 69:8 88:7 93:13 56:22 57:1.3 96:12 101:2,14 obesity 30:6 oncoming 80:12 66:5,8,12 80:21 139:11.16 151:3 54:13,20 178:2 106:7 115:12 ones 18:21,22 158:13 162:10 127:22 128:1 oblivious 56:20 70:14 169:15.16 179:20 obscenities 68.18 177:21 186:5 one's 29:12 normally 152:2 obstructive 30:2 okay 7:3 8:12,17 oneself 88.13 Norvasc 122:16 11:15 13:2,22 obtain 9:14 online 36:2 182:17 14:7,8 32:2 35:8 nose 83:13 182:21 obtained 166:1 onset 28:17 44:17 36:8 38:7 note 4:10 38:18 45:21 48:16 79:2 obtaining 9:14 39:7,13,15,20 77:6 99:14 80:2 100:15 40:2,7,22 **obvious** 161:9 163:12 164:18 104:4 165:16 41:7,9,15,16 175:15 obviously 10:3 166:15 42:8,15 43:6,7 45:13 49:4 50:8 notes 86:20 193:5 44:4 52:19 56:21 onsets 91:19 81:2 124:11 57:12,14,19 58:6 nothing 60:20 78:1 onto 47:3 48:19 occasions 187:2 59:19 61:19 97:16 169:13 open 3:17 6:3 17:3 76:16,19 77:3,9 occur 28:17,19 notice 49:4 108:9 36:3 97:12 99:22 80:14 93:10,22 190:11 102:13,21,22 noticed 45:20 94:10 97:5,9 occurred 107:2 115:13 133:15 94:13 96:20 97:5 99:19 100:19 116:2 156:19 157:17 99:10,16 101:4 101:12,14,15,17 163:4,12,18,20 106:14 occurs 28:15 103:6 104:9

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013

(866) 448 - DEPO www.CapitalReportingCompany.com © 2013

29:1,13

130:2,4,5,14

Page 32

	rag		
164:6	organization	31:16	44:2 75:22 76:1
opened 19:2	95:15 172:21	overwhelming	104:20
Opening 2:7 8:16	organize 156:12	68:15 85:7 91:12	129:14,21 150:21 151:13
Operator 97:9,11	157:10	110:11	paperwork 109:9
98:7,8 99:20,21	organized 95:7,14 125:13	overwhelmingly 76:17	paralysis 28:20
101:14		owner 75:12	57:6 65:12 67:1
opine 10:20	organs 113:18		69:6,21 74:9
opinion 53:17	original 96:4	oxybate 30:15 130:10	76:12 168:21
opinions 38:16	originally 74:5	150.10	169:4
opioids 145:8	orphan 8:2 25:5	Р	paramedics 84:22
opportunities	26:18 122:5,8	p.m 191:12	paramount 38:15
20:19	O'Shaughnessy 105:11,12 120:7	PA 105:10	paranoia 148:20
opportunity 15:20	OSP 2:4,14,22	pace 108:21	paraphernalia
56:3 71:17 87:2,4 116:22	OTC 141:15	pack 156:12	174:3
119:15 120:8	others 17:17 54:5	package 15:10	paraphrase 185:19
126:3 155:16	73:7 80:11	packing 167:20	
158:22 164:9,11	96:17,19 128:22	PAGE 2:1 3:1	pared 123:12
173:10 174:10	140:9 148:13	pages 69:3 119:8	parent 114:3 135:5
optimal 168:3	166:11 178:20 180:17	paid 137:15 138:6	parents 85:1
option 23:9 108:2 121:17 122:1,13	otherwise 149:1	-	147:18 175:3
· · · · · · · · · · · · · · · · · · ·		pain 83:12	park 64:11
options 2:16 5:12,19 24:11	ought 137:5	painful 171:12	parked 64:10
33:2,3 104:15,18	ourselves 87:5	pains 117:17 171:18	parking 72:19
121:4 138:12	outpatient 109:7		114:19 157:12
141:22 150:17 159:13,18	outside 6:5	pamphlet 69:18	participant
r -	39:9,11,17 40:12 103:7 161:9	panacea 140:3	146:12,16
order 10:18 126:15 128:17	173:21	panel 3:2,5,13 5:20 6:1 7:8	participants 35:2
143:12 165:9	outsider 161:3	31:18 33:14,22	36:12,16
166:5 167:10	outweigh 12:2	37:15 43:10	40:12,14 42:5 90:19 146:10
ordinary 28:3	overall 14:2 74:2	44:13 51:12 87:8	
orexin 150:3,4	overdose 83:6	100:20 104:8 105:5 131:5	participate 47:8 125:14 189:9
158:5 182:10	Overnight 106:2	135:12 138:10	participating
184:5 185:21	oversees 8:21	160:1	21:19 126:21,22
Orexinal 182:9		panelist 43:18	188:4 191:8
orexinergic	overview 2:11,20 13:17 27:15	panelists 5:21	particular 9:15
184:5,11,22	15.11 21.15	31:20 33:5,9,16	10:20 12:7

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013 Page 33

	Pag	e 33	
15:18,19,22 149:21	11:2,20 12:19,20	24:2,20 25:6	176:10,14,15,18
	14:19,20 15:2,6,11,21	26:16,20 27:4,6,14 28:7	percentage 147:9
particularly 18:6	17:4,6 18:1,7	29:22 30:1,22	percentages 27:10
26:2,13 183:17 185:5	19:11 20:20	35:13 47:6 65:4	percentile 52:1
	21:11,13,17	71:11,19	perception 184:15
parties 192:8	22:5,10	72:17,20 73:4	perfect 111:3
partner 109:3	23:4,20,21 24:21 26:3,5	82:12 85:2,10 86:6,8	166:17
part-time 167:15	28:1,15,20	87:2,11,14,15,16	perfectly 80:21
party 61:5 65:14	29:2,4,14,16,20	88:15,21	
67:12	30:17 32:13	91:3,10,14 92:18	perform 29:17 85:16 175:21
pass 6:19 79:17	33:2,5,17	95:5,21	
84:21 88:11	37:7,13 93:19	96:1,9,15 103:7	perhaps 18:11 21:3 139:19
108:1 187:19	94:6 104:14,22 106:17 109:18	110:4 115:19 118:2 119:21	161:2
passed 124:9	164:12 165:5	120:10,12	
165:20	175:7 178:15,20	121:1,16 122:3	perimenopause 59:3,9
passes 62:14	180:2,10 182:4	123:21 127:14	period 6:3 18:22
passing 34:21,22	183:3 185:18	128:1 136:3	66:22 159:21
86:3	187:13	137:3,6,8 138:15	163:12,19
passionate 159:15	Patricia 165:13	139:2 141:6,13,17,18	periodic 29:11
past 44:19 89:1	186:6,7	142:22 144:13	periodically 35:20
94:22 152:5	pattern 99:10	145:5,6 146:21	69:10
160:9 178:13,21	Patterson 165:13	147:7,9 148:11	periods 74:4
patents 162:2	181:2,3,4	151:13 152:9	-
patient 3:6,9 9:3	Patty 92:8	155:20 156:19 157:3	permanent 28:3
15:16 17:18 22:8	pay 70:14 98:3	159:1,6,12,17	perpetual 124:13
25:1 32:13,15,16	151:9,10	160:8,10,13,16	perplexed 107:13
33:5,17 35:6 37:7,14 43:9,10	paying 124:17	161:2,8 165:2	persistent 88:8
57:2 69:3 105:1	pays 185:14	167:8 173:15,16 174:22 175:3,13	person 14:12 86:8
110:14 121:20	Peace 165:22	174.22 175.5,15	91:15 95:8
125:14 128:6	pediatric 41:19	182:16 186:9	116:18 117:12 134:20 137:7
164:12 179:5	171:21	187:11	171:2 185:10
191:13	pediatrician 181:5	people's 183:1	personal 38:16,17
patient-focused 1:5 2:11 5:8	pen 69:7	per 33:9 122:9	88:17 183:13
9:10,13 13:16,17	-	percent 28:15,20	personally 84:3
34:14	pencils 174:3	29:2 40:11,13	116:22
patients 3:3,5,9,14	Pentothal 59:6	43:4 101:4	person-by-person
5:18	people 4:6,14 6:10	130:16 174:22	43:14
9:2,8,15,20,22	9:1 22:13 23:1,7	175:1,12,13,19	

	Pag	e 34	
personnel 83:2	183:19	84:13 93:13 103:2 134:8	positive 50:10 75:13
person's 172:15	physically 121:11 143:18 178:6	140:15,16 141:5	positively 152:3
perspective 20:20 21:19 34:17	physician 106:6	142:4 164:14	possess 71:10
149:22 180:6	175:1 178:12	165:3,5 174:16	•
perspectives	179:5 180:11	pleasures 176:6	possessed 65:21
3:3,14 5:19 9:15	182:19	plenty 105:22	possible 24:4
18:15 33:2,18	physicians 179:8,9	157:13	75:15 149:9
34:18 42:20 43:2	180:12,17 181:7	podium 188:1	possibly 97:1
104:14,17	186:17,19	point 66:11,18	172:3
pervades 72:4	physiological	68:1 75:16 79:2	post 18:19 164:4
-	126:19	81:7,8 85:17	posted 23:17 182:8
Peter 101:2		86:19,21 92:21	-
ph 88:17	pick 111:13	100:11 119:20	posting 23:15
pharmaceutical	picture 54:11	140:22	potassium 117:20
56:16 59:11	pile 11:3	144:12,17	potato 152:4
121:17 122:10	pills 112:18 114:3	147:17 152:18	potential 135:6
175:6 185:19	168:7	153:15 169:9	-
Pharmaceuticals	pilot 17:2	173:13	potentially 13:9 54:4
179:3	-	policies 26:15	
pharmacist 73:18	pink 148:16	politely 167:1	pound 178:3
107:19	pisses 147:18	political 185:20	pounds 74:18
pharmacists 73:17	places 86:2 123:10	-	116:9
-	181:20	politically 173:17	power 119:21
pharmacopeia 141:22 142:11	plan 10:21 150:18	poll 35:3	powerful 60:19
	187:5	polling 34:15,21	•
pharmacy 73:22	plane 156:17	35:1,4,5,7 39:5	powerless 166:10
182:11	-	43:8 76:3 129:18	practice 39:5
PhD 2:13,17	planned 11:8,10 14:3 145:18	130:3 132:10,17	pre 122:21 123:19
phenomenal 135:2		133:6	predicted 124:11
175:9	planning 150:22	Pollock 96:3	pregnant 116:7
Philadelphia	188:22	popcorn 154:4	1 0
105:12	plans 72:15 143:19	Poplawski 43:21	prepared 33:11 44:2 105:2
Philips 118:8	176:4	72:2	
₽	plate 85:22	popping 79:21	preparing 4:17
phone 36:13,16,22 38:20 73:8,9	play 10:3,8 112:4	80:1,12	prescribed 107:19
86:16 88:13 97:8	143:14 177:18	,	117:11,12,13
99:20 177:6,9	playing 112:6	population 41:19	prescription 73:19
,		populations 18:15	115:1 179:15
phrases 46:22	please 7:4 16:8 17:9 20:2 32:5	position 124:19	prescriptions
physical 28:11	37:19 38:20,22	positioned 15:2	73:16 141:15
110:10 127:5	57.17 50.20,22	Positionica 15.2	

123:19 presence 31:8 180:6 psych 83:20 present 28:14 **problem** 29:6.7 profoundly 51:15 psychiatric 100:12 46:20 58:1 95:14 117:3 167:9 **Program** 5:8 7:22 118:3 119:11 presented 90:13 26:8,11 psychiatrist 126:13 144:19 166:20,22 press 39:10 programs 2:4 4:17 153:6 181:10.22 psychological 5:7 7:13 8:4,8,11 186:21 pressed 147:15 16:5 23:15 26:4 127:6 problems 29:15 Pressing 39:12 85:10 104:13 **public** 1:4 3:17 30:2 31:1,7,9 40:1,21 41:14 174:1 6:3,6,11 10:4 73:3 152:18.21 42:14 76:15 progress 51:4 18:19 19:2 32:11 130:13 132:18 180:13 34:11 35:21 progressed 185:6 proceeding pressure 31:6 36:2,7,8 47:14 192:3,4,5,7,9,10 106:21 120:20 promote 25:3 72:13 91:15 193:4,5,8 184:14 161:4 173:7 102:21 proceeds 24:19 133:15,17,18 pretty 10:21 20:15 promoting 10:4 135:20,21 41:16 51:19 52:2 process 12:5 128:4 prompt 36:19 140:21 141:2,3,6 53:6 55:12,13 164:17 178:17 pronounce 184:8 159:21 56:2 105:15 processed 123:3 163:12,18,20 108:21 propensity 180:7 128:12,22 133:8 164:2,7,16 processes 184:13 proper 185:1 165:18 167:7 134:16 150:11 **produced** 173:12 proportion 40:11 191:13 152:22 163:4,7 product 15:19 171:2 proprietary puddle 81:1,12 182:9,13,21 182:15 prevalent 132:20 **Pujita** 8:7 14:7 productive 98:20 protect 92:16,17 previous 98:18 16:8 20:3 103:13 productively 104:7 146:8 115:1 protecting 10:4 75:15 125:12 **pull** 68:1 99:7 Previously 108:19 proud 61:9 62:19 productivity 166:10 63:5,6 price 70:14 137:13 124:10 pulled 64:15 proverbial 65:6 primary 69:1 **Products 2:19** pulmonologists **provide** 3:6 6:4 3:21 5:11 6:14 print 41:10 59:21 34:6 36:20 7:16,18,20 8:2 prior 107:8 126:20 164:22 168:13 26:19 purchase 6:21 prioritize 70:10,11 179:4 184:20 118:8 professional 168:6 priority 65:10 Provigil 89:22 purpose 32:12 professor 177:7 112:5 106:12,14 34:15 164:8 professors 48:6,12 107:19 108:4 probably 13:12 pursuing 69:22 166:10 115:11,12 46:5.14 51:16 puts 180:6 124:22 125:6,7 90:19 114:16 profile 50:19 **putting** 48:10 155:6 163:5 provoke 189:2 profiles 49:5 114:19 **probe** 22:2 **PSAT** 134:17 profound 179:1 probiotics 122:21

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013 Page 35

really 9:22 12:11 quit 100:15 115:15 rather 121:18.21 Ο 126:13 127:12 13:7.11 15:15.22 quite 4:13 31:12 quality 114:7,8 165:21 190:15 16:4 17:13 19:21 39:15 42:22 22:18 23:2,5 quarter 42:4 Ray 105:8 111:8 72:13 73:10 24:16,17,20 74:13 80:10 165:13 186:3 question 13:20 26:16 29:3 30:3 87:18 94:4 18:20 22:9,12 **Raynaud's** 120:18 33:6 34:13,16 101:17 131:4 39:20 38:11 40:17 reach 15:6 111:16 133:8 176:2 40:10,13,19 41:9 42:19 43:1 44:5 135:7 42:2,10 44:3 quote/unquote 46:6,8,14,16,20, reached 116:20 55:10 69:5 76:4 144:14 21 47:5,7 87:20 90:13.20 reaching 9:3 48:3,8,9 92:9 93:11.14 R 49:2,4,9,12,13,2 reacted 67:17 94:1 95:1,10 racing 170:20 2 51:10 53:1 reactions 69:13 96:13 97:7.11 57:4 60:13 Radford 105:7 98:8 99:16 115:9 reading 31:13 46:9 62:5,9 63:4 129:18 130:3.17 Radiologic 101:3 119:8 65:7,15 72:9 132:10,17 81:9,16 84:15 rainy 100:7 ready 109:15 138:19 153:19 85:18 87:6,16 156.2raise 34:3 174:19 155:3,16 157:21 88:4,5,15 89:2 real 20:19 52:20 160:6.8 161:8 raised 124:9 91:16 93:15 67:21 69:7,10 94:20 97:14 99:9 questioned 166:11 raising 145:6,20 109:6 116:16 106:22 108:2 172:22 questions 7:4 117:5 119:22 118:9.14.19 19:7,8 21:2,5,7 rally 180:18 148:17 160:21 119:2,14 120:10 23:8 25:19,21 161:3 169:6.8.18 ran 69:12 107:9 121:17 33:12,13,14,22 170:2 177:10 122:11,22 **range** 18:7,9,13,14 34:1,15,16,21 178:1 179:12 124:20 126:4 20:11,14 21:14 35:1.4.5.7 182:10 129:7 131:16 33:10 42:6 49:20 37:18,19 38:21 realistic 151:12 136:8 137:1.5 82:12 104:21 39:5 43:8 44:5 141:22 142:1 184:12 reality 142:21 47:6 67:8 69:12 147:18 148:4 168:5 169:13,18 87:9 90:13 ranges 47:11 149:3 150:13,17 177:4 187:4 100:20 105:3 rap 179:12 151:5 153:10 120:17 138:11 realization 14:21 154:12 156:8 rare 7:22 9:12 149:21 156:7 realize 14:14,20 159:17 170:11 12:9 157:2 159:22 54:4 64:13 67:20 188:12 25:1,2,4,5,8,10 quick 80:10 93:3,6 71:3 73:8 89:18 189:14,19 26:8,9,11,16,20, 96:14 149:9 111:2 147:20 190:20 22 70:18 148:13 149:5 quickly 4:4,20 realm 72:9 rarely 72:7 123:17 31:17 32:15 realized 14:21 realness 169:17 rate 106:21 107:6 48:20 52:16.19 19:21 57:19 79:20 103:17 108:1,5,10,18 **reason** 48:12 57:8 109:17 187:10 152:16 175:17 113:17 155:21 68:6 89:11 realizing 72:17,20 184:14 138:17 139:4,19 163:7 178:2

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013 Page 36

Page 37

	Pag		
reasons 19:17 72:18 105:22	referred 166:19 187:1	relevant 9:1 reliable 90:4	report 23:12,16 124:1
162:19	referring 62:8	relief 70:6 112:16	reported 1:19
receive 107:13 168:3	reflect 18:7 23:20 33:10 104:21	184:21 rely 37:17 90:4	175:19,21 188:14 193:3
received 19:1 103:15 135:12	refresh 74:3	relying 37:22	Reporter 192:1,2,15 193:3
175:2	regard 50:6 185:5	REM 29:19 52:15	Reporter's 193:5
receiving 167:2	regardless 87:3 187:9	139:16,21 140:1 remains 118:13	Reporting 1:20
recent 42:18,20 recently 23:17	regimen 44:21	190:2,4	represent 71:17,18
44:15 100:15 110:16 147:14	51:1 126:10 145:17	remarkable 178:17	representation 37:10 40:16
179:2 reception 174:5	Register 18:19 183:21	remarks 2:7 3:18 6:12 8:14,16	41:17,18,22 42:21
recited 66:1	registered 186:14	32:1 33:11 44:3 105:2 188:2	representative 32:16 33:5
Reckless 187:10	registration 6:7 38:10 163:15	remember 62:12	representatives 3:6,9 15:17
recognize 179:10 recollection 73:10	regular 110:17	65:12 67:11 102:8,20 111:3	32:14 33:17 35:7
154:3	regularly 102:2 regulated 20:12	114:16 121:8 154:8,14 165:17	37:8,14 43:10 105:1 164:12
record 34:11 35:22 36:8	regulates 8:22	remembering	represented 11:18
133:17,19	184:6	29:18 88:14	representing 111:10
164:16 192:7 recorded 34:8	regulation 170:15,21 184:6	remind 174:15 reminder 133:14	requests 129:3
192:4	reiterate 163:22	141:3 163:13	require 21:20
recordings 193:6	relate 14:15 93:7	remote 22:22 36:12 102:5	required 127:10
recurring 67:21	related 20:13 30:6 91:13 94:1 124:4	remotely 35:11	requirements 127:18
recycling 89:5,7,13,14,19,	145:19	36:11	research 1:2 2:5
20 reduce 120:7	164:10,19 192:8 relates 91:17	removed 74:21	4:16 21:20 26:7,22 37:11
reduce 130:7 132:12 133:22 144:7 155:9	relationship 167:22 177:16	rendered 127:7 rep 56:16	104:12 125:15 140:17
reduced 192:5	167:22 177:16 relationships 98:4	repeat 160:6	161:4,9,16,22 162:14,17,20
reduction 146:3	104:2,4 159:4	repeated 44:18	173:1,3 178:14
reel 68:18	relative 144:12	repeating 46:22 138:22	180:19 183:5 reserved 6:21
refer 25:4 162:12	relaxed 57:4	replacement 150:4	1 CSCI VCU 0.21

residency 109:6 110:14 133:6 40:9,17 65:13 safe 9:5 10:5,10 173:14,18 174:8 67:2 69:2 77:8 11:7,15,19 25:3 resource 16:19 83:21 90:17 23:13 retaining 46:6 safely 64:9 105:20 116:5 respect 38:14,18 rethink 64.12 safety 7:19 123:11 130:17 185:3 10:11,18 92:15 146:5.13 152:14 retired 61:9 181:15,22 155:20 168:22 62:17,18 respectful 165:4 172:13 186:19 sales 56:16 review 12:5 17:16 respite 165:19 19:5 21:6 roommate 169:14 Sally 7:19 **respond** 35:2 47:5 reviewed 19:4 **rooms** 6:22 7:2 salts 83:12 respondents 39:1 168:3 reviewers 19:14 175:17,19,21 salty 112:22 186:17 21:4 23:13 176:16 Samantha Rosen 43:19 56:8 responding 35:7 reviewing 97:12,13 63:10 64:1 130:17 164:15 161:16,19 San 182:11 round 4:4 129:14 **revolve** 135:3 responds 78:1 Sariah 88:17 roused 152:13 response 19:15 **rhythm** 31:1.6 89:17 routine 94:21 33:12.22 35:11 **Richard** 142:11 sat 65:19 69:15,19 44:3 90:20 93:12 row 147:5 187:20 **rid** 62:18 155:9,18 **SATs** 136:8 105:2 160:3 **rub** 83:10 186:4 **ride** 83:4 save 141:2 **rude** 85:12 ridiculous 110:21 responses 173:14 saw 12:19 59:22 174:22 **rules** 37:3,4 80:9 107:11 rightly 31:1 166:16 171:11 rest 6:22 74:20 rummaging 154:6 risk 12:4 14:14 80:22 84:2 scared 81:2,13 run 34:4 72:18 risks 12:2,6 173:19 81:8 108:20 scary 66:12 81:19 **Ritalin** 115:1,3 rested 170:17 145:3 165:10 106:11 131:15 141:19 167:21 170:6 153:10,13 restful 170:19 142:17 143:6,7 188:21 runner 90:9 resting 107:8 road 64:10 108:17 108:15 109:1 scattered 32:4 restless 29:10 177:8 runners 34:2,4 scene 79:11 76.12 roads 108:16 **running** 48:15 schedule 96:1,5,6 restorative 161:7 rocket 156:8 74:13 79:7 110:17 124:8.21 restore 184:22 108:18 109:3 role 10:3,8,9 125:12 126:15 185:1 191:5 170:6,8 11:7,21 134:14 136:13 **restroom** 165:18 137:5 150:19 **runs** 26:4 107:10 **roller** 70:12 151:1 138:3 restrooms 39:1 **Ron** 5:9 7:17 scheduled 30:18 run-walk 108:19 rests 96:7 24:12 31:22 96:2 112:5,15 rush 64:16 result 23:12 Ronald 2:17 113:22 137:10 74:17,18 room 32:4 34:2 school 46:11 47:20 S results 42:17

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013 Page 38

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013

Page 39

	Pag	e 39	
48:1,3,10,13 51:14 53:12,15 55:1,16 79:13 95:22 97:22 100:14 106:1 107:17 112:4,9 113:4,5 114:16,18,19 118:18 119:7,12,13 134:12,13,15 135:13,15,18,20, 21 136:6,8,13 138:5 143:8,9,10,14 156:2,5 159:4 172:1,4 174:1,2 175:22 189:5	second 5:18 13:3 40:13 78:12,14 107:6 113:1 121:6 153:4 181:18 seconds 58:13 89:18 secret 161:18 secrets 161:15 162:6 section 134:22 135:1,2,21 sections 25:16 sedate 147:12 sedated 121:22 sedating 123:6	self-employment 116:3 self-esteem 62:21 71:2 self-hatred 166:3 self-image 176:4 sell 75:10 182:12 selling 182:12 semester 98:1 semesters 100:14 semiconscious 29:18 send 164:5 senior 65:12 sensation 69:9	148:18 seven 84:20 several 25:19 34:14 45:8 49:6,17 50:20 73:4,8 106:8 107:3 108:11 124:9 145:9 182:7 187:2 190:5 severe 14:18 44:17 45:2 46:14 48:16 49:21 50:4 70:22 77:16 78:10 82:16 94:16 151:19 176:10,13
schools 135:3 schoolwork 53:14 science 156:9 185:15 scientific 124:7 scissors 115:7 scope 6:5 scored 51:22 scratch 123:17 scream 170:18	sedating 123.6 sedating 123.6 sedation 92:10 121:5,18 seeing 9:20 106:17 115:20 148:16 167:16 seem 31:12 110:16 132:21 seemed 67:18 Seemingly 167:19 seems 55:22 132:20 178:6	80:12 sense 27:15 46:22 64:16 98:17 102:6 sensitivity 110:8 sent 68:22 69:17 separate 88:5,6 168:3 separately 149:10 September 1:7	severely 18:12 52:12 81:2 187:11 severity 14:16 15:4 18:7 45:16 47:11 shake 10:1 64:5 shakiness 30:22 shaking 115:8 Shannon 92:7 shape 120:2
screaming 169:9,15 scripts 85:14 scurrying 79:9 season 94:14 126:8 seasonal 96:18,20 97:1 99:11 103:19 118:4,14 Seasons 94:14 seat 31:21 32:5 seats 103:5	seen 47:21 49:9 67:18 75:5 81:18 107:19 120:22 123:20 178:15,21 seizure 67:5 97:15 seizure-like 121:9 self 118:21 166:4 self-doubt 62:22 self-employed 75:9 151:14	series 9:10,12 14:4 106:7 166:21 serious 86:10 159:16 167:14 173:20 serotonin 184:7 serves 6:19 Service 137:21 session 126:3 164:7,8 setting 71:16	 share 33:18 34:9 77:12 84:11 120:4,8 141:6 144:8 174:19 shared 23:12 129:22 sharing 76:1 129:15 Sharon 105:11 120:6 125:18 sheer 166:3

	Pag	6 40	
she'll 13:15 83:3	151:20 188:15	45:3,4,5,7,8,9,11	136:16 145:13
she's 92:15,21	190:1	46:17 49:18,22	170:16 180:1
151:13,14	significantly	50:3 52:16	188:14 190:17
179:19,20	176:11	55:18,19,20 57:5 59:5 60:8,17,20	sleeping 45:13 60:11
shift 84:1 156:10	sign-ups 165:1	62:9 65:11 66:10	76:12,13,19,22
shipment 137:15	Silver 1:12	67:1 69:21 72:6 10 11 12 17	97:18 139:9
shocking	similar 33:21	72:6,10,11,12,17	171:14 172:2
175:10,12	69:13 110:14	,18,19 74:9	186:15
shop 61:2	129:21 133:8 154:15	75:1,5 76:12 88:8 93:16	sleep-related
short 63:3 68:14		94:4,17 97:21	149:5
74:4 106:15,18	similarly 148:18	99:5 102:3 106:8 110:17	sleeps 143:8,9,10
120:20 127:3,21	simple 91:4 147:11	111:14,15,16	sleep-wake
155:11 174:17	148:21 167:19	111.14,15,16	184:2,16
191:3	simplest 98:22	<i>,</i>	sleepwalking
shot 98:2	176:6	113:21,22 116:3	29:19 31:10
shoulders 110:12	simply 64:5	118:6 120:13,22 121:18,21	76:14,21
showed 11:15	single 106:16	122:18 123:9,10	sleepy 29:7
156:13 166:18	111:9 116:1	124:4,16 126:11	87:15,17
	127:12 172:15	127:4 128:13,21	88:16,18 148:4
shower 59:13 111:4	Sir 160:4	129:8 138:16	slept 99:3 106:3
		139:3,16 140:1	112:8 128:16
shown 173:19	sister 20:12	145:14 146:6	158:14 166:13
178:20	57:19,20	151:19 155:1	
shows 11:19	sit 106:12 113:7	158:17 159:19	slide 16:8 17:9
182:22	168:1,15 177:19	160:20 161:5,7	20:2,9,21 23:11
	,	167:4 168:3,21	25:11 39:14
shut 102:13	sites 182:7	169:4,11,13	104:19
sic 108:20 112:22	sitting 51:18 54:19	171:22 178:14	slides 13:20 24:15
116:9	61:8 64:6 69:2	180:4,7 184:19	31:13
sick 90:22 152:21	107:8 156:20	186:19 191:1,3,5	slight 49:10 77:17
173:5	situation 16:20	sleepiness	8
	118:4	28:2,3,4,8 31:9	slightly 33:21
sight 137:9	situations 82:10	45:15,17,19	108:5
sign 6:6,7,8 64:12	Situations 82:10 Six 107:8	51:15 52:5 53:10	slipped 69:20
signaling		60:16 68:14 72:4	slow 160:19 161:5
184:5,11,22	six-figure 124:19	76:11,17 78:22 84:12,15 85:6	slower 108:10
signed 6:10 165:2	size 152:3	86:5 88:3,5,8,22	slumber 65:14
significant 5:16	slack 52:11	94:18 98:11	slurred 28:11
20:17 32:22 44:7	sleep 28:17,20	99:12 101:22	
76:9,18 90:15	29:1,3,6,8,13,20	113:4 118:14	small 17:11 41:10
94:3 134:3	30:2,15,16 31:2	120:13 127:4	123:5
	, ,		

smaller 29:16 someday 16:20 sound 18:21 **specific** 38:6 44:8 114:3 47:18 90:20 somehow 64:9 sounds 60:19 99:10 138:11 smell 57:17 150:5 126:15 157:5 190:15 smelling 83:12 someone 56:12,18 source 162.21 specifically 99:10 63:20 68:15,16 smiled 167:1 **Southwest** 108:16 75:17 108:22 **spectrum** 122:21 Smith 12:21 **space** 36:2 115:6 117:2 speech 28:11 123:8 126:4 snack 6:20 143:11 spaghetti 11:4 147:15 148:3,18 149:2 149:14,18 snap 64:12 speak 32:18 33:16 168:22 34:6 36:16 spells 85:2 **SNRIs** 139:21 169:1,2,19 180:3 92:8,13 94:18 182:8 spend 38:5 85:8 so-called 138.3 101:20 114:10 86:16,17 182:20 sometime 191:3 social 55:2 65:8 164:10 170:22 spending 170:19 100:10 127:9 somewhat 71:4 speaker 6:10 159:3 189:10 78:19 80:16 82:9 spent 156:3 somewhere 56:18 83:18 87:20 socializing 112:12 119:14 spirals 66:14 88:7,10 93:21 socially 53:15,22 son 57:10 58:7,20 spite 62:20,21 63:7 94:8 97:10 75:2 143:17 78:19 80:16 101:9,10,21 spoke 131:17 81:14,20 142:8 societal 127:6 131:12,14 134:5 spoken 4:13,14 143:3 144:4 135:14,17,19 society 46:1 191:2 153:13 171:8,22 138:20 139:20 125:12 134:11 sponsor 14:12 sons 74:15 75:4,15 140:9,12,16 135:3 163:4 141:5,12 142:7 spontaneity son's 80:2 sodium 30:15 59:6 143:2 150:3 145:19,21 117:20 130:10 sooner 19:11 151:4 153:22 sport 143:15,16 sofa 116:4 sophomore 51:13 154:21 155:15 **spot** 186:17 157:10 software 85:9 sorry 62:1 83:22 158:4,9,11,14,21 spouses 175:2 88:21 93:11 sold 182:10 160:7 161:21 96:12 140:10 spray 182:21 sole 113:19 162:11 165:14 141:11 150:6 **spread** 41:17 solid 125:10 speakers 165:9 sort 6:5 19:3 32:3 76:20 **solution** 127:12 speaking 20:15 92:22 93:5 96:18 spreads 163:6 32:18 51:11 107:5 108:13 solutions 127:19 spring 1:12 71:14 144:11 149:13 109:2 149:15 solve 186:21 94:16 106:4 180:14 181:13 special 21:2 118:9 somebody 32:18 182:14 35:10,14 52:14 65:1 69:11 springing 71:11 sorts 65:14 136:19 specialist 107:12 116:14 119:9 squeeze 143:15,19 sought 110:1 138:8 154:15 specialists 47:21 SSRIs 139:21 160:1 163:6 116:14 Soujanya 2:3,21 172:4,10 175:10 4:11 32:7 103:14 staff 17:14 83:13 specialized 171:22 104:11 158:9 84:3 186:15

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013 Page 41

Page 42

	Pag		
187:20	107:9 109:5	141:20 146:1	stretches 45:7
stair 108:13	112:17 118:11	stomach 31:2	strict 126:10
stairs 91:4 106:16	189:4	124:2	strikes 66:7
stakeholders 26:3	state 34:5 46:18 72:22 84:13	stonewalling	strings 54:8
stand 58:18 78:4	87:12 92:5 134:8	162:8	stroke 58:14 60:10
113:6	146:12 149:15	stop 21:21 58:11 64:10,19,20,21	strong 19:15,18,21
standard 127:2	151:19 164:20 170:20	65:3 78:7 108:21	33:6 69:6
standardized 52:1	statements 85:11	121:11,13	stronger 170:10
standing 32:2	States 25:7 27:5	144:17	struck 69:6
48:17 53:3 67:13 86:2 117:7	137:20	stopped 125:7 155:21 170:5	structure 146:6
132:22 156:19	station 106:20	stops 177:11	struggle 46:10
standpoint 175:6,7	statistics 175:9,12	store 47:12 177:19	48:11 86:4 99:2
Stanford 161:1	status 122:5,8	stories 65:14 76:2	116:17 118:13
173:4 178:12	stay 37:12 38:3	120:8 129:15	struggled 117:10
stare 47:6	46:5,10 61:4	story 128:10 176:3	strung 167:18
start 3:7 17:20	68:7 70:2 92:3	183:13	stuck 112:19 166:7
27:21,22 39:4	95:22 103:8 112:2 125:1	straight 79:13	student 45:19,21 52:2 53:16,18
46:20 47:2 50:13 51:8 64:20	128:13 143:18	108:20 123:22	98:2
105:17 117:13	182:21	172:2 178:4	students 53:13
128:20 129:4	stayed 123:22	strained 167:22	studied 163:3
131:8 133:11,21 134:2 143:12	staying 46:3	strangle 169:3	studies 11:8,10,13
144:18 157:18	steady 28:3	Strategic 2:4 4:16	60:9 106:8
165:8 172:20	stellar 109:9	5:6 7:13 8:4,8,11 104:12	175:5,20
started 5:1 43:16	steps 14:22	strategies 127:13	stuff 52:1 55:17
44:12 52:2 55:14	stick 48:4 110:17	strategy 126:6	148:15
56:21 57:15 59:3 74:16 77:4 78:20	165:5 174:16,18	Strattera 55:14,15	stupid 62:6 185:21
85:9 96:3 103:7	sticking 83:7	stray 38:4	submission 15:10
104:10 105:5	sticks 102:6,9	stress 49:18 63:2,5	submit 35:16 36:5 102:21
106:12 108:8 109:6 110:16	sticky 86:20	104:2 126:7,21	
111:12 128:13	stifling 71:9	127:6 128:2	submitted 10:12 176:1
131:20	stigma 91:9,13	169:19	subpopulations
163:11,18 171:9 174:21 177:14	stimulant 115:4	stressed 49:22 50:2 168:19	18:10
186:10 187:18	126:10	stressful 117:5	subside 121:10
starting 4:9 79:20	stimulants 30:9,21		substances 104:5
84:20 88:19	31:3 90:1 115:9	stretch 45:4 72:11	

Page 43				
subtle 147:21	supply 182:12	symptomatic 17:22 184:20	systematic 15:5 16:9 17:8	
subtlety 27:13	support 30:19			
suburban 105:12	71:6 124:10,12	symptoms 3:4	systems 122:18	
suburbs 22:20	132:14 133:1	5:17 11:1,9,20	184:10 185:2	
	148:13 160:10	12:15,22		
success 126:9	172:22	27:21,22 28:1,6 29:9 32:22	T	
successful 4:10	supposed 29:22	44:5,6,10	table 173:21 174:8	
62:20 75:10	123:7,19 155:22	45:1,16,21	tables 31:20	
98:13	sure 10:22 11:18	49:1,6,8,13,14,1	tablets 50:18	
sudden 58:10	27:1 35:6	5 50:4,12,14,16		
59:3,21 60:17	38:5,17 42:13	52:21 53:11	tailor 21:2	
62:9 95:15 97:20	46:14 53:12	54:15	Tailored 127:13	
176:9	56:21 63:11 72:9	55:4,10,16,17,19	tailoring 21:8	
suddenly 64:12	82:8 92:2 94:12	56:22 59:9 60:12	taking 21:21 50:13	
Sue 98:9,10	110:18	66:15 68:13 74:2	51:10 52:17	
, i i i i i i i i i i i i i i i i i i i	130:12,22 131:13 140:19	76:7,10,14 77:1	90:10 98:4	
suffered 63:19	144:20 149:11	78:21 79:2 80:2	109:13,20	
Suffering 168:4		84:16 90:14	111:4,21	
suffers 25:9	survey 69:12	93:15,17	112:2,13,18	
sugar 158:6 178:3	173:13 174:8	94:2,3,5 96:17 99:17 101:5	113:10,15,20	
0	surveys 175:5	103:18 104:1,3,4	114:5 117:8,9	
sugars 68:8	survival 22:6	110:2,10 111:12	121:13 125:7	
suggest 127:17	survive 68:7 116:1	110:2,10 111:12	131:14,20	
suggested 118:8		114:15 123:13	141:20 146:17	
166:22	survives 22:8	126:18 130:7	147:3 166:20	
suggests 142:3	suspect 162:22	132:12 134:1	167:10 172:15	
00	swallow 168:8	141:16 144:7	186:16 190:4,5	
suicide 187:5	swelling 113:8	146:3,14 147:8	talented 90:3	
summarize 35:18	8	149:8 155:4	talents 71:10	
103:10,17 188:7	switch 47:4 84:10	159:2 167:13	talk 9:16 13:15	
summer 94:19	switched 110:3	168:16 170:9,12	24:9 27:9 47:16	
sums 51:5 56:2	symptom 28:8,21	171:9 175:14	60:6 62:3 84:10	
	29:10 44:17	177:3 183:19 188:13,20	120:10 125:20	
sun 49:19 118:5,7	46:13 48:16	188.15,20	130:20 133:2	
Sunday 169:10	51:16 60:14 72:3	199:1,20	134:1 141:13	
sunnier 78:3	76:18 88:5		144:5 147:1	
Sunshine 68:17	100:2,21 101:19	syndrome 20:5 21:10 23:17	148:10,12	
	132:8 138:16	76:13	168:18 173:16	
super 56:9 63:15	139:2 157:7		174:6 178:1 188:21	
supplements	186:22	system 86:18		
122:19 146:18	188:16,18 190:18	135:15 165:6	talked 14:10 84:2	
	170.10	184:1	100:21 152:8	

Page 44 155:4,10 162:19 54:1,3,7,10,21 terms 12:14,16 105:16,18 111:6 27:9 90:12,13 114:9,11 55:9,15,17,21 talking 43:8,13 120:3,4,5,7 60:20 61:15 149:13 188:22 46:21 47:3.4 189:16 190:12 125:16,18,22 63:21 70:11,21 60:8 87:12 137:9 126:2 129:12,13 80:2 82:5,14 147:19 148:17 terrible 12:10 132:1 133:9 97:6 119:3,11 108:11 tall 126:15 134:7 138:9 120:3 122:4,7 terribly 137:6 140:20 141:10 123:14 124:4 Tan 8:10 163:21 171:20 142:5 128:12 129:21 171:5 174:14 143:1,21,22 132:10 135:4 terrified 119:7 176:21 178:8 181:1 183:8 144:10,20 137:8 139:2 terrorizing 78:12 146:7,19,20 142:4.21 143:7 186:2,5 187:17 188:22 149:11 150:20 144:15 147:21 tardiness 166:11 terrors 128:12 155:16 148.14 149.11 target 98:20 157:2,16,19 150:5,19 151:20 test 10:14.15 11:22 153:3.17 162:11 158:8,18,21 50:1,5 109:15 targets 190:14 159:20 160:7 164:21 169:4 134:22 tasks 167:19 161:12 163:10 171:18 175:19 tested 110:6 taught 87:6 168:9,11,14 178:7,10 179:22 tests 52:1 107:2 171:4,5,7 180:8 181:8,10 tea 6:20 171:12 174:12,14 182:9 183:3,4 teachers 53:19 176:20,21 177:2 185:21,22 text 177:5,10 136:1 174:1 186:21 178:8.10 180:22 Textbook 83:18 teaching 181:7 181:1 183:8,10 themselves 7:8 thank 4:6,9 8:12 185:22 186:2 team 7:19 25:12 31:8 32:19 43:11 13:11 24:10 187:15,17,20 49:8 108:22 technical 13:20 31:14,21,22 32:6 188:1,3 191:7,10 176:12 technology 34:22 39:18,19 40:6 thankful 37:12 therapeutic 2:16 41:4,8,20 43:2,6 teenage 149:4 151:14 24:11 157:7 44:14 51:6 teenagers 114:4 thankfully 67:16 56:6,8 63:10,22 therapies 18:5 70:18 109:16 64:1,2 teeth 74:19 131:16 130:6.11.18.19 71:15,20,21 thanks 13:16 51:9 132:11,15,16 temperature 75:20,22 76:1,2 56:3 64:1 183:7 133:2.3.22 144:7 103:20 77:9 78:15,16,19 145:6 146:5 that's 6:2 9:6,7 temporary 28:21 80:9,14,16 82:6 11:7,17,21 therapist 147:16 69:6 84:9 87:1,6,7 12:2,7,8 13:4 therapy 15:13 90:6.12 91:22 **Ten** 128:14 18:3.5 19:16.19 124:6 132:20,21 93:2,10 95:2,6 tend 137:2 20:18 21:8 22:19 134:3 144:18 96:10 24:21 25:1,9 147:16 150:4 Tennessee 173:6 97:5,6,7,11 98:6 26:3 36:8 40:17 155:6 157:5,22 99:12,13,19 tension 110:10 45:11 46:4 100:1.18 101:15 thereafter 192:5 47:13,20 51:3 term 92:10 113:15 102:17 103:14 52:11,13 therefore 94:17 120:21 144:12 104:6,7 53:12,22 162:6

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013

Theresa 2:13 5:5,9 125:2 track 92:3 165:7 toll 68:9 91:17,21 7:12 9:16 13:14 98:4 113:20 ticket 156:17 trade 161:14.17 14:1 31:22 96:13 167:14 177:15 162:6 tight 106:18 155.2tone 28:10 69:6 transcribed 34.8 tilt 107:14 Theresa's 99:15 78:13 164:16 157:21 timer 165:6 tons 98:2 transcript 192:6 they'll 34:2 36:15 time-released tools 71:4 193:4,6 154:9 138.8toothpaste 131:21 transcription they're 17:13 timers 86:14,15 193:1,7 toothpicks 115:13 26:21 33:6 56:20 tired 64:19 65:3 transparent 70:19 75:16 top 19:20 25:13 82:2 105:21.22 164:17 102:12 124:16 45:17 106:17 106:1.2.3.4.6 137:9 141:20 141:20 transpired 178:17 110:11 120:11 142:1 145:11 166:13 168:2 topic trap 146:11 154:2 171:19 3:2,3,8,13,14,16 71:3,4,7,8,12,14 163:14,15 169:6 5:18,20 6:1,5 today 5:16 12:5 trash 89:6,12,15 173:17 31:20 32:21 14:18 16:2 18:4 180:12,13 travel 22:21 23:3.4 33:1,9,12,22 19:17 21:12,22 137:19 they've 105:1 38:3,4 43:10,13 23:3 24:4 27:2 175:5 44:3,5,13 51:6 traveled 13:12 32:19 34:9,13 69:16 77:10 thighs 117:6 35:18 36:10 trazodone 160:19 103:1,9,11 38:12,15 39:3 third 27:6 29:20 treat 15:12,19 104:8,10,14,21 40:4 51:12 64:6 41:2 46:13 16:3,6 18:6 105:3 133:13,20 71:13,15 80:18 111:22 115:14 21:12 24:7 149:21 87:4 116:5 147:5 treated 22:14 30:8 130:17 133:16 topics 5:14,16 thirds 41:1 50:9 110:13 156:13 159:11 24:18 32:9.21 172:17 177:21 thirties 58:6 163:17 175:8 164:11 180:16 187:3 treating 3:15 24:6 **Thompson** 8:3 torn 176:5 188:8 140:2 149:10 105:9 114:13 **Toronto** 173:4,5 179:14 187:8 today's 4:12 thoughts 36:5 tortured 83:10 32:8,13 37:20 treatment 5:12,19 144:8 150:1 40:6 104:13 total 102.6 9:16 22:3 33:1,2 thousands 176:1 166:13 168:19 104:15,18 totally 95:12,16 174:4 threat 127:4 120:15 122:15 touch 84:16 131:1 125:15 126:17 toe 77:22 thrilled 173:18 169:2.6 127:7,11 131:7 throat 112:19 toilet 181:20 tough 54:3 55:14 138:11 140:18 tolerance 70:12 throughout 145:17 146:22 towards 7:3 126:7,13,19 79:12,21 184:13 147:2 149:22 36:13,19,22 146:2 190:11 153:2 161:2 throwing 79:10 119:17 166:2 167:6,13 tolerated 117:14 Thursday 50:2 tower 9:19 22:18 176:12 189:19

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013

Page 45

Page 46

Page 46					
190:15 treatments 12:17	true 62:5 75:18 184:3 192:6	Turner 165:13 183:9,10,11	underrecognized 12:9 27:3		
14:17 15:8 20:6	193:7	turns 107:4 121:9	underrepresented		
21:14,18,21	truly 59:2	TV 102:5,8	12:10		
24:10 25:4 26:22 30:9,20 71:13	trust 78:14 169:13	tweak 121:12	understand 10:2		
130:21 131:4	trustee 186:7	twenties 84:19	11:4,9 12:12,21 15:3 16:1,13		
146:15 167:2	Trustees 181:5	158:16	18:9 22:4 26:20		
175:16 179:4	truth 25:19 167:5	twice 181:17	27:12 30:4 68:2		
182:5 189:16	185:21		85:19 117:19		
190:2,6,11		twins 116:8	119:22 120:12		
treats 153:5	try 16:11 17:19 20:19 25:17 35:8	two-thirds 40:3 175:17	135:10 148:22 159:16 183:18		
tremendous	41:15 67:4	type 30:6 85:13			
141:16 180:18	70:15,20 75:13	118:12	understanding		
tremor 115:3	91:20 110:17		9:14 12:6 18:12		
126:5	111:1 115:10	typed 193:4	34:17 46:7 91:11		
trials 10:10 18:2,4	118:8 142:20 156:10	types 29:15	159:14 179:11		
108:11	160:19,20 165:5	typewriting 192:5	understands 121:20		
Tricyclics 140:2	169:3 174:15	typically 15:18	underwent 171:11		
tried 19:11 65:4	179:4 182:4,21 188:6				
70:21 79:13		U	Undoubtedly 127:8		
115:22 116:12	trying 9:14 10:2	ultimately 10:10			
121:6,11 124:22	16:17 17:2,10,12	unable 32:18 66:7	uneasy 124:1		
176:16 186:21	20:16,22 21:1,14	161:18 162:7	unfortunately		
189:17	22:22 23:5 24:1	168:1	75:8 84:4 157:14		
tries 23:19	29:13 44:20 46:8	unavailable 184:5	161:13 163:9		
trigger 48:17 80:6	47:14 48:4,10 61:11 79:14		174:17 179:9		
91:18	85:12 89:5	unbelievable	189:22		
triggering 99:17	102:11 111:22	61:17	Unger 2:8 5:3 7:10		
00 0	114:1 134:12	uncontrollable	8:13,17,19 14:9		
triggers 28:12	142:1 161:4	28:12	16:13 93:11		
128:8 168:16	166:3 183:4	uncontrolled	162:1,16		
Trioptal 50:18	186:12 189:18	154:16	UNIDENTIFIED		
trip 39:18	Tuesday 1:7 89:4	underdiagnosed	78:19 80:16 82:9		
triplicate 179:15	÷	27:3	83:18 87:20		
-	tunnel 69:16	underfunded	88:7,10 93:21		
trouble 89:2	turn 8:13 13:14	187:14	94:8 101:9,10,21		
114:17	24:8 33:17 45:10		131:12,14 134:5		
truck 64:10	87:8 98:1 102:2	undergrad 45:18	135:14,17,19		
89:6,8,9,12,13,1	138:10	underlying 68:13	138:20 139:20		
4,15 110:5	turned 115:17	183:20	140:9,12,16		
			141:5,12 142:7		

Page 47					
143:2 150:3 151:4 153:22 154:21 155:15	useful 140:2 usual 48:17	viewpoint 112:18 113:14 Vinginie 81:5	113:7 169:22 170:1 walked 106:20		
157:10 158:4,9,11,14,21 160:7 161:21 162:11	usually 10:7 100:8 107:13 166:9 169:1 170:22 171:2	Virginia 81:5 105:7,14 108:16 150:10 156:16 visible 183:19	walking 48:16 49:20 62:14 74:13 86:2 91:4		
unique 91:16	utter 167:10	vision 100:8	151:21 165:17		
uniquely 15:2		visit 79:13	wander 181:21		
Unite 173:11,12	V	visual 89:10	waning 28:4		
174:20	vague 154:3	vitals 106:20	war 84:4 118:15		
United 25:7 27:4 units 100:12	Vaidya 8:7 103:14 133:7 146:9 Valentine 8:5 40:8	Vitamin 122:20 146:17	ward 83:20 warn 81:15		
University 161:1	41:5 42:3 43:3	vitamins 142:3	Washington 16:21		
173:4 178:12	77:6 90:12 145:3	voices 174:11	39:9,10		
unknown 89:11 182:20	valuable 18:8 22:15 37:8	void 127:7 volume 19:12	wasn't 12:19 48:8,10 58:17 60:10,11 62:5		
unmet 14:17 15:4	value 133:17	voluntary 38:10	88:15 89:7 98:14		
190:3	Vanderbilt 173:6	134:6 163:16	99:1 106:6,7		
unmotivated 70:7 unpredictable	variable 27:22 variation 18:10	volunteer 124:14 166:1	107:4,20 108:2 116:15 148:15 169:14		
94:9	27:13	vulnerable 187:13	waste 172:18		
unreliable 73:4	variations 96:20		watch 102:8		
untreated 176:10 updates 42:1	varies 55:17 122:6 variety 26:4 27:13	W wake 65:20 67:3,6 102:2 110:6	Watchers 116:15 wave 160:19		
upon 28:22 84:16	various 14:11	111:19 112:10	waxing 28:4		
131:1	189:1 190:7	123:11 152:3			
ups 148:7 upset 31:2	vegetables 123:4 version 138:8	154:9 169:20 170:16,21 171:8 172:20 173:8,22	ways 21:15 22:17,22 25:15 92:17 116:1		
upsetting 135:5	versions 147:11	wakeful 75:14	weakness 28:12		
upside 179:12	versus 88:8	wakefulness 75:18	web 4:6 34:10		
upstairs 81:8	via 36:7,13 103:11	166:7 176:9	35:2,13,15		
urge 29:11,12	164:5	waking 29:1	36:15,17 40:17		
35:15 72:6 urgency 64:16	vicious 65:5 videotape 79:15	72:5,22 73:7 76:11 102:1 121:15 144:17	41:5 42:1,4 43:3 90:8,19 91:9 103:11,16		
urging 46:11	view 12:6 17:1	walk 48:20 79:9	133:5,7 144:2,22		
URL 141:6	24:16 26:13 65:4	109:2,3 111:18	145:2		

Page 48					
146:9,12,16	158:19 160:5	wherewithal 58:18	149:2 156:4		
149:15 164:4	178:9	whether 87:3,22	166:7 169:12		
webcast 23:9	well-worn 121:4	89:5 90:21 96:1	woken 112:22		
35:3,4,16 36:18	we're 5:2,5 8:18	98:11 108:13	woman 63:13		
40:9 77:7	9:2,4,7,19	157:8 161:21	89:17 90:3		
webinar 36:18	10:2,15 12:8	162:14 181:12	179:13		
website 23:16	14:4 17:3	182:17 189:5	women 99:16		
25:16 122:2	19:17,19 20:22	whew 119:10			
141:8,10 163:1	21:1,8 22:17	White 1:10 9:18	won 166:9		
week 22:8 48:7	23:5 24:1,18,19	whoever 157:2	wonder 122:11		
51:4 111:1	33:4,13 34:12,14		124:4 137:13		
115:14 124:15	35:18,19	whole 16:1 47:1	151:11 167:8		
137:15 182:8	36:9,10,11 37:8,9,11 94:12	55:14 56:10,20	wondered 62:7		
weekends 119:5	104:15 111:22	60:14 112:9 123:5 150:5	96:17		
	118:11 133:12	156:3 160:15,17	wonderful 174:10		
weekly 126:10,12	162:7,8,16,18	, ,	wondering 87:13		
weeks 79:13	163:11 173:18	whom 192:3	93:19 94:5		
106:14 124:21	174:5,17 183:4	wide 20:11,14 61:4	138:14 139:2		
152:5 172:1	186:8	156:21 184:12	wording 24:3		
180:4	we've 4:17 20:3	wider 183:17	U		
weighing 14:14	22:16,21 23:16	wife 75:7 92:8	work 14:18		
weight 91:6	35:12 79:22	144:11	17:13,15 25:12 26:11 30:1 44:21		
113:12	140:22 147:14	Williams 105:8	46:7 62:5 70:3		
116:6,7,11,13,14	162:19 165:1	111:10	75:7 90:21		
,15,19 117:6	whatever 11:14		91:1,2 95:18,22		
151:21	17:3,4 57:21	willing 86:6 157:3 182:20	97:18 98:3 99:1		
weird 62:13	88:22 144:16		100:10 106:8		
welcome 2:2 4:2	153:6	willingness 125:14	107:2 112:9		
6:6 13:13	whatnot 27:10	willpower 166:4	128:5 129:7		
35:10,14	174:3	wind 108:14 163:6	136:1,5,7,15,21		
we'll	wheel 64:7	window 63:3	137:11,17		
5:1,9,20,21,22	wheelchair 151:7		141:19 144:13 166:18		
6:3,9,12 7:5	159:7	winning 61:2	167:15,16		
27:1,15 31:20		winter 94:15	175:21 177:14		
33:14 34:22 35:8	wheelchair-bound 152:22	118:15	179:22 180:19		
36:22 43:15,16		wish 13:8 86:6	worked 17:16		
76:3 84:14 99:20	wheels 177:20	withdrawn 75:1	34:13 53:6 115:5		
100:22 101:15	whenever 64:22	witnessed 67:1	119:4 124:6		
102:18 103:7	whereas 99:8	186:14,15	158:22 166:1		
105:4 130:4,20 132:16 133:2	Whereupon	woke 66:1,11	worker 89:7,11,13		
144:1 157:20	191:12	68:15 124:22	working 9:20		
			······································		

Page 49 49:19 56:17 write 60:5 62:1 185:3 68:10 85:8 99:3 73:15 85:14 youngest 81:8 106:1 118:10 123:16 yourself 74:11 157:15 177:11 written 60:4 124:8 123:2 152:21 186:13 wrong 58:9,19 **vourselves** 33:8 workplace 135:13 59:19 79:16 81:3 105:4 136:12 wrote 179:15 you've 4:5 32:12 works 17:4 104:16 33:21 63:11 108:12 Х 116:8 130:22 131:20,21 **Xyrem** 90:2 136:16 148:1,5 world 56:18 116:21 117:8,9 180:16 58:8,17 71:10 118:3 119:10,13 118:17 135:8 121:6,13,17 Ζ 166:13 122:4,10,14 zombie 74:5 173:19,20 130:10,18 153:22 180:17 183:17 137:13,19 zombie-like worry 30:22 138:6,7 141:21 146:12 149:15 142:8,9,15 worse 49:16,17 151:19 143:4,12 50:16 51:2 60:13 150:11,17 74:10,16 137:3 151:1,5,10,18 worsen 167:13 152:8,15 worst 60:14 72:2 160:12,13,14 177:12 181:10 82:10 94:15,20 110:10 118:17 134:19 Y Yasuda 7:19 worth 22:10 138:14,22 139:1 worthwhile Yep 140:13 154:14 175:15 vet 46:16 89:7 90:3 worthy 66:19 110:15 118:9 wound 116:2 119:12 126:9 125:1 yield 125:15 wow 39:15 40:2 yoga 170:8 64:4 119:13 130:14 **you'll** 6:18,19 36:19,21 39:10 wrap 101:15 43:1 63:16 96:9 wrapping 165:8 young 1:19 95:21 wraps 43:7 192:2,14 wreck 61:10 62:20 younger 41:11 wrestler 81:21 79:6 81:5,7,14

FDA Narcolepsy Public Meeting on Patient-Focused Drug Development 09-24-2013