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UNITED STATES DISTRICT COURT CENTRAL DISTRICT OF CALIFORNIA CAUSE NO. 2: 13ev2700-GHK(SS) SIDNEY CARTER, Plaintiff, -vs- ELI LILLY AND COMPANY, an Indiana corporation, Defendant. 30(b)(6) VIDEO DEPOSITION OF CHRISTINE PHILLIPS, Ph.D. The deposition upon oral examination of CHRISTINE PHILLIPS, Ph.D., a witness produced and sworn before me, Amy Doman, CSR, RPR, CRR, Notary Public in and for the County of Hamilton, State of Indiana, taken on behalf of the Plaintiff, at the offices of COHEN & MALAD, LLP, One Indiana Square, Suite 1400, Indianapolis, Indiana on Friday, July 18, 2014, pursuant to the Federal Rules of Civil Procedure.	1 APPEARANCES CONTINUED: 2 Dawne Davis 3 ELI LILLY & COMPANY 4 Lilly Corporate Center 5 Indianapolis, Indiana 46285 6 Phone: 317-651-2925 7 ddavis@lilly.com 8 9 VIDEOGRAPHER: Sara Williams 10 11 EXAMINATION INDEX 12 WITNESS: Christine Phillips, Ph.D. 13 BY MR. O'BRIEN (page-6) 14 15 16 17 18 19 20 21 22 23 .
Page 2 APPEARANCES FOR THE PLAINTIFF(S): Kevin O'Brien POGUST BRASLOW & MILLROOD, LLC Solution 1520 161 Washington Street Conshohocken, Pennsylvania 19428 Phone: 610-941-4204 kobrien@pbmattorneys.com FOR THE DEFENDANT(S): Phyllis Jones Jaclyn Martinez Resley COVINGTON & BURLING, LLP 15 1201 Pennsylvania Avenue, NW Washington, D.C. 20004 Phone: 202-662-5662 pajones@cov.com Phone: 202-662-5662 pajones@cov.com Page 2 Page 2 APPEARANCES Revin O'Brien POGUST BRASLOW & MILLROOD, LLC Brown And Language Conshohocken, Pennsylvania 19428 Phone: 610-941-4204 Burling, LLP 1201 Pennsylvania Avenue, NW Washington, D.C. 20004 Phone: 202-662-5662 Pajones@cov.com Page 2 Page 2 Page 2 Page 3 Page 2 Page 3 Page 3 Page 4 Page 4	Page 4 EXHIBIT INDEX Exhibit 1 Notice (page-10) Exhibit 2 Resume (page-96) Exhibit 3 Cymbalta label changes (page-181) Exhibit 4 Discontinuation warning for Cymbalta since 2004 (page-182) Exhibit 5 May 2007 label changes (page-209) Exhibit 6 October 2007 label changes (page-209) Exhibit 7 Defendant's responses and objections to plaintiff's 30(b)(6) notice (page-212) Exhibit 7 Defendant's responses and objections to plaintiff's 30(b)(6) notice (page-212)

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1	THE VIDEOGRAPHER: We are now	1	BY MR. O'BRIEN:
2	on the video record. This is the video	2	
3	deposition of Christine Phillips taken by	3	•
	· · · · · · · · · · · · · · · · · · ·	l .	
4	the plaintiff in the matter of Sidney	4	Q. We had an opportunity to
5	Carter versus Eli Lilly & Company, in	5	introduce each other earlier today. My
6	the United States District Court,	6	name is Kevin O'Brien. I represent the
7	Central District of California, Case	7	plaintiffs in this action against Eli
8	No. 2:13cv2700-GHK.	8	Lilly.
9	This deposition is being held	9	Could you please state your
10	at the law offices of Cohen & Malad,	10	full name?
11	One Indiana Square, Suite 1400,	11	A. Christine Ann Phillips.
12	Indianapolis, Indiana, on Friday,	12	Q. And would you provide me your
13	July 18th, 2014, at 8:56 a.m.	13	address?
14	I am Sara Williams, the	14	MS. JONES: I'm sorry, do you
15	videographer. The court reporter is Amy	15	want her work address?
16	Doman. We represent James DeCrescenzo	16	BY MR. O'BRIEN:
17	Reporting at 1880 John F. Kennedy	17	Q. Business address would be fine.
18	Boulevard, Philadelphia, Pennsylvania.	18	A. Okay. Lilly Corporate Center,
19	Counsel will now introduce themselves and	19	Drop Code 2653, Indianapolis, Indiana,
20	state whom they represent.	20	.46285.
21	MR. O'BRIEN: Kevin O'Brien on	21	Q. And your current employer?
22	behalf of plaintiffs.	22	A. Eli Lilly.
23	MS. JONES: Phyllis Jones on	23	Q. And your current title?
24	behalf of Eli Lilly and Company.	24	A. Advisor, global regulatory
24	benan of En Emy and Company.	24	A. Advisor, global regulatory
	Page 6		Page 8
1	Page 6 MS. MARTINEZ RESLY: Jaclyn	1	Page 8 affairs.
1 2		2	affairs.
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2	MS. MARTINEZ RESLY: Jaclyn Martinez Resly on behalf of Eli Lilly and	2 3	affairs. Q. Have you ever been deposed
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	MS. MARTINEZ RESLY: Jaclyn Martinez Resly on behalf of Eli Lilly and Company. THE VIDEOGRAPHER: The reporter will now swear in the witness. CHRISTINE PHILLIPS, Ph.D., having been duly sworn to tell the truth, the whole truth, and nothing but the truth relating to said matter, was examined and testified as follows: DIRECT EXAMINATION BY MR. O'BRIEN: Q. Hello, Dr. Phillips. MR. O'BRIEN: Just one thing for the record, before we get started. I just want to put on the record that this case is also being noticed in the Hixon versus Eli Lilly and the Herrera versus Eli Lilly, the accompanying California cases. Do you understand that to be true? MS. JONES: Yes, I understand	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	affairs. Q. Have you ever been deposed before? A. I have. Q. How many times have you been deposed before? A. Once. Q. How recently was that deposition? A. That was in December of 2013. Q. In what context were you deposed? A. I was deposed as a 30(b)(6) witness on behalf of Lilly in another product liability case. Q. Did it involve Cymbalta? A. It did not. It involved Prozac. Q. Do you know if you have copies of your deposition transcripts? A. I do not. Q. Do you know if they exist

	Page 9		Page 11
1	Q. Where do they exist?	1	BY MR. O'BRIEN:
2	A. I believe Lilly legal has them	2	Q. Dr. Phillips, let me know when
3	as well as Pepper Hamilton, which was the	3	you've finished taking a look at the
4	external counsel on that case.	4	document.
5	Q. And that was my next question.	5	A. Yes.
6	In that matter you were represented by	6	Q. Have you seen this deposition
7	Pepper Hamilton?	7	notice before?
8	A. Yes.	8	A. I have.
9	Q. Do you remember the name of the	9	Q. This deposition notice relates
10	counsel from Pepper Hamilton that you were	10	to areas of regulatory issues. Are you
11		11	familiar with that area at Eli Lilly?
12	represented by?	12	•
	A. Andy Kantra and John, began	13	,
13	with a B, his last name.	1	Q. Would you mind turning to
14	Q. Are they local counsel?	14	page .8.
15	A. No, they're based out of	15	A. I'm there, yes.
16	Philadelphia, I believe.	16	Q. This begins a list of 11 topics
17	Q. I know you probably understand	17	that you have been designated by Eli
18	the basic instructions of depositions.	18	Lilly to testify in the company's behalf.
19	And I just want to go over them again	19	Would you please take a moment to review
20	with you. I'm just going to ask that	20	them if you haven't done so already.
21	you let me finish my question before you	21	A. I have already done so.
22	provide a response. And I'll extend the	22	Q. Are you prepared to address
23	same courtesy. If you do not understand	23	each and every one of the topics
24	my question, just let me know and I'll	24	addressed on page .8 and 9 of the
	Page 10		Page 12
1	Page 10 repeat it or rephrase it as necessary.	1	Page 12 deposition notice?
2		2	deposition notice? A. Yes, I am.
	repeat it or rephrase it as necessary.		deposition notice?
2 3	repeat it or rephrase it as necessary. If at any time you need to take a break,	2	deposition notice? A. Yes, I am.
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	Page 13		Page 15
1	designated by Eli Lilly, it requires you	1	agencies concerning Cymbalta."
2	to testify about all information known or	2	A. Okay.
3	reasonably known to Eli Lilly?	3	Q. Can you give me the names of
4	A. Yes.	4	people that are most knowledgeable in that
5		5	area?
	Q. Are you the person with the	1	
6	most knowledge at Eli Lilly regarding	6	A. Could you clarify? Are you
7	regulatory affairs?	7	asking about the divisions within
8	MS. JONES: Objection to the	8	regulatory?
9	form. You can answer.	9	Q. Yes, individuals.
10	A. Well, there are a number of	10	A. Okay.
11	folks in our regulatory affairs	11	Q. Individuals within regulatory.
12	department. I am fairly experienced, so	12	A. Okay. At present day or
13	I know quite a bit about it.	13	Q. Present day.
14	BY MR. O'BRIEN:	14	A. Present day. Okay. Well, I
15	Q. Would you mind providing me	15	am the regulatory advisor responsible for
16	some names of other people who have a	16	Cymbalta currently in the U.S., although I
17	strong knowledge base of regulatory	17	am moving into a new position shortly. I
18	affairs in your department?	18	report to Carl Garner, who is the senior
19	MS. JONES: Same objection.	19	director for the business bio-medicines
20	A. Our vice president, Dr. Robert	20	business unit, which includes neuroscience.
21	Metcalf. Are you referring specifically	21	He reports to Dr. Robert Metcalf, who is
22	to U.S. regulatory affairs or	22	the vice president of U.S. regulatory
23	BY MR. O'BRIEN:	23	affairs. The other people within
24	Q. Let's start with U.S. regulatory	24	regulatory that work on Cymbalta include
24	Q. Let's start with 0.5. regulatory		regulatory that work on Cymodita include
	Page 14		Page 16
1		1	_
1 2	affairs and then we'll move to global.	1 2	Sara Mescher, she is in our global
2	affairs and then we'll move to global. A. Okay. We have several senior	2	Sara Mescher, she is in our global labeling department. We do have
2 3	affairs and then we'll move to global. A. Okay. We have several senior directors that report to Dr. Metcalf in	2 3	Sara Mescher, she is in our global labeling department. We do have regulatory chemistry manufacturing and
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2 3 4 5	affairs and then we'll move to global. A. Okay. We have several senior directors that report to Dr. Metcalf in various positions, including CMNC, different therapeutic areas, advertising,	2 3 4 5	Sara Mescher, she is in our global labeling department. We do have regulatory chemistry manufacturing and controls, CMC. I'm actually trying to remember who that is. We're in
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	affairs and then we'll move to global. A. Okay. We have several senior directors that report to Dr. Metcalf in various positions, including CMNC, different therapeutic areas, advertising, promotional policy. Q. Could you start with the therapeutic areas if they relate to Cymbalta? A. Okay. We have our bio-medicines business unit. The senior director there is Dr. Carlos Garner. And then there's several individuals that report to him across the bio-medicines business unit; for neuroscience, Robin Wojcieszek, Janice Hitchcock, and there's a few others, but those are probably the two most experienced. Q. Okay. Let's do this by topic. Would you take a look at Topic No. 1 on page .8. The testimony strike that. "Testimony on the organization internal	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Sara Mescher, she is in our global labeling department. We do have regulatory chemistry manufacturing and controls, CMC. I'm actually trying to remember who that is. We're in late-stage development. I'm not certain who that person is. From an advertising and promotional perspective, that is Jo Secnik. Q. Jo, how do you spell Secnik? A. S-e-c-n-i-k. Q. And what's Jo's title? A. I believe it's advisor or senior manager in global regulatory affairs-U.S. advertising and promotions. Q. Is he assigned Cymbalta among other different drugs? A. It's a she, Josephine, actually. Q. Oh, sorry. A. I believe she does have responsibility for other molecules. Q. And let's go to Topic No. 2.

	Page 17		Page 19
1	education, training, selection, job title,	1	you direct me to?
2	and responsibility of defendant's employees	2	A. Well, pretty much anybody in
3	whose job includes dealing with regulatory	3	regulatory affairs will have knowledge of
4	agencies concerning Cymbalta."	4	these written procedures. That's part of
5	Can you list other individuals	5	our training program, which we have a
6	that would have knowledge regarding that	6	pretty robust training program. We do
7	topic?	7	have quality directors that oversee that
8	A. Not beyond the ones I just	8	area.
9	listed for you. There is one person I	9	Q. How about names of individuals
10	did not include that a regulatory	10	`
11	• •	11	that were responsible for creating those
12	associate, Victoria Papademas is also	12	standard operating procedures or that are
	involved. She works with our registration	1	responsible for training people on those
13	group who actually submits a lot of the	13	standard operating procedures?
14	electronic documents to FDA.	14	A. There are a variety of folks.
15	Q. Would you spell Victoria's last	15	We have people in our quality group who
16	name?	16	oversee and then different subject matter
17	A. P-a-p-a-d-e-m-a-s.	17	experts contribute to those policies and
18	Q. And would all the individuals	18	procedures. They are ultimately approved
19	that you listed under Topic 1 be	19	by Robert Dr. Robert Metcalf, our vice
20	knowledgeable on Topic 2?	20	president, or senior directors, such as
21	A. Yes.	21	Nancy Allen, who is responsible for
22	Q. Can you turn to sorry.	22	operations and labeling within U.S.
23	With regard to Topic No. 3.	23	regulatory affairs, Nikki Mehringer
24	A. Uh-huh.	24	oversees the quality systems within
	Page 18		Page 20
1	Q. "Testimony to identify written	1	regulatory.
2	standard operating procedures pertaining to		
		2	Q. Now, let's turn our attention,
3	defendant's regulatory affairs."	2 3	Q. Now, let's turn our attention, Topic No. 4. "Testimony on the policy and
3 4	defendant's regulatory affairs." Same line of questioning, who	3 4	Q. Now, let's turn our attention, Topic No. 4. "Testimony on the policy and procedures of defendants for creating,
3	defendant's regulatory affairs."	3	Q. Now, let's turn our attention, Topic No. 4. "Testimony on the policy and
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3 4 5 6 7	defendant's regulatory affairs." Same line of questioning, who are individuals who would have knowledge on this topic? A. Well, anybody who is in	3 4 5 6 7	Q. Now, let's turn our attention, Topic No. 4. "Testimony on the policy and procedures of defendants for creating, editing, reviewing, revising, and filing all materials, documents, studies, or communications with regulatory agencies
3 4 5 6 7 8	defendant's regulatory affairs." Same line of questioning, who are individuals who would have knowledge on this topic? A. Well, anybody who is in regulatory affairs is required to review	3 4 5 6 7 8	Q. Now, let's turn our attention, Topic No. 4. "Testimony on the policy and procedures of defendants for creating, editing, reviewing, revising, and filing all materials, documents, studies, or communications with regulatory agencies concerning Cymbalta."
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	defendant's regulatory affairs." Same line of questioning, who are individuals who would have knowledge on this topic? A. Well, anybody who is in regulatory affairs is required to review standard operating procedures that relate to our day-to-day job and interactions with regulatory agencies. Q. Who would have the most knowledge regarding that topic? MS. JONES: Objection to the form; vague. You can answer. A. I'm not sure I follow. Do you mean the director of the quality systems who is responsible for the LGPs orBY MR. O'BRIEN: Q. If I wanted to speak to somebody other than yourself regarding testimony to identify written standard operating procedures pertaining to	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. Now, let's turn our attention, Topic No. 4. "Testimony on the policy and procedures of defendants for creating, editing, reviewing, revising, and filing all materials, documents, studies, or communications with regulatory agencies concerning Cymbalta." Can you name some individuals that are involved with Topic No. 4? A. Those are basically the same people as what I discussed for Section 3. The policies and procedures are created by those individuals. And then within regulatory affairs, we are required to be trained and to understand those SOPs. Q. And that's fair enough. I understand there's going to be overlap. So we'll just keep on going down the list. A. Okay. Q. Topic No. 5, "Testimony on the preparation and attendance of defendant at
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	defendant's regulatory affairs." Same line of questioning, who are individuals who would have knowledge on this topic? A. Well, anybody who is in regulatory affairs is required to review standard operating procedures that relate to our day-to-day job and interactions with regulatory agencies. Q. Who would have the most knowledge regarding that topic? MS. JONES: Objection to the form; vague. You can answer. A. I'm not sure I follow. Do you mean the director of the quality systems who is responsible for the LGPs or BY MR. O'BRIEN: Q. If I wanted to speak to somebody other than yourself regarding testimony to identify written standard	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Now, let's turn our attention, Topic No. 4. "Testimony on the policy and procedures of defendants for creating, editing, reviewing, revising, and filing all materials, documents, studies, or communications with regulatory agencies concerning Cymbalta." Can you name some individuals that are involved with Topic No. 4? A. Those are basically the same people as what I discussed for Section 3. The policies and procedures are created by those individuals. And then within regulatory affairs, we are required to be trained and to understand those SOPs. Q. And that's fair enough. I understand there's going to be overlap. So we'll just keep on going down the list. A. Okay. Q. Topic No. 5, "Testimony on the

	Page 21		Page 23
1	FDA, if any, concerning Cymbalta and all	1	name?
2	issues involved in such hearings."	2	A. K-u-n-t-z.
3	I want to start with	3	Q. And what is Michael Robinson's
4	individuals who may have attended or	4	title?
5	prepared for the attendance at an advisory	5	A. He was a senior medical
6	committee meeting related to Cymbalta. Can	6	director for Cymbalta.
7	you list those names and individuals and	7	Q. Do you have an understanding of
8	their titles for me, please?	8	how many advisory committee meetings were
9	A. Yes. Well, I am the	9	held for Cymbalta?
10	subject-matter expert within our group for	10	A. Yes, there was only one.
11	preparing for advisory committee meetings	11	Q. And would you go through
12	for FDA. There are other individuals who	12	Claire's title and Matthew's title?
13	serve in that capacity. Jane Amos, she	13	A. Okay. Matthew was a principal
14	is with our submission, approval, and	14	consultant within regulatory affairs.
15	expert network, as well as Shelly Rickert,	15	Claire, I think she was her title is
16	who is also involved in that capacity. I	16	senior project management advisor.
17	was involved with the team that was	17	Q. Are all the individuals you
18	preparing for Cymbalta advisory committee	18	just listed still with the company?
19	meeting, although I was there as a	19	A. No, they are not.
20	consultant around process for that	20	Q. Who is still there and who is
21	particular advisory committee meeting. So	21	not?
22	then within Lilly was a team of	22	A. Dr. Baker is still there. Dr.
23	individuals working on Cymbalta that were	23	Robinson is not. Dr Dr. Vladimir
24	actually at the FDA advisory committee	24	Skljarevski is there, Claire Farrand is
	detaily at the 1271 daysory committee		Sinjure voin is there, Staire I divade is
	Page 22		Dago 24
1			Page 24
1	meeting.	1	there, Matt Kuntz is not.
2	Q. Can you identify that team and	2	there, Matt Kuntz is not. Q. With regard to Dr. Robinson,
	Q. Can you identify that team and their titles?	l	there, Matt Kuntz is not. Q. With regard to Dr. Robinson, Matt Kuntz, do you know where they
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meetings. But do you have an indication of when that occurred? A. I think it was 2010. It was around our chronic pain indications. Q. And, Doctor, would you mind taking a look at Topic No. 6? It says, "Testimony on all areas of safety and efficacy discussed between regulatory agencies and defendant concerning to would it be some of the names you mentioned earlier, are there additional names that you can think of? A. Yes, I mean, there were previous regulatory solutions regulatory solutions regulatory solutions and previous regulatory solutions and previous regulatory solutions and solutions are solutions. The solutions are solutions are solutions and solutions are solutions. So let me go backwards if that would help. So I've been responsible for Cymbalta since of 2013. Rich Hoffman was responsible for about a year before that. Prior to that was Isabelle and I think she only was responsible for about a year before that. Prior to that was Isabelle and I think she only was responsible for 2013. Rich Hoffman was responsible for 2013. Rich Hoffman was responsible for 2013. And I think she oil 2013 and I think she oil 2013. And then prior to that was Isabele, and I think she oil 2014 and th	August ble ggs,
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MS. JONES: Hoog is H-o-o-g. 24 with global patient safety. Page 26	
Page 26	
<u> </u>	
	age 28
1 A. And then Richard Hoffman. 1 Q. Does she still have any	
2 BY MR. O'BRIEN: 2 responsibilities as it relates to	
3 Q. Richard Hoffman. Doctor, do 3 Cymbalta?	
 4 you know if you recently put together a 5 list of those people that were involved 5 Q. Would you take a look at 	
6 in the development of Cymbalta? 6 Topic 7 now. "Testimony on commu	ication
7 A. Yes. 7 between the FDA and defendant conc	
8 Q. Do you have the list available 8 Cymbalta advertisements, promotiona	
9 with you today? 9 materials, or communications to the p	
10 A. I do not.	
11 Q. With all the names that you 11 A. Yes.	
just mentioned, could you go back and 12 Q. And I think you provided me the	e l
tell me their titles and their job 13 name of the person that's responsible	
responsibilities? 14 advertising earlier.	~^
15 A. They so our job titles do 15 A. Yes.	
16 vary by level. And so I'm not sure if I 16 Q. Will you	l l
17 can get all of them correct. 17 A. Currently just	
18 Q. It doesn't have to be exact. 18 MS. JONES: I'm sorry, Dr.	
19 A. Okay. 19 Phillips. When you say "responsible	
20 Q. Just 20 advertising," you mean in the global	or.
21 A. Isabelle is a principal 21 regulatory affairs context?	or
22 consultant. 21 regulatory arians context? 22 MR. O'BRIEN: Correct.	`or
	ör
Q. During what time period was 23 A. Currently that's Josephine this? 24 Secnik.	òr
24 Scellik.	òr

	Page 29		Page 31
1	BY MR. O'BRIEN:	1	Q. Just to understand the process,
2	Q. Do you know who reports to	2	once Josephine receives a prospective
3	Josephine?	3	advertisement from the marketing
4	A. I don't believe she has anybody	4	department, she takes a look, she sees if
5	that reports to her directly.	5	it's compliant or not. If she makes a
6	Q. So she handles all the Cymbalta	6	determination if it's compliant, is there
7	advertisements on a day-to-day basis?	7	another review that goes on before it
8	A. Yes, and currently there's none	8	gets submitted to the office of
9	or very little.	9	prescription drugs?
10	Q. Is that her only job	10	A. Yes. She will make the initial
11	A. No, it's not.	11	determination, suggest revisions, if
12	Q or is she and what are	12	necessary, to bring the piece into
13	her responsibilities as they relate to	13	compliance, and then it does go through a
14	Cymbalta advertisements?	14	legal, medical, regulatory review that the
15	A. In that role, the GRAUS	15	acronym is PCA, it's prepare, create, and
16	advertising and promotional, she is	16	advise. I apologize. But there is a
17	would is excuse me is	17	formal process. And that is the ultimate
18	responsible for reviewing any promotional	18	approval prior to submission to the agency
19	materials that are created by our	19	and implementation of the materials.
20	marketing department to ensure compliance	20	Q. Now, part of the PCA
21	with our SOPs, with FDA regulations,	21	A. Yes.
22	consistency with our label, and she would	22	Q. Lilly loves acronyms.
23	be part of our formal review process that	23	A. We do.
24	includes regulatory, medical, and legal.	24	Q. What individuals would
2 1	merudes regulatory, medical, and regal.	2 4	Q. What individuals would
	Page 30		Page 32
1	Q. When you mean "formal review	1	participate in a PCA review?
2	process," is it my understanding that	2	A. It will include the three
3	Josephine takes a look at the label from	3	functions that I listed; regulatory
4	marketing to see if there's if it	4	affairs, including the senior director,
5	needs to be changed or altered and then	5	Dr. Michele Sharp; legal, I don't know
6	there is a team that kind of does a	6	I believe I'm not sure who the legal
7	final approval?	7	representative is on the group. But
8	MS. JONES: Objection to the	8	there would be at least one lawyer
9	form. Go ahead.	9	involved with that review that's familiar
10	BY MR. O'BRIEN:	10	with the product; and then medical would
11	Q. She's going to object from time	11	include the brand medical, U.S. medical,
12	to time. If she doesn't want you to	12	currently the senior director for U.S.
13	answer, believe me, she'll let you know.	13	medical is Dr. Elizabeth Brunner.
14	A. Yes. Josephine, in her role,	14	Q. And does Dr. Elizabeth Brunner
15	that role is not to change the label.	15	have responsibilities for Cymbalta?
16	The role is to ensure compliance with the	16	A. Yes, as she is the U.S.
17	label and that the marketing materials are	17	affiliate responsible senior medical
18	appropriately in compliance. And then,	18	director.
19	also, she is responsible for regulatory	19	Q. Do you know who held
20	submissions to the office of prescription	20	Josephine's position before she did?
21	drug OPDPM. I can't remember all the	21	A. I believe, and I'm not entirely
22	words. But they are the division of FDA	22	positive, it was Dr. John Camacho.
23	that is responsible for promotional	23	Q. Do you have a time do you
24	review.	24	have a time frame of when he held that

1	Page 33		Page 35
1	position?	1	United States prescribing information or,
2	A. Not an exact one. I'd say,	2	for example, the European summary product
3	maybe 2010 to 2013, but I'm guessing	3	characteristics. The core data sheet is
4	honestly.	4	created by the Cymbalta team, which would
5	Q. Do you have any idea who held	5	include physician, statistician, global
6	the position before John?	6	patient safety, regulatory affairs,
7	A. I don't.	7	labeling.
8	Q. Is Josephine a physician?	8	Q. Just to slow you down.
9	A. No, she's not.	9	A. Okay.
10	Q. Do you understand what her	10	Q. Can you explain to a jury what
11	background is?	11	a "core data sheet" is?
12	A. I don't.	12	A. Okay. It is a document, it's
13	Q. Once it goes through the PCA	13	created in compliance with CIOMS'
14	`	14	•
15	review, who is the individual that's	15	guidance. It's an international council
16	responsible for submitting the	1	that provides guidance on the structure of
17	advertisement to the office of	16 17	such documents. And it includes all the
18	prescription drugs?	1	all the safety information around the
	A. It would be Josephine in this	18	product as well as efficacy information.
19	case.	19	And just to clarify, when I say "all," it
20	Q. And what was the title of her	20	is succinct, it is you know, it
21	position?	21	captures all the safety concepts
22	A. She's a principal consultant.	22	associated with the product and it is the
23	Q. And what department was that?	23	foundation for all local labeling. So
24	A. Global regulatory affairs-United	24	it's the core but then the local labeling
	Page 34		Page 36
1	States, advertising and promotions.	1	implements the core according to their
2	Q. Are you aware of a contact		
	Z. The jou aware of a contact	2	local regulations. So there may be
3	person at the FDA who would receive that	3	local regulations. So there may be variance between local labels but they
3 4	•	1	
	person at the FDA who would receive that	3	variance between local labels but they
4	person at the FDA who would receive that advertisement? A. I do not.	3 4	variance between local labels but they have to be consistent with the core data
4 5	person at the FDA who would receive that advertisement? A. I do not.	3 4 5	variance between local labels but they have to be consistent with the core data sheet.
4 5 6	person at the FDA who would receive that advertisement? A. I do not. Q. The next topic, "Testimony on communication" actually, never mind.	3 4 5 6	variance between local labels but they have to be consistent with the core data sheet. Q. And who creates the core data
4 5 6 7	person at the FDA who would receive that advertisement? A. I do not. Q. The next topic, "Testimony on	3 4 5 6 7	variance between local labels but they have to be consistent with the core data sheet. Q. And who creates the core data sheet? A. It's created as a team. The
4 5 6 7 8	person at the FDA who would receive that advertisement? A. I do not. Q. The next topic, "Testimony on communication" actually, never mind. Strike that. We just covered that.	3 4 5 6 7 8	variance between local labels but they have to be consistent with the core data sheet. Q. And who creates the core data sheet?
4 5 6 7 8 9	person at the FDA who would receive that advertisement? A. I do not. Q. The next topic, "Testimony on communication" actually, never mind. Strike that. We just covered that. Topic No. 8, will you take a	3 4 5 6 7 8 9	variance between local labels but they have to be consistent with the core data sheet. Q. And who creates the core data sheet? A. It's created as a team. The global labeling department is the one
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4 5 6 7 8 9 10 11 12 13	person at the FDA who would receive that advertisement? A. I do not. Q. The next topic, "Testimony on communication" actually, never mind. Strike that. We just covered that. Topic No. 8, will you take a look? A. Yes. Q. "Testimony on the organization	3 4 5 6 7 8 9 10 11 12 13	variance between local labels but they have to be consistent with the core data sheet. Q. And who creates the core data sheet? A. It's created as a team. The global labeling department is the one is the group responsible for creating and maintaining the core data sheet. Q. Now, within the global labeling department, is there a Cymbalta team or do they move from product to product?
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4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	person at the FDA who would receive that advertisement? A. I do not. Q. The next topic, "Testimony on communication" actually, never mind. Strike that. We just covered that. Topic No. 8, will you take a look? A. Yes. Q. "Testimony on the organization and internal structure divisions of defendant where employees deal with Cymbalta labeling." Are you able to talk about that organizational structure? A. Yes. Q. Can you give me an overview? A. Okay. We when creating labeling, we first create a core data	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	variance between local labels but they have to be consistent with the core data sheet. Q. And who creates the core data sheet? A. It's created as a team. The global labeling department is the one is the group responsible for creating and maintaining the core data sheet. Q. Now, within the global labeling department, is there a Cymbalta team or do they move from product to product? A. There is not a Cymbalta team within labeling. The associates in that department are assigned to specific products. And they may include more than one. Q. Is it broken down by neuroscience or
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	person at the FDA who would receive that advertisement? A. I do not. Q. The next topic, "Testimony on communication" actually, never mind. Strike that. We just covered that. Topic No. 8, will you take a look? A. Yes. Q. "Testimony on the organization and internal structure divisions of defendant where employees deal with Cymbalta labeling." Are you able to talk about that organizational structure? A. Yes. Q. Can you give me an overview? A. Okay. We when creating labeling, we first create a core data sheet and then the core data sheet forms	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	variance between local labels but they have to be consistent with the core data sheet. Q. And who creates the core data sheet? A. It's created as a team. The global labeling department is the one is the group responsible for creating and maintaining the core data sheet. Q. Now, within the global labeling department, is there a Cymbalta team or do they move from product to product? A. There is not a Cymbalta team within labeling. The associates in that department are assigned to specific products. And they may include more than one. Q. Is it broken down by neuroscience or A. Generally speaking, yes.
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	person at the FDA who would receive that advertisement? A. I do not. Q. The next topic, "Testimony on communication" actually, never mind. Strike that. We just covered that. Topic No. 8, will you take a look? A. Yes. Q. "Testimony on the organization and internal structure divisions of defendant where employees deal with Cymbalta labeling." Are you able to talk about that organizational structure? A. Yes. Q. Can you give me an overview? A. Okay. We when creating labeling, we first create a core data	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	variance between local labels but they have to be consistent with the core data sheet. Q. And who creates the core data sheet? A. It's created as a team. The global labeling department is the one is the group responsible for creating and maintaining the core data sheet. Q. Now, within the global labeling department, is there a Cymbalta team or do they move from product to product? A. There is not a Cymbalta team within labeling. The associates in that department are assigned to specific products. And they may include more than one. Q. Is it broken down by neuroscience or

	Page 37		Page 39
1	team located?	1	labeling team per se. It's individuals
2	A. The global team is are	2	from labeling who are part of the team,
3	located here in Indianapolis at Lilly	3	just like there's individuals from
4	Corporate Center.	4	regulatory, from medical, from patient
5	Q. Who strike that.	5	safety.
6	Do you know the individuals	6	Q. Fair enough. What is a
7	that are on the global labeling team as	7	Cymbalta product team?
8	it relates to Cymbalta?	8	A. The product team, it is a
9	A. Currently, that is Sara Mescher.	9	cross-functional group that's responsible
10		10	<u> </u>
11	Q. And what's her position?	11	for developing Cymbalta and the clinical
	A. I believe she is a principal	1	program, conducting the clinical program,
12	consultant.	12	the approval of the initial indication as
13	Q. And who else would be on that	13	well as subsequent indications as well as
14	team?	14	the marketing aspects of the product. So
15	A. She Barbara Brown is the	15	because we're no longer actively
16	assistant that works on Cymbalta labeling	16	developing Cymbalta, and the drug is off
17	as well.	17	patent, that team is much smaller. We
18	Q. Is she an assistant and	18	really are not doing any advertising at
19	principal or just an assistant?	19	this point in time. So by virtue of that,
20	A. I don't know her exact title.	20	the team is smaller now than it would
21	It is I think she might actually be	21	have been in 2004.
22	an associate. She is at a lower level	22	Q. And does the Cymbalta product
23	than Sara.	23	team, does that fall under regulatory?
24	Q. Okay. Is there anybody else on	24	A. No, like I said, it's a
			,
	Page 38		Page 40
1	Page 38 that team?	1	Page 40 cross-functional
2	that team? A. No.	2	_
1	that team?		cross-functional
2 3 4	that team? A. No.	2 3 4	cross-functional Q. Oh, cross-functional.
2 3	that team? A. No. Q. Back if we go back in time	2 3	cross-functional Q. Oh, cross-functional. A team and ultimately, you know, so their members, it's a matrix
2 3 4	that team? A. No. Q. Back if we go back in time to 2004 when Cymbalta was first on the	2 3 4	cross-functional Q. Oh, cross-functional. A team and ultimately, you
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	Page 41		Page 43
1	Q. Sorry, I just want to go one	1	what they do.
2	by one what they do.	2	A. Okay. Laura Cox-Heuer,
3	A. Okay. Sorry. He actually,	3	H-e-u-e-r, is the chief operating officer
4	we have a slightly different structure now	4	for the neuroscience platform. So she has
5	at Lilly than we did back in 2004. So	5	the same responsibilities, if you will, as
6	Dr. Escobar is responsible for the	6	Dr. Escobar. I mean, she functions in a
7	neuroscience platform.	7	different capacity. She's kind of like
8	Q. And what does that mean?	8	the project manager in charge, making sure
9	A. That means all of the approved	9	things get done as needed.
10	neuroscience products, so, for instance,	10	Q. And what are her day-to-day
11	that would include Cymbalta, Zyprexa,	11	responsibilities on that team?
12	Prozac, Symbyax, Strattera.	12	A. It's operations, making sure
13	Q. And when we talk about the	13	things get done that need to get done,
14	Cymbalta product team, let's talk about	14	that clinical trial, if there are issues,
15		15	that they're getting addressed. We have
16	how what specifically they do for	16	
17	Cymbalta.	17	regulatory responses to agencies, getting
	A. Okay.	1	the right personnel in the room, the
18	Q. Just to streamline things.	18	right resources to get that done.
19	A. There is no Cymbalta product	19	Q. What type of can you give
20	team anymore.	20	me examples of what type of regulatory
21	Q. Okay.	21	responses would need to take place on
22	A. Because of the structure that	22	that team?
23	we currently employ, it's the neuroscience	23	MS. JONES: Objection to the
24	platform.	24	form. Go ahead.
	D 42		
1	Page 42		Page 44
1		1	_
1 2	Q. Okay. Perfect. A. So that's what Dr. Escobar is	1 2	A. Okay. An example, more just
	Q. Okay. Perfect.A. So that's what Dr. Escobar is	1	A. Okay. An example, more just very recently was FDA has created class
2 3	Q. Okay. Perfect.A. So that's what Dr. Escobar is responsible for of which that includes	2 3	A. Okay. An example, more just very recently was FDA has created class labeling for all antidepressants regarding
2 3 4	Q. Okay. Perfect.A. So that's what Dr. Escobar is responsible for of which that includes Cymbalta.	2	A. Okay. An example, more just very recently was FDA has created class labeling for all antidepressants regarding angle-closure glaucoma. So when FDA sent
2 3	Q. Okay. Perfect.A. So that's what Dr. Escobar is responsible for of which that includes Cymbalta.Q. Okay.	2 3 4	A. Okay. An example, more just very recently was FDA has created class labeling for all antidepressants regarding angle-closure glaucoma. So when FDA sent that letter to us, we had a team, a
2 3 4 5	 Q. Okay. Perfect. A. So that's what Dr. Escobar is responsible for of which that includes Cymbalta. Q. Okay. A. So there's with the there 	2 3 4 5	A. Okay. An example, more just very recently was FDA has created class labeling for all antidepressants regarding angle-closure glaucoma. So when FDA sent that letter to us, we had a team, a regulatory response team get together to
2 3 4 5 6 7	 Q. Okay. Perfect. A. So that's what Dr. Escobar is responsible for of which that includes Cymbalta. Q. Okay. A. So there's with the there are people dedicated to working on 	2 3 4 5 6 7	A. Okay. An example, more just very recently was FDA has created class labeling for all antidepressants regarding angle-closure glaucoma. So when FDA sent that letter to us, we had a team, a regulatory response team get together to review that request, to look at our core
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	Page 45		Page 47
1	Q. And what are Dan White's	1	interaction between the product team and
2	day-to-day responsibilities on that team?	2	the drug safety surveillance team?
3	A. He's an extension of Laura and	3	A. Yes.
4		4	Q. And can you give me an idea of
5	is really you know, he's scheduling	5	• •
	meetings, getting people in a room,		what type of interaction there is?
6	getting timelines together, making sure	6	A. Okay. Well, as I was just
7	that the individual projects are getting	7	mentioning with the right-to-operate
8	done, an example of which is just the	8	documents, that is the team working
9	angle-closure glaucoma that I just	9	together with our safety organization.
10	mentioned.	10	The safety the safety team for
11	Q. And then there's some you	11	Cymbalta, they are responsible for
12	were about to mention some European	12	literally the day-to-day surveillance of
13	counterparts?	13	the safety, what's out there in the
14	A. Yes, European regulatory, that	14	literature, what has been reported to
15	is Beth Heaviside, H-e-a-v-i-s-i-d-e.	15	Lilly, what has been reported to FDA to
16	Because we do like global interactions.	16	continuously monitor and they do this on
17	Statistics would be Na Cai, C-a-i, and	17	a global basis.
18	Yoko Tanaka, T-a-n-a-k-a. We have lots	18	Then when we do periodic
19	of Iris Ferchland-Howe is our clinical	19	reporting, so we have annual reports and
20	project manager. She is based in	20	we have also have periodic reports that
21		21	
22	Belgium. Do you want me to spell that	22	are due at different points in time
	too? Iris is I-r-i-s, her last name is		during the year. They lead that effort,
23	F-e-r-c-h-l-a-n-d hyphen H-o-w-e.	23	but that involves, you know, folks from
24	Q. And, Doctor, what type of	24	regulatory, from medical, from statistics
	Page 46		Page 48
1	Page 46 strike that.	1	
	strike that.		to put all that information together to
1 2 3	strike that. Doctor, what are the day-to-day	1 2 3	to put all that information together to analyze it. They take the lead but it
2	strike that. Doctor, what are the day-to-day responsibilities of the statisticians on	2 3	to put all that information together to analyze it. They take the lead but it involves other people from the platform
2 3 4	strike that. Doctor, what are the day-to-day responsibilities of the statisticians on that product team?	2 3 4	to put all that information together to analyze it. They take the lead but it involves other people from the platform team.
2 3 4 5	strike that. Doctor, what are the day-to-day responsibilities of the statisticians on that product team? A. Primarily at this point in	2 3	to put all that information together to analyze it. They take the lead but it involves other people from the platform team. Q. Are members from the Cymbalta
2 3 4 5 6	strike that. Doctor, what are the day-to-day responsibilities of the statisticians on that product team? A. Primarily at this point in time, they are responsible for what we	2 3 4 5 6	to put all that information together to analyze it. They take the lead but it involves other people from the platform team. Q. Are members from the Cymbalta safety surveillance team also members of
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	strike that. Doctor, what are the day-to-day responsibilities of the statisticians on that product team? A. Primarily at this point in time, they are responsible for what we call "right-to-operate" documents, which includes our annual reports to agencies as well as our periodic safety update reports that go to regulatory agencies. So they're doing the programming, the statistical analysis that we do on an ongoing basis as part of our safety surveillance. Q. And that A. They Q. Go ahead. A. Sorry, they're also involved with regulatory response documents. Q. And, Doctor, I understand that	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	to put all that information together to analyze it. They take the lead but it involves other people from the platform team. Q. Are members from the Cymbalta safety surveillance team also members of the Cymbalta product team? A. Yes. Q. So are all those members involved or is there only some of the members? A. Well, like I said, there's not a Cymbalta product team anymore. It's the platform team. So it's primarily the GPS physician that is in charge of the safety team that is represented on the platform team. Q. Anybody else from the safety surveillance team that's on the platform team?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	strike that. Doctor, what are the day-to-day responsibilities of the statisticians on that product team? A. Primarily at this point in time, they are responsible for what we call "right-to-operate" documents, which includes our annual reports to agencies as well as our periodic safety update reports that go to regulatory agencies. So they're doing the programming, the statistical analysis that we do on an ongoing basis as part of our safety surveillance. Q. And that A. They Q. Go ahead. A. Sorry, they're also involved with regulatory response documents. Q. And, Doctor, I understand that Cymbalta has a drug safety surveillance team.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	to put all that information together to analyze it. They take the lead but it involves other people from the platform team. Q. Are members from the Cymbalta safety surveillance team also members of the Cymbalta product team? A. Yes. Q. So are all those members involved or is there only some of the members? A. Well, like I said, there's not a Cymbalta product team anymore. It's the platform team. So it's primarily the GPS physician that is in charge of the safety team that is represented on the platform team. Q. Anybody else from the safety surveillance team that's on the platform team? A. No, although they do attend meetings as needed for specific documents.

	Page 49		Page 51
1	A. Yes. There are operation team	1	G 10 meetings where Cymbalta was
2	meetings that are held every other week.	2	discussed?
3	There is a broader kind of management	3	A. Yes. I mean, could you be
4	team meeting, which is about once a	4	more specific or, you know
5	month, that's called G 10, but that's	5	Q. I'm just asking, do you
6	across the entire neuroscience platform,	6	remember the individuals that spoke on
7	it's not just Cymbalta. And then there	7	behalf of Cymbalta?
8	are ad hoc team meetings as needed for	8	A. Yes.
9	various topics.	9	Q. Can you name them for me?
10	Q. What types of issues get	10	A. Well, Laura Cox-Heuer that I
11	discussed typically at a G 10 meeting?	11	,
12	MS. JONES: Hold on just a	12	noted before, also Rodrigo Escobar. Iris
13		13	has presented previously, that's Iris
	second. Let me just lodge an objection.		Ferchland-Howe that I had mentioned
14	We've been outside of the scope of the	14	earlier. Those have been the primary
15	notice for the last several questions, I	15	folks that have been involved. I guess,
16	think. So to the extent that you're	16	actually, I have presented to them, so
17	going to pursue this, Dr. Phillips can	17	Q. Is there a share drive where
18	answer the questions, but she's doing it	18	some of these materials, presentation
19	in her capacity as an individual, not on	19	materials at these G 10 meetings are
20	behalf of the company. Go ahead.	20	saved?
21	A. Okay. We have several	21	A. I believe there is a we
22	post-marketing commitments for Cymbalta.	22	have a collaboration site, a SharePoint
23	So we update the G 10 on the status of	23	site for the team. I believe they are
24	those commitments and any interactions	24	housed there.
		1	
	Page 50		Page 52
1	Page 50 we've had with the agency around that.	1	Q. When you say "a collaboration
2	-	2	Q. When you say "a collaboration site for the team," are you talking about
	we've had with the agency around that.	1	Q. When you say "a collaboration
2 3 4	we've had with the agency around that. That's one example of what the G 10 team	2	Q. When you say "a collaboration site for the team," are you talking about
2 3 4 5	we've had with the agency around that. That's one example of what the G 10 team would do.	2 3	Q. When you say "a collaboration site for the team," are you talking about the G 10 meeting or are you talking about
2 3 4	we've had with the agency around that. That's one example of what the G 10 team would do. BY MR. O'BRIEN: Q. As it relates to Cymbalta, are	2 3 4	Q. When you say "a collaboration site for the team," are you talking about the G 10 meeting or are you talking about the platform team or are you talking
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2 3 4 5 6	we've had with the agency around that. That's one example of what the G 10 team would do. BY MR. O'BRIEN: Q. As it relates to Cymbalta, are	2 3 4 5 6	Q. When you say "a collaboration site for the team," are you talking about the G 10 meeting or are you talking about the platform team or are you talking about the drug safety surveillance team? A. We have a collaboration site for Cymbalta. So that would team
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1	A. Yes.	1	your product team at that point would put
2	Q. And do you understand if	2	together that label with directions by our
3	there's minutes for the G 10 meetings?	3	labeling department.
4	A. Yes, there are.	4	Q. Actually, sorry, Doctor, let me
5	Q. And that would all be saved on	5	back up. So can we go back to the
6	a collaborative site?	6	product team that would have existed back
7	A. I believe so.	7	around 2004? Would there have been a
8	Q. Usually in the neuroscience	8	Cymbalta platform? I mean strike
9	platform?	9	that.
10	A. I don't know. I'd have to go	10	Would there have been a
11	and look.	11	
12		12	Cymbalta product team that only dealt with
	Q. Let's go back to the notice.	13	Cymbalta at that time?
13	And let's talk about No. 10. "The	1	A. Yes.
14	testimony on the policy and procedures of	14	Q. Do you have any idea of the
15	defendants for pursuing the implementation	15	identities of the people that were on
16	of language into Cymbalta labeling,	16	that team at that time?
17	package insert, core data sheet, or	17	A. I know some of them. I was
18	summary of product characteristics."	18	not on the team at that time. I've only
19	Do you know individuals that	19	been recently responsible for Cymbalta.
20	could talk about the policy and	20	So I know the regulatory people who were
21	procedures, are you able to identify the	21	involved at that time and primarily those
22	policies and procedures as it pertains to	22	folks. So I can't give you a complete
23	Topic No. 10?	23	list.
24	A. Yes, I can do that.	24	Q. That's fine. Can you just give
	Page 54		Page 56
			=
1	Q. Thank you. Would you mind,	1	me the people that you understand that
1 2	Q. Thank you. Would you mind, Doctor?	1 2	me the people that you understand that were on the team at that time and their
	Doctor?		were on the team at that time and their
2 3	Doctor? A. Okay. Which one would you like	2 3	were on the team at that time and their titles and their responsibilities then and
2 3 4	Doctor? A. Okay. Which one would you like where would you like to start?	2 3 4	were on the team at that time and their titles and their responsibilities then and where they are now if they're still with
2 3 4 5	Doctor? A. Okay. Which one would you like where would you like to start? Q. Whatever you would like to	2 3	were on the team at that time and their titles and their responsibilities then and where they are now if they're still with the company.
2 3 4 5 6	Doctor? A. Okay. Which one would you like where would you like to start? Q. Whatever you would like to start with.	2 3 4 5 6	were on the team at that time and their titles and their responsibilities then and where they are now if they're still with the company. A. Okay.
2 3 4 5 6 7	Doctor? A. Okay. Which one would you like where would you like to start? Q. Whatever you would like to start with. A. Okay. The core data sheet is	2 3 4 5 6 7	were on the team at that time and their titles and their responsibilities then and where they are now if they're still with the company. A. Okay. Q. And how they may be employed
2 3 4 5 6 7 8	Doctor? A. Okay. Which one would you like where would you like to start? Q. Whatever you would like to start with. A. Okay. The core data sheet is the fundamental basis for all labeling	2 3 4 5 6 7 8	were on the team at that time and their titles and their responsibilities then and where they are now if they're still with the company. A. Okay. Q. And how they may be employed with Lilly today.
2 3 4 5 6 7 8 9	Doctor? A. Okay. Which one would you like where would you like to start? Q. Whatever you would like to start with. A. Okay. The core data sheet is the fundamental basis for all labeling regarding a product within Lilly. So	2 3 4 5 6 7 8 9	were on the team at that time and their titles and their responsibilities then and where they are now if they're still with the company. A. Okay. Q. And how they may be employed with Lilly today. A. Okay. Dr. Sharon Hoog was the
2 3 4 5 6 7 8 9	Doctor? A. Okay. Which one would you like where would you like to start? Q. Whatever you would like to start with. A. Okay. The core data sheet is the fundamental basis for all labeling regarding a product within Lilly. So there's a core data sheet for Cymbalta	2 3 4 5 6 7 8 9	were on the team at that time and their titles and their responsibilities then and where they are now if they're still with the company. A. Okay. Q. And how they may be employed with Lilly today. A. Okay. Dr. Sharon Hoog was the one of the regulatory scientists
2 3 4 5 6 7 8 9 10 11	Doctor? A. Okay. Which one would you like where would you like to start? Q. Whatever you would like to start with. A. Okay. The core data sheet is the fundamental basis for all labeling regarding a product within Lilly. So there's a core data sheet for Cymbalta and for every other product that we have	2 3 4 5 6 7 8 9 10 11	were on the team at that time and their titles and their responsibilities then and where they are now if they're still with the company. A. Okay. Q. And how they may be employed with Lilly today. A. Okay. Dr. Sharon Hoog was the one of the regulatory scientists assigned to Cymbalta. She was primarily
2 3 4 5 6 7 8 9 10 11 12	Doctor? A. Okay. Which one would you like where would you like to start? Q. Whatever you would like to start with. A. Okay. The core data sheet is the fundamental basis for all labeling regarding a product within Lilly. So there's a core data sheet for Cymbalta and for every other product that we have at Lilly. We have an SOP that addresses	2 3 4 5 6 7 8 9 10 11 12	were on the team at that time and their titles and their responsibilities then and where they are now if they're still with the company. A. Okay. Q. And how they may be employed with Lilly today. A. Okay. Dr. Sharon Hoog was the one of the regulatory scientists assigned to Cymbalta. She was primarily responsible for the approval of the major
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Doctor? A. Okay. Which one would you like where would you like to start? Q. Whatever you would like to start with. A. Okay. The core data sheet is the fundamental basis for all labeling regarding a product within Lilly. So there's a core data sheet for Cymbalta and for every other product that we have at Lilly. We have an SOP that addresses what is the content and format of the core data sheet, which follows CIOMS' guidance, international council for international and I can get the rest of it for you, but I can't remember. But it is recognized as internationally by FDA, by other regulatory agencies as kind of like the basis for core labeling. There is a process by which, in this case, usually at the time that that is initially prepared, that's before your	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	were on the team at that time and their titles and their responsibilities then and where they are now if they're still with the company. A. Okay. Q. And how they may be employed with Lilly today. A. Okay. Dr. Sharon Hoog was the one of the regulatory scientists assigned to Cymbalta. She was primarily responsible for the approval of the major depressive disorder indication as well as the diabetic peripheral neuropathy indication. At the same time, in parallel, Dr. Ann Sakai, S-a-k-a-i, she is now Dr. Ann Robbins, she's been divorced, R-o-b-b-i-n-s, was responsible for our stress urinary incontinence program. Q. What does that acronym mean? A. Which one? Q. OBBIS? MS. JONES: I think she was
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 20 21 22	Doctor? A. Okay. Which one would you like where would you like to start? Q. Whatever you would like to start with. A. Okay. The core data sheet is the fundamental basis for all labeling regarding a product within Lilly. So there's a core data sheet for Cymbalta and for every other product that we have at Lilly. We have an SOP that addresses what is the content and format of the core data sheet, which follows CIOMS' guidance, international council for international and I can get the rest of it for you, but I can't remember. But it is recognized as internationally by FDA, by other regulatory agencies as kind of like the basis for core labeling. There is a process by which, in this case, usually at the time that that	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	were on the team at that time and their titles and their responsibilities then and where they are now if they're still with the company. A. Okay. Q. And how they may be employed with Lilly today. A. Okay. Dr. Sharon Hoog was the one of the regulatory scientists assigned to Cymbalta. She was primarily responsible for the approval of the major depressive disorder indication as well as the diabetic peripheral neuropathy indication. At the same time, in parallel, Dr. Ann Sakai, S-a-k-a-i, she is now Dr. Ann Robbins, she's been divorced, R-o-b-b-i-n-s, was responsible for our stress urinary incontinence program. Q. What does that acronym mean? A. Which one? Q. OBBIS?

	Page 57		Page 59
1	A. Oh, yeah, I was just yeah,	1	first and then they go into the other
2	sorry.	2	regions of the world. So we do have
3	BY MR. O'BRIEN:	3	active submissions in the other parts of
4	Q. Sorry. I've got acronyms on	4	the world. Dr. Arei Regev is still in
5	the brain.	5	Lilly. He is also in global patient
6	A. Yeah, I'm trying to avoid that.	6	safety in much the same capacity as he
7	It can be challenging. I can speak only	7	was at that point in time. Dr. Wernicke
8	in acronyms if you'd like. So those are	8	has retired.
9	the two regulatory leads at that point in	9	Q. Dr. Phillips, what is the
10	time. Dr. Michael Robinson was involved	10	dynamic of the product team back in 2004?
11	in the team at that time. I'm not sure	11	Are certain physicians assigned different
12	in exactly what capacity, but he was, at	12	assignments? You mentioned, I believe,
13		13	-
14	a minimum, one of the senior medical	14	Vladimir was responsible kind of for the
	folks involved. Dr. Vladimir Skljarevski,	l .	pain indications. How are those
15	whose name I can never pronounce	15	assignments distributed?
16	correctly, was also involved with the	16	MS. JONES: Objection to the
17	team.	17	form. You can answer.
18	Q. Do you know how?	18	A. It may vary from team to team.
19	A. He has been primarily involved	19	But with what was we had three
20	with the more the pain indications.	20	indications under review for Cymbalta at
21	So that would have been DPNP, diabetic	21	the same time. So we had different
22	peripheral neuropathic pain. Dr. Arei	22	physicians as the lead by indication. So
23	Regev, R-e-g-e-v, he is a safety physician	23	Dr. Robinson was on depression. Vlad was
24	with a specialty in hepatotoxicity. I	24	probably on DPNP, I'm not sure.
	Page 58		Page 60
1	believe Dr. Wernicke, W-e-r-n-i-c-k-e, was	1	Actually, I think it was Tim Garnett.
2	involved with the team as a safety	2	Timothy Garnett was the lead physician for
3	physician at that time. And that's I	3	the stress urinary incontinence indication.
4	don't know beyond that who was involved.	4	BY MR. O'BRIEN:
5	Q. And of the names you listed,	5	Q. And my understanding is Timothy
6	who is still with the company and what's	6	Garnett is still with the company?
7	their current capacity?	7	A. He is.
8	A. Dr. Hoog is with the company.	8	Q. And what's
9	She's a physician in global patient	9	A. He is our chief medical
10	safety. Dr. Robbins is no longer	10	officer.
11	employed by Lilly but she is a consultant	11	Q. And did he have any other
12	and we do continue to work with her on	12	responsibilities as it relates to Cymbalta
13	certain projects.	13	at the time that you know of?
14	Q. Where is she a consultant at?	14	A. No, I mean, when you're first
15	A. She's an independent consultant,	15	getting a drug approved, it's pretty all
16	although I think she contracts through INC	16	consuming. You're only working on one
17	Research. Dr. Robinson is no longer with	17	product. And in this case only one part
18		18	of the product by indication.
	the company and I am not sure where he		or are product of marchion.
	the company, and I am not sure where he	l .	•
19	is. Dr. Vladimir is at the company, he	19	Q. Doctor, do you have an
19 20	is. Dr. Vladimir is at the company, he continues to support Cymbalta, primarily	19 20	Q. Doctor, do you have an understanding that this case deals with
19 20 21	is. Dr. Vladimir is at the company, he continues to support Cymbalta, primarily activities in China and Japan. So we	19 20 21	Q. Doctor, do you have an understanding that this case deals with Cymbalta discontinuation?
19 20 21 22	is. Dr. Vladimir is at the company, he continues to support Cymbalta, primarily activities in China and Japan. So we have follow-on indications, they don't get	19 20 21 22	Q. Doctor, do you have an understanding that this case deals with Cymbalta discontinuation? A. Yes.
19 20 21 22 23	is. Dr. Vladimir is at the company, he continues to support Cymbalta, primarily activities in China and Japan. So we have follow-on indications, they don't get approved and their indications are	19 20 21 22 23	 Q. Doctor, do you have an understanding that this case deals with Cymbalta discontinuation? A. Yes. Q. Do you have any knowledge of
19 20 21 22	is. Dr. Vladimir is at the company, he continues to support Cymbalta, primarily activities in China and Japan. So we have follow-on indications, they don't get	19 20 21 22	Q. Doctor, do you have an understanding that this case deals with Cymbalta discontinuation? A. Yes.

	Page 61		Page 63
1	the label from 2004 to present?	1	done, how the drug was developed, the
2	A. I know the regulatory personnel	2	chemistry manufacturing and controls, as
3	who have been involved with that.	3	well as your initial protocol and so that
4	Q. Was that piece of the label?	4	the agency can review to determine if it
5	A. The discontinuation emergent	5	is safe enough to proceed into clinical
6	adverse events, yes.	6	trials with humans. So that is done
7	· ·	7	
	Q. Could you take me through their	l	before you can initiate any clinic trial
8 9	names of responsibilities and the dates?	8	in humans. And that's the IND is
10	A. Okay.	9	specific to FDA. So that's FDA
	Q. And if you have do you have	10	terminology, but there are similar
11	a list that you happen to have on you?	11	processes across the world with different
12	A. I don't.	12	names or acronyms, clinical trial
13	Q. Okay.	13	application, or CTA, being the most
14	MS. JONES: Let me just note,	14	common. So once FDA reviews and agrees
15	Kevin, to the extent that you're looking	15	that we can proceed with clinical testing,
16	for lists of names and time frames for	16	every protocol that we conduct is
17	different positions, I believe we produced	17	submitted to the agency under the IND and
18	a set of organizational charts for global	18	is subject to FDA regulation and
19	regulatory affairs and we can point you	19	oversight.
20	towards those afterwards if they would be	20	So those studies are conducted
21	useful to you.	21	under the IND. They are reported to the
22	MR. O'BRIEN: Okay. Phyllis, I	22	IND, as well as any changes in chemistry,
23	wasn't thank you.	23	manufacturing, controls, along the way, as
24	MS. JONES: Go ahead.	24	well as toxicology studies that are
			G.
	Page 62		Page 64
1	Page 62 A. Okay. Dr. Sharon Hoog, I know,	1	Page 64 completed. So it's an application that
1 2		1 2	_
	A. Okay. Dr. Sharon Hoog, I know,	l .	completed. So it's an application that you continue to add to as you proceed
2	A. Okay. Dr. Sharon Hoog, I know, was involved with Cymbalta late '90s through 2005. The depression NDD	2	completed. So it's an application that you continue to add to as you proceed through phases of development.
2 3	A. Okay. Dr. Sharon Hoog, I know, was involved with Cymbalta late '90s through 2005. The depression NDD application was filed in 2001.	2 3 4	completed. So it's an application that you continue to add to as you proceed through phases of development. Q. I wanted to ask you about that.
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	Page 65		Page 67
1	have submitted what are called	1	the question.
2	"supplemental NDAs" or little S big NDA,	2	A. I believe what you're asking is
3	which that can be labeling changes, that	3	she was involved with compiling the
4	can be chemistry changes, it can be a new	4	NDA and working with the teams that were
5	indication for the product. But	5	creating the integrated summary of safety.
6	everything that's submitted to the NDA	6	So that's looking at the safety across
7	outside of just routine correspondence is	7	all of the trials that have been
8	typically a supplement and is assigned a	8	conducted for Cymbalta and looking at what
9	number and reviewed accordingly.	9	are the key safety concepts that needed
10	Q. Thank you, Doctor. And getting	10	to be conveyed in labeling, one of which
11	back to Dr. Hoog	11	were discontinuation emergent adverse
12	A. Uh-huh.	12	events. So while she was not the hands-on
13	Q you said she was involved in	13	person doing the statistical analysis, she
14	the late '90s to 2000 and we're just	14	
15	A. 2005.	15	was part of the team interpreting the
16		16	data, although that was led by GPS and
17	`	1	our medical group. She is a physician,
18	involvement with the discontinuation part of the Cymbalta label.	17 18	so she does she is a psychiatrist, and
			that had practiced extensively before
19	A. Okay. Well, she was part of	19	coming to Lilly, so she did have an
20	the team that put together the NDA. She	20	informed opinion as to that well, most
21	was the regulatory U.S. regulatory lead	21	of the label, so
22	for the NDA and was responsible during	22	BY MR. O'BRIEN:
23	the three-year review period as well as	23	Q. Okay. And who would be the
24	the just the initial approval of both	24	next person that would have
	Page 66		Page 68
1	the NDA for depression as well as the NDA	1	responsibilities with regard to the
1 2	the NDA for depression as well as the NDA for diabetic peripheral neuropathic pain,	1 2	responsibilities with regard to the discontinuation part of the Cymbalta
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	Page 69		Page 71
1	global patient safety group.	1	A. Well, we have several. We have
2	Q. This sorry, Doctor. The	2	a regulatory quality system, RQS, that
3	senior medical director, is that under	3	includes different SOPs regarding
4	regulatory?	4	communicating with agencies and how to
5		5	document those communications. For
6	1 1 1	6	
7	through our medical organization and	7	instance, we every time we have a
	ultimately to Dr. Garnett as the chief	1	phone call or an e-mail with somebody at
8	medical officer now.	8	FDA, we do a record of contact and that
9	Q. Do you have an idea who the	9	is logged in our electronic e-files.
10	senior medical director was back in 2004?	10	Q Where do the calls from the FDA
11	A. I don't know.	11	come through? Is there a contact person
12	Q. Do you have an idea strike	12	at Lilly?
13	that.	13	A. Yes. There is a contact person
14	Can you think of anybody that	14	for each molecule. So for me, right now,
15	was a senior medical director from 2004	15	I am the contact for Cymbalta. So FDA
16	to present day?	16	would call me first. My name is on the
17	MS. JONES: Objection to the	17	correspondence. And then I can direct
18	form.	18	them to other team members as needed.
19	A. I'm not sure I'm following.	19	There may be occasions in which they
20	BY MR. O'BRIEN:	20	contact our GPS physician or our CMNC
21	Q. I'm just trying to get a list	21	lead in some situations. But the
22	of individuals that you know of that held	22	majority of the contact would go through
23	that position since Cymbalta has been on	23	me as the U.S. regulatory scientist.
24	the market.	24	Q. Does most of your contact with
	Page 70		Page 72
1			
1	MS. JONES: Please also note my	1	the FDA, does that come through letters,
1 2	MS. JONES: Please also note my objection to this line of questioning as	1 2	the FDA, does that come through letters, phone calls, e-mails?
1		1	
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2 3 4	objection to this line of questioning as being outside of the scope of the notice. A. Well, as I said, Dr. Escobar is	2 3 4	phone calls, e-mails? A. In today's day and age, it's primarily e-mails and phone calls. You
2 3 4 5	objection to this line of questioning as being outside of the scope of the notice. A. Well, as I said, Dr. Escobar is the current lead for the neuroscience	2 3 4 5	phone calls, e-mails? A. In today's day and age, it's primarily e-mails and phone calls. You know, ten years ago, that was a lot of
2 3 4 5 6	objection to this line of questioning as being outside of the scope of the notice. A. Well, as I said, Dr. Escobar is the current lead for the neuroscience platform. Prior to that, it was Dr.	2 3 4 5 6	phone calls, e-mails? A. In today's day and age, it's primarily e-mails and phone calls. You know, ten years ago, that was a lot of it was faxed or letters in the mail. Q. Once you receive an e-mail for
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	Page 73		Page 75
1	there would be any follow-up, which is	1	Q. Okay. So you can search for
2	also logged into e-files.	2	all incoming correspondence from the FDA
3	Q. Now, the CRR group, is that a	3	with regard to Cymbalta and you would see
4	group that's put together kind of just	4	kind of would you see just a field of
5	save the communication, is that their	5	all the different letters and
6	function?	6	communications that have come in?
7	A. Well, they have a broader	7	A. You would see a listing by date
8	function than that. That's one of the	8	of the various submissions. And there'll
9	things they do is, you know, they are	9	be a brief description. It will be the
10	responsible for ensuring that e-files is	10	date, the sequence number, the NDA number,
11	kept up to date, which includes records	11	and then you can click on that to get
12	of contact, incoming, outgoing	12	more information about the actual
13	correspondence. They are responsible for	13	submission or what was received.
14	submitting through the gateway to FDA.	14	Q. And who provides the summary?
15	We submit everything electronically now.	15	What that be the CRR group or would it
16	Previously it was on paper or some	16	be you who did that before you sent the
17	combination, but that group was always	17	correspondence to the CRR group?
18	responsible for those submissions and	18	A. It would be one or of us,
19	making sure we're in compliance with the	19	depending on what it was. So when we're
20	standards of the day for FDA.	20	•
21	Q. Now, all communication that is,	21	submitting a protocol to the agency, the
22	I guess, covered in the e-files, is that	22	CRR associate would typically put that in. When it's a record of contact or
23	saved on a certain database that's	23	
24	searchable?	24	incoming, I usually provide the summary
24	searchable?	24	for the group to, you know, to make that
	Page 74		Page 76
1			
1	A. Yes.	1	searchable field. But it is a free text
1 2	A. Yes.Q. What's the name of the	1 2	searchable field. But it is a free text field that I would fill out, my
		I	
2	Q. What's the name of the	2	field that I would fill out, my
2 3	Q. What's the name of the database?	2 3	field that I would fill out, my colleagues in regulatory affairs or within
2 3 4	Q. What's the name of the database?A. It's called "e-files."	2 3 4	field that I would fill out, my colleagues in regulatory affairs or within CRR.
2 3 4 5	Q. What's the name of the database?A. It's called "e-files."Q. Easy enough.	2 3 4 5	field that I would fill out, my colleagues in regulatory affairs or within CRR. Q. Once you receive a contact from
2 3 4 5 6	 Q. What's the name of the database? A. It's called "e-files." Q. Easy enough. A. Yes, it's a document based I 	2 3 4 5 6	field that I would fill out, my colleagues in regulatory affairs or within CRR. Q. Once you receive a contact from the FDA, do you distribute it to anybody
2 3 4 5 6 7	 Q. What's the name of the database? A. It's called "e-files." Q. Easy enough. A. Yes, it's a document based I guess you would call it a collaboration, 	2 3 4 5 6 7	field that I would fill out, my colleagues in regulatory affairs or within CRR. Q. Once you receive a contact from the FDA, do you distribute it to anybody other than the CRR group? Is there
2 3 4 5 6 7 8	 Q. What's the name of the database? A. It's called "e-files." Q. Easy enough. A. Yes, it's a document based I guess you would call it a collaboration, our website, it is access controlled and 	2 3 4 5 6 7 8	field that I would fill out, my colleagues in regulatory affairs or within CRR. Q. Once you receive a contact from the FDA, do you distribute it to anybody other than the CRR group? Is there somebody that works in your same
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. What's the name of the database? A. It's called "e-files." Q. Easy enough. A. Yes, it's a document based I guess you would call it a collaboration, our website, it is access controlled and is maintained within Lilly. Q. And it's a searchable database? A. It is. Q. What are some of the searchable fields that you can utilize in order to locate documents with the FDA? A. You can search based on the drug name. You can search based on the NDA or IND number. You can search by date. Is there a drop-down field of certain types of submissions, whether they be amendments or supplements or annual reports. So there are a couple different categories. You can search for incoming	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	field that I would fill out, my colleagues in regulatory affairs or within CRR. Q. Once you receive a contact from the FDA, do you distribute it to anybody other than the CRR group? Is there somebody that works in your same department that has sort of involvement in receiving that communication? A. It depends on what the communication is. If it you know, so we distribute the information accordingly. If it's an update on something that's under review, then you send it to your team, your boss, you know, to be for awareness, if there's action we have to take. So it really does depend on the content of the communication. Q. And you said there's something called a "gateway to the FDA." I believe you characterized it as like an electronic
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. What's the name of the database? A. It's called "e-files." Q. Easy enough. A. Yes, it's a document based I guess you would call it a collaboration, our website, it is access controlled and is maintained within Lilly. Q. And it's a searchable database? A. It is. Q. What are some of the searchable fields that you can utilize in order to locate documents with the FDA? A. You can search based on the drug name. You can search based on the NDA or IND number. You can search by date. Is there a drop-down field of certain types of submissions, whether they be amendments or supplements or annual reports. So there are a couple different	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	field that I would fill out, my colleagues in regulatory affairs or within CRR. Q. Once you receive a contact from the FDA, do you distribute it to anybody other than the CRR group? Is there somebody that works in your same department that has sort of involvement in receiving that communication? A. It depends on what the communication is. If it you know, so we distribute the information accordingly. If it's an update on something that's under review, then you send it to your team, your boss, you know, to be for awareness, if there's action we have to take. So it really does depend on the content of the communication. Q. And you said there's something called a "gateway to the FDA." I believe

	Page 77		Page 79
1	A. Well, I'm not sure I can give	1	form.
2	you the inner workings, but we do submit	2	A. I there is I interact
3	, , , , , , , , , , , , , , , , , , ,	3	with various project managers on the basis
4	Q. You can give me the CliffNotes	4	of indications. And so there's not one
5	version.	5	person that I would talk to about any
6	A. We all of our okay. So	6	safety-related issue that let me take
7	the IND and the NDA, they're separate	7	a step back. FDA is a very large
8	applications but they essentially are a	8	organization.
9	backbone, information goes into specific	9	BY MR. O'BRIEN:
10	parts of it. There's modules that are	10	Q. Yes.
11	standardized by FDA as well as	11	A. And there are many different
12	actually a lot of the content has been	12	parts. There's different review
13	globally harmonized so the idea is they	13	divisions. So there's a division for
14	have a common structure. It's an XML	14	psychiatry products. There's a division
15	backbone and information gets slotted into	15	for anesthetics and analgesics. There is
16	certain sections within the NDA and then	16	a division for reproductive health. So,
17		17	-
	that is electronically submitted to the	18	for instance, our depression indications
18	agency, they receive it in the same	1	and anxiety indications are reviewed by
19	format, so they kind of have the same	19 20	the psychiatry division. Our pain
20	parallel structure so that we can see the	1	indications, diabetic neuropathic pain,
21	same thing.	21	fibromyalgia, and chronic pain are within
22	So, for instance, our annual	22	the anesthetics and analgesic division.
23	reports go into Module 1. Study reports	23	So there's different review divisions
24	will go into Module 5. Chemical reports	24	based on their expertise who review them.
	Page 78		Page 80
1	go into Module 3. Toxicology reports go	1	Separate from that is the
2	into Module 4. And within those modules,	2	office of surveillance and epidemiology,
3	there's further breakdown as to what the	3	who are primarily responsible for safety,
4	structure is. But that way, FDA is	4	although the review division also has
5	receiving information in a common format	5	safety. They're equal but separate. The
6	from everybody that's submitting to them	6	idea on FDA is to have a separate safety
7	so that they have some consistency and	7	surveillance in addition to the review
8	where to locate information.	8	division and they concur on projects and
9	Q. Now, with regard to Cymbalta,	9	then would recommend changes to the label.
10	do you have a contact at the FDA? Is	10	So they work together to
11	there an individual employed by the FDA	11	provide information to us or to request
12	that you have day-to-day interaction with?	12	information from us about the label.
13	A. Yes, I actually work with	13	That would ultimately get communicated to
14	several different project managers at FDA.	14	me through a specific project manager at
15	They assign project managers by compound	15	FDA that are usually from the review
16	but then also by IND or NDA. So because	16	divisions, although they do have project
17	we have multiple INDs and NDAs, I have	17	managers within OSC. So, most recently,
18	different project managers that I interact	18	I think it was Terry Henderson that
19	with for those specific indications.	19	communicated the example I gave before
20	Q. Can you provide me a list of	20	around the angle-closure glaucoma
21	the project managers at the FDA that you	21	class-labeling changes.
22	may interact with regarding the Cymbalta	22	Q. Now, do you have the contact of
23	discontinuation syndrome?	23	somebody that you have regular
24	MS. JONES: Objection to the	24	communications with from the FDA in the
0	•		

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1	office of surveillance?	1	paper archives prior to December of 2010.
2	A. I do not have a routine contact	2	Q. So prior to December 2010, if
3	with that division office.	3	you received an e-mail from the FDA,
4	Q. Can you identify any project	4	would that be printed and placed in the
5	managers or employees from that division	5	paper archives?
6		6	A. Yes.
7	at the FDA that you've had contact with?	7	
	A. Just this most recent, Terry,		Q And where is the paper
8	and I think it's Henderson, but I'm not	8	archives? Where does it exist?
9	.100 percent sure.	9	A. It exists here in Corporate
10	Q. Does Lilly keep a log of	10	Center in Indianapolis, Lilly Corporate
11	contacts that they would have with the	11	Center. That includes the most recent
12	office of surveillance?	12	applications. We do have off-site storage
13	A. We keep a record of all	13	for some of the older communications.
14	contacts with FDA regardless of division	14	Q. And is it your understanding
15	or office.	15	that Lilly no longer keeps a paper
16	Q. Is that contact list I mean,	16	archive as in, you know, if you got an
17	would it be searchable? So you want to	17	e-mail tomorrow, would it be printed and
18	go back and take a look of all the	18	placed in the paper archive?
19	contacts you've had with the FDA but you	19	A. No, it would not. It would be
20	really only wanted to look at contact you	20	electronic.
21	had with the office of surveillance, how	21	Q. Do you have an understanding
22	would you go about doing that?	22	how the paper archive system is indexed?
23	A. Within e-files, you can you	23	A. Uh-huh. Yes. It is indexed
24	could do a keyword search for records of	24	by NDA or IND by the number for that.
	court do a ney word scaren for records of		by 11,511 of 11,15 by the number for that.
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1	contact that involved OSC, because that is	1	And it literally is a chronological
2	input as to what division so or part	2	record. So it's you literally,
3	of FDA. However, that's a free text	3	there are tabs within binders by date.
4	field, so it may not be always obvious,	4	There are different colored tabs that
5	you know, sometimes you have to do a	5	indicate different types of communication,
6	little bit of digging.	6	whether it be incoming, outgoing, whether
7	And then e-files has only been	7	it be promotional types of communications.
8	•	8	And the notes to file are kept in a
	online since the end of 2010. So prior		•
9	to that, notes to files were captured	9 10	separate binder, but they're also by
10	electronically in a Documentum database		chronology.
11	and also in our paper archive. And prior	11	Q. At the time that Lilly made the
12	to 2010, our paper archive is the	12	decision or to go paperless, do you
13	official repository of all communications	13	know if they scanned the old paper
14	between Lilly and FDA.	14	archives so they're available in
15	Q. So before 2010, all	15	electronic platform?
16	communications with the FDA were paper,	16	A. They have scanned quite a few
17	most communications?	17	of them. We had some summer interns that
18	A. Most were. Well, we had	18	did a lot of that work. But it is not
19	electronic, they were often hybrid of	19	a complete record. So that's where, you
20	paper and electronic. So there is	20	know, if you want an absolutely, you
21	electronic information that can be	21	know, complete record, you have to go to
22	searched, but it is not a complete	22	the paper. But, yes, there are quite a
23	record. So if you want an absolutely	23	few documents that were scanned into the
24	complete record, you have to go to the	24	system and our searchable within e-files.
			·

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1	Some of them are scanned in, some of them	1	Q Ann Robbins?
2	only have the information to say "sequence	2	A. It was very similar, the two of
3	No. XYZ from this date," but you still	3	them, when I was speaking to them since
4	have to go to the paper to actually get	4	they were responsible for Cymbalta at the
5	the content.	5	time of approval it was, you know, what
6		6	was what information was provided in
7	Q. Now, Doctor, I want to turn our attention to	7	^
		l	the NDA, what discussions were had with
8	MS. JONES: Is this a sensible	8	the FDA during the negotiation label
9	time to take a break? We've been going	9	process prior to approval, and some of
10	about an hour and a half.	10	the outcomes of those conversations. So I
11	MR. O'BRIEN: Yeah. I mean,	11	did speak to them about that. The
12	absolutely. I was just looking at the	12	creation of the core data sheet. I speak
13	time. It looks like there's 12 minutes	13	I spoke with Dr. Torkil Fredborg, he
14	before the tape breaks.	14	is an EU regulatory.
15	MS. JONES: Oh, okay.	15	Q. Would you mind spelling that?
16	MR. O'BRIEN: We can go now	16	A. T-o-r-k-i-l. His last name is
17	and they can put in a new tape or	17	F-r-e-d-b-o-r-g. He was a European
18	MS. JONES: No, we can burn	18	scientist involved with the initial
19	the tape, that's fine. Is that okay with	19	Cymbalta submissions and approvals. So I
20	you, Dr. Phillips?	20	did speak to him about language in the
21	THE WITNESS: That's fine.	21	SPC.
22	BY MR. O'BRIEN:	22	Q. And would you mind telling the
23	Q. Doctor, can you give me an idea	23	jury what the "SPC" is?
24	of the preparation that you did for	24	A. Sorry. That's the European
	or the preparation that you true for		11. Sorry. That's the European
	Page 86		Page 88
1	today's deposition?	1	summary of product characteristics, so
2	A. Okay. I met with counsel to	2	that's the equivalent of the USPI for
3	understand the content of the deposition,	3	Europe.
4	the information. I reviewed SOPs. I	4	Q. And what was his day-to-day
5	talked to a couple individuals who were	5	responsibilities as it related to Cymbalta
6	involved with Cymbalta previously. And I	6	back in 2004?
7	reviewed some of the Cymbalta	7	A. It was the same as the
8	correspondence with FDA.	8	day-to-day responsibilities as what I
		l	
9	Q. And what individuals did you	9	described for Dr. Hoog and Dr. Robbins on
10	speak to regarding Cymbalta in preparation	10	the European side. They were global
11	for your deposition? And can you list	11	submissions, though, so he was involved
12	their names, you know, their titles, if	12	with the creation of the the entire
13	you haven't told us already, their	13	NDA or as it's called in Europe the
14	responsibilities as it related to	14	"MAA," the marketing authorization
15	Cymbalta?	15	application.
16	A. Uh-huh. Well, I spoke with Dr.	16	Q. And what type of information
17	Hoog, who I have already described for	17	did you ascertain from Dr. Fredborg?
18	you. I also spoke with Ann Robbins, Dr.	18	A. We talked about the approval,
19	Ann Robbins.	19	what was in the label, particularly
20	Q. And, also, would you mind	20	regarding discontinuation emergent adverse
21	telling me the type of information that	21	events and how did that labeling change
22	you were trying to ascertain from Dr.	22	over time.
23	Hoog and Dr	23	Q. And what did he tell you about
24	A. Uh-huh.	24	that?

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1	A. He went through the initial	1	of the the fact name of the document.
2	submission, which was very much based on	2	A. It's the Rapporteur's assessment
3	the core data sheet as you would expect.	3	of the second PSUR, periodic safety update
4	And then just that there was a change for	4	report.
5	class labeling, much like in the U.S., in	5	Q. Did you review any other
6	2000 end of 2005, 2006 based on, you	6	documents with Dr. Fredborg?
7	know, the European review of periodic	7	A. We looked at the SPC itself,
8	safety update report and then their	8	but which summary product
9	standardization of wording for	9	characteristics.
10	discontinuation symptoms across the labels	10	Q. And how long was your meeting
11	for all antidepressants. FDA did	11	for?
12	=	12	A. It was like a half hour.
13	something very similar right as Cymbalta	13	
14	was initially approved in 2004, so you	14	Q. And what about with Dr. Hoog?
	will see class labeling reflected in the	15	A. May be an hour.
15	initial label in addition to what was	1	Q. And what documents did you
16	we initially provided.	16	review with Dr. Hoog?
17	Q. Where is Dr. Fredborg located?	17	A. We looked at the labeling for
18	A. He is located in the UK, in	18	Cymbalta over time.
19	our offices there.	19	Q. And then she strike that.
20	Q. So this was was this a	20	Did Dr. Hoog have any comments
21	phone conversation you had with him?	21	of the label changes for Cymbalta over
22	A. Actually, no, he was visiting	22	time?
23	Indianapolis. So I just happened to, you	23	MS. JONES: Objection to the
24	know, catch him when he was here locally.	24	form.
	Page 90		Page 92
1	Q. Did you guys review any	1	A. I mean, we did discuss when did
2	documents?	2	this change and why, so, yes, we did have
3	A. We looked at the Rapporteur's	3	that conversation, specifically around
4	assessment of our second PSUR, periodic	4	discontinuation emergent adverse events.
5	update report. So the Rapporteur is the	5	BY MR. O'BRIEN:
6	their reviewer. That's the name for	6	Q. And did you have that
7	their scientific medical reviewer.	7	conversation with anybody else, not
8	Q. And when was the Rapporteur's	8	including your lawyers?
9	assessment created?	9	A. I spoke with Dr. Robbins about
10	A. It was in late 2005. That's	10	the same thing because, although they were
11	when they made the change to their class	11	working in different indications, they
12	labeling.	12	were obviously coordinating because the
13	Q. Is that document publicly	13	label would be consistent across divisions
14	available?	14	with the exception of the actual
15	A. No, it's not.	15	indications and clinical study section.
16	Q. If I wanted to obtain a copy	16	Q. Did you meet with Dr. Hoog and
17		17	· · · · · · · · · · · · · · · · · · ·
	of that assessment if it hasn't already	I 1/	Dr. Kopinson Dr. Koppins at the same
	of that assessment, if it hasn't already	1	Dr. Robinson Dr. Robbins at the same time?
18	been produced, how would I go about	18	time?
18 19	been produced, how would I go about asking for it?	18 19	time? A. No.
18 19 20	been produced, how would I go about asking for it? MS. JONES: You would ask	18 19 20	time? A. No. Q. When did you have those
18 19 20 21	been produced, how would I go about asking for it? MS. JONES: You would ask Lilly's lawyers.	18 19 20 21	time? A. No. Q. When did you have those meetings?
18 19 20 21 22	been produced, how would I go about asking for it? MS. JONES: You would ask Lilly's lawyers. A. Okay.	18 19 20 21 22	time? A. No. Q. When did you have those meetings? A. Probably in June. I know I
18 19 20 21 22 23	been produced, how would I go about asking for it? MS. JONES: You would ask Lilly's lawyers. A. Okay. BY MR. O'BRIEN:	18 19 20 21 22 23	time? A. No. Q. When did you have those meetings? A. Probably in June. I know I met with Dr. Robbins on July 1st.
18 19 20 21 22	been produced, how would I go about asking for it? MS. JONES: You would ask Lilly's lawyers. A. Okay.	18 19 20 21 22	time? A. No. Q. When did you have those meetings? A. Probably in June. I know I

	82	200	
	Page 93		Page 95
1	estimate of the number of documents that	1	some, you know, the organizational charts.
2	you looked at in preparation of today's	2	I pointed her to where they reside on the
3	deposition?	3	collaboration sites, that kind of thing.
4	A. I didn't count them. I mean,	4	MS. JONES: And those have been
5	I looked at some of the correspondence.	5	produced.
6	I looked at versions of labels. I looked	6	BY MR. O'BRIEN:
7	at SOPs. I had to do training anyway,	7	Q. Did you bring any documents
8	so it was kind of timely. So and we	8	here today with you?
9		9	
10	have lots of SOPs. Maybe a hundred.	10	A. I had kept an SOP binder that
11	Q. Are there any other documents	11	I brought with me. That's one of her
1	that you can think of you looked at other	1	binders.
12	than SOPs, the label changes, and anything	12	Q. Anything else other than SOP
13	that you've already mentioned?	13	documents?
14	A. No.	14	A. No. I take that back. I
15	Q. Without telling me what you	15	think there was a timeline of when the
16	spoke about with your attorneys, did you	16	various INDs were submitted and when the
17	have an opportunity to meet with your	17	NDAs were submitted and approved. There
18	attorneys in preparation of today's	18	was that timeline.
19	deposition?	19	Q. Is that with you today?
20	A. Yes.	20	A. Yes.
21	Q. And when did you meet with your	21	MR. O'BRIEN: Why don't we take
22	attorneys?	22	our break?
23	A. I met with them in June and	23	MS. JONES: Okay.
24	then earlier this week.	24	THE VIDEOGRAPHER: We are going
	Page 94		Page 96
1	Q. And how much time did you spend	1	off the record. The time is 10:25 a.m.
2	with your attorneys?	2	
3	A. A few hours each time. Met	3	(A recess was taken at 10:25
4	with them four times.	4	a.m.) THE VIDEOGRAPHER: This is the
5		5	
6	Q. Was it did you also meet with Dr. Knowles?		beginning of Tape 2 in the deposition of
7		6 7	Dr. Christine Phillips. The time is 10:34
1	A. No, I did not.	1	a.m., and we are back on the record.
8	Q. And which attorneys did you	8	BY MR. O'BRIEN:
9	meet with?	9	Q. Dr. Phillips, I just want to
10	A. I met with Ms. Jones, Ms.	10	take a moment and I'm going to mark your
11	Martinez Resly, Ms. Dire, Dawne Dire, as	11	resume as Plaintiff's Exhibit 2.
12	well as Mr. Christopher Gramling of Lilly,	12	(Plaintiff's Exhibit-2 was
13	and there was also a lawyer from Pepper	13	marked for identification.)
14	Hamilton on the phone. And I'm not sure	14	BY MR. O'BRIEN:
15	what the name was.	15	Q. Will you take a look at it?
16	Q. Do you remember if it was a	16	A. Okay. I'm familiar with it.
17	man or a woman?	17	MS. JONES: Do you have a copy
18	A. It was a woman. Is it Alison	18	for us, Counsel? Just one will do. We
19	or Nicole? Anyway, I'm not sure.	19	can share.
20	Q. It's okay. Did you gather any	20	MR. O'BRIEN: I'm sorry,
21	documents in preparation of today's	21	Phyllis.
22	deposition?	22	MS. JONES: Thank you.
23	A. I gathered some SOPs and	23	BY MR. O'BRIEN:
1 04	pointed I know Dawn had asked for	24	Q. Dr. Phillips, is this your most
24	pointed - I know Dawn had asked for		Q. Dr. 1 mmps, is this your most

	O _i	201	
	Page 97		Page 99
1	recent resume? I see up top it looks	1	genetics at the Medical University of
2	like under parentheses on top by your	2	South Carolina, which is located in
3	name it says, "May of 2014." Is that	3	Charleston. And that was up through
4	the last time it was updated or reviewed?	4	early '97.
5	A. Yes, it was.	5	Q. So you're a doctor in
6		6	
	• • •	1	biochemistry and molecular genetics,
7	A. Well, I'm actually moving jobs	7	correct?
8	currently, staying within regulatory	8	A. My doctorate is specifically in
9	affairs but I'm going to be focusing on	9	pharmaceutics.
10	devices. So I will no longer support	10	Q. Pharmaceutics?
11	Cymbalta or Zyprexa Relprevv as of Monday.	11	A. Yes.
12	Q. So what will your new position	12	Q. Not a medical doctor but in
13	be?	13	pharmaceutics?
14	A. I will be in regulatory affairs	14	A. That's correct. I'm not a
15	for devices.	15	medical doctor.
16	Q. Is that all devices or is there	16	Q. And following college, would you
17	one in particular?	17	take me or strike that.
18	A. I will be working on several.	18	Following your postgraduate
19	We have	19	degree, will you take me through your
20	MS. JONES: Let me just note	20	employment background?
21	for the record that if there is anything	21	A. Following my postdoctoral
22	in development that you're not permitted	22	fellowship, I worked at a contract
23	to talk about because it's in development,	23	research organization called "PPD
24	please just be mindful of that. I defer	24	PharmaCo," located in North Carolina,
24	please just be initiatin of that. I deter		Tharmaco, Tocated in Ivortii Caronna,
	Page 98		Page 100
1	to your good judgment on that issue.	1	Research Triangle Park. I worked there
2	A. Okay. That's a very good	2	as a medical writer.
3	point. We do have several marketed	3	
3 4	point. We do have several marketed devices as well as ones in development	3 4	Q. And then where did you go after
4	devices as well as ones in development.	4	Q. And then where did you go after that?
4 5	devices as well as ones in development. I'm primarily working on ones in	4 5	Q. And then where did you go after that? A. After that, I was recruited by
4 5 6	devices as well as ones in development. I'm primarily working on ones in development.	4 5 6	Q. And then where did you go after that? A. After that, I was recruited by Lilly as a medical writer and began
4 5 6 7	devices as well as ones in development. I'm primarily working on ones in development. BY MR. O'BRIEN:	4 5 6 7	Q. And then where did you go after that? A. After that, I was recruited by Lilly as a medical writer and began working at Lilly in October of 1998.
4 5 6 7 8	devices as well as ones in development. I'm primarily working on ones in development. BY MR. O'BRIEN: Q. Okay. So up until now, this	4 5 6 7 8	 Q. And then where did you go after that? A. After that, I was recruited by Lilly as a medical writer and began working at Lilly in October of 1998. Q. In what department were you a
4 5 6 7 8 9	devices as well as ones in development. I'm primarily working on ones in development. BY MR. O'BRIEN: Q. Okay. So up until now, this resume is accurate, and on Monday it	4 5 6 7 8 9	 Q. And then where did you go after that? A. After that, I was recruited by Lilly as a medical writer and began working at Lilly in October of 1998. Q. In what department were you a medical writer?
4 5 6 7 8 9 10	devices as well as ones in development. I'm primarily working on ones in development. BY MR. O'BRIEN: Q. Okay. So up until now, this resume is accurate, and on Monday it won't be accurate?	4 5 6 7 8 9	Q. And then where did you go after that? A. After that, I was recruited by Lilly as a medical writer and began working at Lilly in October of 1998. Q. In what department were you a medical writer? A. Medical writing is its own
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4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	devices as well as ones in development. I'm primarily working on ones in development. BY MR. O'BRIEN: Q. Okay. So up until now, this resume is accurate, and on Monday it won't be accurate? A. Yes, that's correct. Q. Will you take me through your educational background? A. Okay. Graduated from high school. I went to Wofford College in South Carolina and received a BS in biology in 1991. From there, I went into graduate school at the University of South Carolina, which is in Columbia, South Carolina, where I received a doctorate in pharmaceutics in '95, which pharmaceutics is drug delivery systems. And then from	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. And then where did you go after that? A. After that, I was recruited by Lilly as a medical writer and began working at Lilly in October of 1998. Q. In what department were you a medical writer? A. Medical writing is its own department. It's a function that supports various teams. I was a member of the Prozac product team. So that was my area of focus as a medical writer. Q. And what were your day-to-day responsibilities as a medical writer? A. I worked on various regulatory submissions with the other team members. So I worked on reports, study reports, protocols, briefing documents that would go to FDA prior to a meeting that we might have with the agency, and various

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	Page 101		Page 103
1	until June of 2000?	1	July 2002 and where did you go next?
2	A. Yes.	2	A. I came into U.S. regulatory
3	Q. And from June of 2000, your	3	affairs at that time.
4	· · · · · · · · · · · · · · · · · · ·	4	
	resume indicates you were team leader in	1	-
5	global science information and	5	regulatory scientist?
6	communications.	6	A. Yes.
7	A. Yes. So we renamed medical	7	Q. What does a U.S. regulatory
8	writing to be global scientific	8	scientist do?
9	information and communications. By "team	9	A. It is very much the job I do
10	leader," that meant I was a supervisor of	10	today but at a lower level. I mean, as
11	about seven writers and two editors on	11	you get more experience, you get promoted
12	the Prozac team. So that job was partly	12	kind of approach. So when I initially
13	administrative, partly technical, and	13	came into U.S. regulatory affairs, I was
14	training new staff.	14	responsible for some early development
15	Q. And what were the writers	15	molecules. I covered molecules in
16	what type of documents were the writers	16	cardiovascular, some oncology, it was kind
17	drafting?	17	of a variety, some autoimmune sets.
18	8	18	Q. And you didn't have any
	A. The same as what I just	19	•
19	described, you know, study protocols,		involvement during that time with
20	clinical study reports, briefing documents,	20	Cymbalta; is that correct?
21	submission documents that would go into an	21	A. That's correct.
22	NDA, that would include, you know, study	22	Q. And then in October 2005, you
23	reports as well as integrated summaries of	23	left for Amgen?
24	safety or efficacy and also regulatory	24	A. That's correct, yes.
	Page 102		Page 104
1	response documents.	1	Q. And what was your position
2	Q. And what other departments did	2	there?
3	you work with?	3	
	•	1	A. I started as a senior manager
4	A. I worked closely with	4	and was promoted to director while I was
5	regulatory, medical, statistics, data	5	at Amgen and I was a global regulatory
		l _	
6	sciences in some cases, our safety	6	leader.
7	personnel.	7	leader. Q. And what were your
		1	leader.
7	personnel.	7	leader. Q. And what were your
7 8	personnel. Q. And was it limited to the	7 8	leader. Q. And what were your responsibilities there?
7 8 9	personnel. Q. And was it limited to the Prozac team at that time? A. At that time, yes.	7 8 9	leader. Q. And what were your responsibilities there? A. They were similar to my
7 8 9 10 11	personnel. Q. And was it limited to the Prozac team at that time? A. At that time, yes. Q. And then you left that position	7 8 9 10 11	leader. Q. And what were your responsibilities there? A. They were similar to my responsibilities at Lilly, the exception being that I was responsible for the U.S.
7 8 9 10 11 12	personnel. Q. And was it limited to the Prozac team at that time? A. At that time, yes. Q. And then you left that position July 2001 and then what happened? Where	7 8 9 10 11 12	leader. Q. And what were your responsibilities there? A. They were similar to my responsibilities at Lilly, the exception being that I was responsible for the U.S. interactions but I was also the lead of a
7 8 9 10 11 12 13	personnel. Q. And was it limited to the Prozac team at that time? A. At that time, yes. Q. And then you left that position July 2001 and then what happened? Where did you go next?	7 8 9 10 11 12 13	leader. Q. And what were your responsibilities there? A. They were similar to my responsibilities at Lilly, the exception being that I was responsible for the U.S. interactions but I was also the lead of a global regulatory team, which meant I
7 8 9 10 11 12 13 14	personnel. Q. And was it limited to the Prozac team at that time? A. At that time, yes. Q. And then you left that position July 2001 and then what happened? Where did you go next? A. I was a team leader over the	7 8 9 10 11 12 13 14	leader. Q. And what were your responsibilities there? A. They were similar to my responsibilities at Lilly, the exception being that I was responsible for the U.S. interactions but I was also the lead of a global regulatory team, which meant I coordinated activities across the globe
7 8 9 10 11 12 13 14 15	personnel. Q. And was it limited to the Prozac team at that time? A. At that time, yes. Q. And then you left that position July 2001 and then what happened? Where did you go next? A. I was a team leader over the endocrine therapeutic area for scientific	7 8 9 10 11 12 13 14 15	leader. Q. And what were your responsibilities there? A. They were similar to my responsibilities at Lilly, the exception being that I was responsible for the U.S. interactions but I was also the lead of a global regulatory team, which meant I coordinated activities across the globe with our European lead, with our Japan
7 8 9 10 11 12 13 14 15	personnel. Q. And was it limited to the Prozac team at that time? A. At that time, yes. Q. And then you left that position July 2001 and then what happened? Where did you go next? A. I was a team leader over the endocrine therapeutic area for scientific communications, so same role, different	7 8 9 10 11 12 13 14 15 16	leader. Q. And what were your responsibilities there? A. They were similar to my responsibilities at Lilly, the exception being that I was responsible for the U.S. interactions but I was also the lead of a global regulatory team, which meant I coordinated activities across the globe with our European lead, with our Japan lead, Australian. And because of that
7 8 9 10 11 12 13 14 15 16 17	personnel. Q. And was it limited to the Prozac team at that time? A. At that time, yes. Q. And then you left that position July 2001 and then what happened? Where did you go next? A. I was a team leader over the endocrine therapeutic area for scientific communications, so same role, different therapeutic area, and then a much larger	7 8 9 10 11 12 13 14 15 16 17	leader. Q. And what were your responsibilities there? A. They were similar to my responsibilities at Lilly, the exception being that I was responsible for the U.S. interactions but I was also the lead of a global regulatory team, which meant I coordinated activities across the globe with our European lead, with our Japan lead, Australian. And because of that role, I traveled globally to different
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7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	personnel. Q. And was it limited to the Prozac team at that time? A. At that time, yes. Q. And then you left that position July 2001 and then what happened? Where did you go next? A. I was a team leader over the endocrine therapeutic area for scientific communications, so same role, different therapeutic area, and then a much larger staff, so that job was more administrative. Q. And in that position, you had no involvement with Cymbalta; is that correct?	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	leader. Q. And what were your responsibilities there? A. They were similar to my responsibilities at Lilly, the exception being that I was responsible for the U.S. interactions but I was also the lead of a global regulatory team, which meant I coordinated activities across the globe with our European lead, with our Japan lead, Australian. And because of that role, I traveled globally to different regulatory meetings with PMDA in Japan, Health Canada, that kind of thing. Q. And then looks like September of 2007 you came back to Lilly? A. That's correct.

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	Page 105		Page 107
1	Q. What does a U.S. regulatory	1	is in Global Regulatory Affairs-U.S. So
2	consultant do?	2	that is my title.
3	A. Again, it's fundamentally the	3	Q. So U.S. regulatory affairs and
4	same job but our titles have changed over	4	global regulatory affairs are synonymous?
5	the years with different systems, but it's	5	A. No. Global regulatory
6	really on par with director level position	6	affairs-U.S. is equivalent to U.S.
7	that I had at Amgen. The difference	7	regulatory affairs. We also have a vice
8	being that we don't have a global	8	• '
9		9	president of global regulatory
	regulatory leader role at well, that's	1	affairs-international that covers Europe,
10	not true. We have a global regulatory	10	Japan, and essentially the rest of the
11	coordinator role at Lilly, which I also	11	world.
12	have served in that capacity.	12	Q. Now, I kind of want to go
13	Q. And then it looks like in March	13	through the corporate structure in the
14	of 2010, you became a U.S. regulatory	14	U.S. regulatory affairs. I really only
15	advisor director?	15	want to focus on kind of the
16	A. Yes.	16	neuroscience. I know there's probably
17	Q. And same type of job	17	different divisions. You're in
18	responsibilities?	18	neuroscience regulatory affairs. Who do
19	A. Yes. At that time things	19	you report to?
20	we restructured slightly and I had	20	A. I report to Carlos, Dr. Carlos
21	somebody reporting to me at one point in	21	Garner. And he is the senior director
22	time. So we did regulatory and	22	global regulatory affairs-U.S. for the
23	learning regulatory is somewhat of an	23	bio-medicines business unit.
24	apprenticeship so that's how you learn.	24	Q. The bio-medicines business unit?
	appronticeship so that's now you rearn.		Q. The old medicines dusiness dime.
	Page 106		Page 108
1	So although it's hard to describe at	1	A. Yes.
2	times, the fundamental job	2	
3		3	
	responsibilities, you increase in	1	report to?
			A II (A D D 1 A
4	responsibility in taking the lead and you	4	A. He reports to Dr. Robert
5	have less, I guess, not oversight, but	5	Metcalf, who is the vice president of
5 6	have less, I guess, not oversight, but you're relying on your mentors less	5 6	Metcalf, who is the vice president of global regulatory affairs-U.S.
5 6 7	have less, I guess, not oversight, but you're relying on your mentors less because you've got that on-the-job	5 6 7	Metcalf, who is the vice president of global regulatory affairs-U.S. Q. And who does Robert Metcalf
5 6 7 8	have less, I guess, not oversight, but you're relying on your mentors less because you've got that on-the-job experience over time.	5 6 7 8	Metcalf, who is the vice president of global regulatory affairs-U.S. Q. And who does Robert Metcalf report to?
5 6 7 8 9	have less, I guess, not oversight, but you're relying on your mentors less because you've got that on-the-job experience over time. Q. And then in August of last	5 6 7 8 9	Metcalf, who is the vice president of global regulatory affairs-U.S. Q. And who does Robert Metcalf report to? A. He reports to Dr. Timothy
5 6 7 8	have less, I guess, not oversight, but you're relying on your mentors less because you've got that on-the-job experience over time.	5 6 7 8 9	Metcalf, who is the vice president of global regulatory affairs-U.S. Q. And who does Robert Metcalf report to? A. He reports to Dr. Timothy Garnett, our chief medical officer.
5 6 7 8 9 10 11	have less, I guess, not oversight, but you're relying on your mentors less because you've got that on-the-job experience over time. Q. And then in August of last year, you became the U.S. regulatory advisor but within neuroscience, correct?	5 6 7 8 9 10 11	Metcalf, who is the vice president of global regulatory affairs-U.S. Q. And who does Robert Metcalf report to? A. He reports to Dr. Timothy Garnett, our chief medical officer. Q. Does Dr. Garnett does he
5 6 7 8 9 10	have less, I guess, not oversight, but you're relying on your mentors less because you've got that on-the-job experience over time. Q. And then in August of last year, you became the U.S. regulatory	5 6 7 8 9 10 11 12	Metcalf, who is the vice president of global regulatory affairs-U.S. Q. And who does Robert Metcalf report to? A. He reports to Dr. Timothy Garnett, our chief medical officer.
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5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	have less, I guess, not oversight, but you're relying on your mentors less because you've got that on-the-job experience over time. Q. And then in August of last year, you became the U.S. regulatory advisor but within neuroscience, correct? A. That's correct. Q. Also being a director? A. Yes. Q. One thing I notice, you were a U.S. regulatory advisor, that was your title, but within neuroscience, it's a global regulatory affairs. Is there a difference between U.S. regulatory affairs and global regulatory affairs? A. No. It was a reorganization in title. So we used to be called "United"	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Metcalf, who is the vice president of global regulatory affairs-U.S. Q. And who does Robert Metcalf report to? A. He reports to Dr. Timothy Garnett, our chief medical officer. Q. Does Dr. Garnett does he report to the CEO? A. I believe so, yes. Q. Is there a bio-medicines president? A. Yes. Q. Is Dr. Garnett on the same level of the bio-medicines president? A. No. Well, our chief medical officer is also a senior vice president, president to the vice of the business units. I don't quite understand how all

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1	is kind of high up, though.	1	course. Dr. Greg Brophy was the
2	Q. Yeah, I wasn't sure if Dr.	2	director, senior director of neuroscience
3	Garnett reported to David Ricks.	3	in U.S. regulatory affairs for at least
4	A. No, he does not. He reports	4	ten years.
5	to John Lechleiter, our CEO. Dave Ricks	5	•
6		6	Q. Dr. Brophy, you said? A. Uh-huh.
7	would also, I believe, report to Dr. Lechleiter.	7	
		1	Q. B-r-o-p-h-y?
8	Q. Okay.	8	A. Correct.
9	A. And David Ricks is the	9	Q. And you believe he held that
10	president of the bio-medicines business	10	position since 2000
11	unit.	11	A. Early 2000s.
12	Q. Yeah, he's still the he's a	12	Q. Early 2000s?
13	senior VP and I guess the president of	13	A. He recruited me into regulatory
14	president of the Lilly bio-medicines unit?	14	affairs, so he's been there quite some
15	A. Yeah.	15	he was there for quite some time.
16	Q. Who reports to you?	16	Q. Is he still with the company?
17	A. No one.	17	A. No, he's retired.
18	Q. Are there other U.S. regulatory	18	Q. Did he have a medical degree?
19	affairs directors for neuroscience	19	A. No. He has a Ph.D. in
20	currently?	20	toxicology.
21	A. Dr. Janice Hitchcock.	21	Q. Is there anybody else that you
22	Q. Now, Dr. Janice Hitchcock, how	22	can think of since 2000 in U.S.
23	long has she been in that position? Is	23	regulatory that had responsibilities as it
24	she your replacement when you leave?	24	relates to Cymbalta?
2 -	site your repracement when you reave.		Totales to Cymouna:
	Page 110		Page 112
1	A. No. She's been in that	1	
1 2		1 2	
3	position for quite some time. She's		previously, Richard Hoffman, Isabelle
	responsible for our Alzheimer's platform.		
	And non outing to be mis Mr. Aslance	3	Murray, Bryan Boggs, Sharon Hoog, Ann
4	And reporting to her is Mr. Ashraff	4	Robbins, and, I'm sorry, also Robert
5	Rampersaud, A-s-h-r-a-f-f,	4 5	Robbins, and, I'm sorry, also Robert Conley, Dr. Robert Conley, he was the
5 6	Rampersaud, A-s-h-r-a-f-f, R-a-m-p-e-r-s-a-u-d, he will be taking	4 5 6	Robbins, and, I'm sorry, also Robert Conley, Dr. Robert Conley, he was the he had Carl's position for a year and a
5 6 7	Rampersaud, A-s-h-r-a-f-f, R-a-m-p-e-r-s-a-u-d, he will be taking over Cymbalta and Zyprexa Relprevv from	4 5 6 7	Robbins, and, I'm sorry, also Robert Conley, Dr. Robert Conley, he was the he had Carl's position for a year and a half, two years prior to Carl coming into
5 6 7 8	Rampersaud, A-s-h-r-a-f-f, R-a-m-p-e-r-s-a-u-d, he will be taking over Cymbalta and Zyprexa Relprevv from me.	4 5 6 7 8	Robbins, and, I'm sorry, also Robert Conley, Dr. Robert Conley, he was the he had Carl's position for a year and a half, two years prior to Carl coming into that position. He moved on just within
5 6 7 8 9	Rampersaud, A-s-h-r-a-f-f, R-a-m-p-e-r-s-a-u-d, he will be taking over Cymbalta and Zyprexa Relprevv from me. Q. And what position did he	4 5 6 7 8 9	Robbins, and, I'm sorry, also Robert Conley, Dr. Robert Conley, he was the he had Carl's position for a year and a half, two years prior to Carl coming into that position. He moved on just within the last six months.
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	Page 113		Page 115
1	A. All of it is.	1	training plan, which includes, you know,
2	Q. All of it is?	2	reviewing various SOPs and then
3	A. Uh-huh.	3	regulations from FDA including, you
4	Q. I wasn't sure if there was	4	know, the 21 CFR, 312, 314, 201, you
5	another office in the United States that	5	know, 600s, 800s. They are also assigned
6	deals with regulatory affairs.	6	a mentor coach, because, as I was saying,
7	A. Well, we have the YOS	7	there's a lot of on-the-job training.
8	affiliate, but that's located here in	8	There's a lot of guidance documents, all
9	Indianapolis as well.	9	of which are open to interpretation. And
10	Q. Is there an investigational side	10	so there is that. And there's a series of
11	of regulatory?	11	one-on-one meetings with various experts
12	MS. JONES: Objection to the	12	within the regulatory organization, let's
13	form.	13	say orphan drugs, advisory committee
14	A. What do you mean by that?	14	meetings, that kind of thing, so they
15	A. What do you mean by that?	15	know who to go to. And then, you know,
16	BY MR. O'BRIEN:	16	as you're well, all documents, when
17		17	we're creating them to go to FDA,
18	Q. I guess if there were some sort	18	• •
19	of issues with a drug, that there's like	19	typically undergo a peer review. We do
20	a team that whose job it is to go out	20	that regardless if you're new or not,
	and investigate those issues.	21	just to you know, it's always good to
21	MS. JONES: Same objection.	22	have another pair of eyes and different
22	A. All safety issues are monitored	1	experience looking at the documents and
23	and on a regular basis by our global	23	reviewing them.
24	patient safety organization.	24	Q. Is there an individual within
	Page 114		Page 116
1	Page 114 BV MR O'BRIEN:	1	Page 116
1	BY MR. O'BRIEN:	1 2	regulatory that's responsible for
2	BY MR. O'BRIEN: Q. And that's what I was kind of	2	regulatory that's responsible for coordinating the training for new
2 3	BY MR. O'BRIEN: Q. And that's what I was kind of getting at. I wasn't sure if that is	2 3	regulatory that's responsible for coordinating the training for new employees?
2 3 4	BY MR. O'BRIEN: Q. And that's what I was kind of getting at. I wasn't sure if that is mainly handled by the drug safety	2 3 4	regulatory that's responsible for coordinating the training for new employees? A. Yes, that's Janet Fourman,
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	Page 117		Page 119
1	A. No, she been in that position	1	regulatory affairs oncology.
2	for as long as I can remember, as long	2	0 1
			Q. Any other live training that
3	as I've been in regulatory affairs.	3	you can think of, instructors?
4	Q. Now, with regard to SOPs and	4	A. Well, I instruct around advisory
5	protocols, how would somebody in	5	committee meetings as needed. When a
6	regulatory access them?	6	team finds out they have an advisory
7	A. Well, we have our ITP,	7	committee meeting, I usually I go
8	individual learning or training plan.	8	there and train. We have submission, a
9	And we can go to that electronically and	9	submission group led by Jane Amos who
10	tells you which one is due when, you can	10	does training when you're a year or two
11	click on the link and go to the SOP.	11	out from submitting an NDA or a BLA,
12		12	
	The SOPs are maintained electronically on		which is a biologics application. It's
13	the Lilly Intranet. So you go to a	13	the equivalent, it's just not a small
14	collab site for the regulatory quality	14	molecule on oral medication and biologic
15	system or the medical quality system and	15	is usually injectable medication.
16	you can pull up SOPs there.	16	Q. Now, you've never attended a
17	Q. You mentioned ITP, individual	17	Cymbalta advisory committee, correct?
18	training program. What is an "ITP"?	18	A. I viewed it through the webcast
19	A. It's by role. There is a	19	link, but I was not physically there in
20	specific training plan that you need to	20	DC with the team. I did watch it. I
21	what SOPs are relevant for that role	21	
			helped the team prepare and then I
22	and what are the coursework you need to	22	watched it.
23	take to be qualified in that role. So	23	Q. Is there a transcript for that?
24	that would be different for me as	24	Was it recorded?
		l .	
	Page 118		Page 120
1	Page 118 compared to a statistician, for instance.	1	Page 120 A. Uh-huh, there is.
1 2	compared to a statistician, for instance.	1 2	A. Uh-huh, there is.
2	compared to a statistician, for instance. Q. Is it like an interactive	2	A. Uh-huh, there is. MS. JONES: The transcript is
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	compared to a statistician, for instance. Q. Is it like an interactive learning? Are there tests? A. It varies. Some of them are just reading SOPs, but there are a number of courses that are interactive that do knowledge checks and have various tests involved with it. There is also some instructor-led classes that are quite interactive. Q. And who are the instructors in regulatory or for regulatory training? A. That varies. Again, it's based Janet would coordinate. But it would be subject-matter experts that would teach whatever the topic was. Q. Say, for instance it's FDA reporting. Do you know who that would be? A. It's changed over the years. It used to be Melanie Bruno. Most currently it's probably Dan Brady.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Uh-huh, there is. MS. JONES: The transcript is on the FDA's website. A. All the briefing materials and the transcripts are available on the FDA website. BY MR. O'BRIEN: Q. And from somewhere, I don't know if it was in your resume, you actually participated in an advisory committee meeting but maybe for a different drug? A. It was for Zyprexa. Q. Were you strike that. You were involved in the preparation for the advisory committee for Cymbalta, correct? A. Yes. I was involved in the sense of helping the team describing what an advisory committee was to the team. Kind of talking about what was involved, how to do the briefing

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	Page 121		Page 123
1	content support.	1	would be the primary contact to the
2	Q. Do you know if the materials or	2	European regulatory authorities.
3	notes that were prepared in preparation of	3	Q. And who would be your
4	that meeting, are they saved anywhere?	4	colleagues in Europe that were the primary
5	A. There are some that were saved	5	contacts with European regulatory
6	on the collab site for the team. The	6	authorities as it relates to Cymbalta?
7	public record is the briefing documents	7	A. Currently that's Beth Heaviside,
8	submitted to the agency, the transcript,	8	who I mentioned earlier.
9	the slides, all of that is publicly	9	Q. Would you mind spelling that
10	available in the FDA website.	10	again?
11	Q. I know you mentioned that there	11	A. Yeah, H-e-a-v-i-s-i-d-e.
12	are SOPs for new employees that come into	12	·
13	- ·	13	Q. And where is Beth Heaviside located?
14	regulatory. A. Uh-huh.	14	A. She's located in the UK.
15		15	
	Q. Is there a handbook that	16	Q. And what is her position in the
16	employees receive?	1	UK?
17	A. Well, there's kind of the Lilly	17	A. I don't know her exact title.
18	red book, which is, you know, our	18	I think she's a principal consultant.
19	underlying philosophy and ethical	19	Q. And she deals with European
20	standards, I guess is the way to put it.	20	regulatory bodies as they relate to
21	Our ITP is it's done electronically.	21	Cymbalta?
22	And I think they now call it "success	22	A. Yes.
23	factors." They've changed the name	23	Q. Is there anybody else over
24	recently. But basically the list of what	24	there that you can think of?
	Page 122		Page 124
			1 dyc 121
1	you're required to do in your position is	1	-
1 2	you're required to do in your position is available electronically.	1 2	A. I mean, not currently. She is
2	available electronically.	2	A. I mean, not currently. She is the lead. In the past it's been Dr.
2 3	available electronically. Q. Now, you just discussed a red	2 3	A. I mean, not currently. She is the lead. In the past it's been Dr. Carly Anderson. And before her, it was
2 3 4	available electronically. Q. Now, you just discussed a red book, which	2 3 4	A. I mean, not currently. She is the lead. In the past it's been Dr. Carly Anderson. And before her, it was Torkil Fredborg, who I mentioned earlier.
2 3 4 5	available electronically. Q. Now, you just discussed a red book, which A. Uh-huh.	2 3 4 5	A. I mean, not currently. She is the lead. In the past it's been Dr. Carly Anderson. And before her, it was Torkil Fredborg, who I mentioned earlier. Do you want me to spell that again?
2 3 4 5 6	available electronically. Q. Now, you just discussed a red book, which A. Uh-huh. Q we had some conversation	2 3 4 5 6	A. I mean, not currently. She is the lead. In the past it's been Dr. Carly Anderson. And before her, it was Torkil Fredborg, who I mentioned earlier. Do you want me to spell that again? Q. Please. Would you mind
2 3 4 5 6 7	available electronically. Q. Now, you just discussed a red book, which A. Uh-huh. Q we had some conversation yesterday about. Do you know how	2 3 4 5 6 7	A. I mean, not currently. She is the lead. In the past it's been Dr. Carly Anderson. And before her, it was Torkil Fredborg, who I mentioned earlier. Do you want me to spell that again? Q. Please. Would you mind spelling that again?
2 3 4 5 6 7 8	available electronically. Q. Now, you just discussed a red book, which A. Uh-huh. Q we had some conversation yesterday about. Do you know how detailed the red book is?	2 3 4 5 6 7 8	A. I mean, not currently. She is the lead. In the past it's been Dr. Carly Anderson. And before her, it was Torkil Fredborg, who I mentioned earlier. Do you want me to spell that again? Q. Please. Would you mind spelling that again? A. Oh, okay. T-o-r-k-i-l,
2 3 4 5 6 7 8 9	available electronically. Q. Now, you just discussed a red book, which A. Uh-huh. Q we had some conversation yesterday about. Do you know how detailed the red book is? A. It's conceptual, so it does go	2 3 4 5 6 7 8 9	A. I mean, not currently. She is the lead. In the past it's been Dr. Carly Anderson. And before her, it was Torkil Fredborg, who I mentioned earlier. Do you want me to spell that again? Q. Please. Would you mind spelling that again? A. Oh, okay. T-o-r-k-i-l, F-r-e-d-b-o-r-g. We are a very
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2 3 4 5 6 7 8 9 10 11	available electronically. Q. Now, you just discussed a red book, which A. Uh-huh. Q we had some conversation yesterday about. Do you know how detailed the red book is? A. It's conceptual, so it does go into detail. And when we do have online interactive training, they use scenarios	2 3 4 5 6 7 8 9 10 11	A. I mean, not currently. She is the lead. In the past it's been Dr. Carly Anderson. And before her, it was Torkil Fredborg, who I mentioned earlier. Do you want me to spell that again? Q. Please. Would you mind spelling that again? A. Oh, okay. T-o-r-k-i-l, F-r-e-d-b-o-r-g. We are a very international company. Q. So Beth Heaviside, she would
2 3 4 5 6 7 8 9 10 11 12	available electronically. Q. Now, you just discussed a red book, which A. Uh-huh. Q we had some conversation yesterday about. Do you know how detailed the red book is? A. It's conceptual, so it does go into detail. And when we do have online interactive training, they use scenarios to help illustrate the specific concepts	2 3 4 5 6 7 8 9 10 11 12	A. I mean, not currently. She is the lead. In the past it's been Dr. Carly Anderson. And before her, it was Torkil Fredborg, who I mentioned earlier. Do you want me to spell that again? Q. Please. Would you mind spelling that again? A. Oh, okay. T-o-r-k-i-l, F-r-e-d-b-o-r-g. We are a very international company. Q. So Beth Heaviside, she would have responsibility for England and the
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	Page 125		Page 127
1	MR. O'BRIEN: Let me restate	1	"interactions with regulatory agencies," I
2	it.	2	think it is that simple as a title. And
3	BY MR. O'BRIEN:	3	that and separate there is one for
4	Q. Do you know if there was ever	4	documenting interactions, which is more
5	an issue with Cymbalta being denied	5	the record of contact. So the formal
6	approval in any international country?	6	meetings, there is an SOP around
7	MS. JONES: Objection to the	7	around that interaction.
8	form. You may answer.	8	Q. Do you know any of the details
9	A. Well, I guess I'm not sure	9	of the what happens? Is it recorded
10	exactly what you're asking.	10	on a certain form or is it saved? Who
11	MS. JONES: When you say	11	is it sent to?
12	"international countries," you mean outside	12	
13	of the U.S.?	13	A. Okay. I will commit specifically on FDA interactions because
14	MR. O'BRIEN: Outside of the	14	-
15	U.S.	15	they do differ somewhat, but fundamentally
		1	it's the same concept. We submit a
16 17	MS. JONES: Okay.	16	formal meeting request to FDA. There is
	A. I don't have knowledge of every	17	a certain format specified by FDA that
18	submission we've made outside of the U.S.	18	that meeting request is submitted that
19	So I don't think I can answer that	19	gives the agency an idea of what the
20	question.	20	topics are, background on the molecule,
21	BY MR. O'BRIEN:	21	what questions you want to discuss with
22	Q. Do you have any idea who would	22	them. And then FDA either grants that
23	be able to answer that question?	23	meeting or they deny it. They can grant
24	A. Yes. We have a system called	24	the meeting as a face-to-face, they can
	D 100		Da. 12.0
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1	"RAPT," regulatory activity and planning	1	grant the meeting as a teleconference, or
2	tracker, which does list all of the	2	they can grant it as meeting granted,
3	approved indications by country as well as	3	written responses only. So they would
4	the approved presentations in that	4	only provide written feedback. Prior to
5	country. And it will go through and list	5	they assign a date for the meeting. Prior
6	out if an application has been submitted,	6	to that meeting, we submit a briefing
7	withdrawn, approved, et cetera, what is	7	package to the agency, which outlines what
8	the status of those indications. So you	8	we want to discuss, the relevant
9	can look at that by country.	9	background, and what questions we
10	Q. Now, earlier today, we discussed	10	specifically want them to answer for us.
11	a little bit about what happens when you	11	And then during the meeting,
12	receive a phone call with the FDA and how	12	there's a back-and-forth discussion, it's
13	that is recorded.	13	all based on the questions. There's no
14	A. Uh-huh.	14	presentation. You assume everybody has
15	Q. Is there any policy and	15	done their homework, read the document,
16	procedure if there's a meeting with the	16	and that you really just go into the
17	FDA as far as how that meeting is	17	questions. There's a dialogue. Actually,
18	recorded?	18	let me back up.
19	A. Yes, there is an SOP about	19	Prior to the meeting, usually a
20	that.	20	few days prior to the meeting, FDA,
21	Q. Could you tell me what the	21	through their good review practices
22	policy and procedure is, generally if you	22	initiative, will provide us with
23	don't know specifically?	23	preliminary written meeting minutes. So
24	A. Okay. I think that it's called	24	basically their preliminaries are not
	Onay. I min man it o outfor		casically alon prominingles are not

final, but they do provide their initial pass at the answers to those questions. So as a regulatory scientist, we talk with the team. If they've answered a specific question sufficiently, then we won't discuss it at the meeting. And so then at the meeting, we that you're asking about individual cutside of regulatory affairs, I'm go to object to the extent that it's outs the scope of the notice, but she ca answer to the extent that she know her individual capacity. A. That's a difficult question of	going side in
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6 then we won't discuss it at the meeting. 6 her individual capacity. 7 And so then at the meeting, we 7 A. That's a difficult question f	νs III
7 And so then at the meeting, we 7 A. That's a difficult question f	
into so then at the meeting, we	.
do focus on questions that require further 8 me to answer because we have mu	
9 resolution or clarification. And then 9 INDs for Cymbalta because they a	
following the meeting, we, Lilly, through 10 there's an IND for each indication	
the led by the regulatory scientists, 11 we have studied and evaluated ov	
will create our internal version of the 12 So we have an IND or depression	
meeting minutes which we then submit to 13 an IND for anxiety, we have an IN	√D for
the agency. And then they issue final 14 diabetic peripheral neuropathic pa	ain, for
official minutes within 30 days of the 15 fibromyalgia, chronic pain, so we	have
meeting. And those minutes will reflect 16 several open INDs. They were op	
the questions, the preliminary comments 17 various points in time and I'd have	
that FDA sent us prior to the meeting, as look at our list to know when the	
well as any discussion that happened at 19 IND was submitted, but that was p	
the meeting and kind of like their final 20 in the '80s when I wasn't at the co	
21 answer to that specific question. 21 and I don't know who would have	
22 And that is your official 22 involved. But that's drug development	
record of the FDA meeting. 23 is a very long process. So that's v	
Q. And where would that record be 24 clinical trials would have started in	
2. And where would that record be 2. Chinesis that would have stated i	*
Page 130	Page 132
1 saved? 1 humans and then progressed ultin	_
2 A. That would be in our e-file 2 resulting in an NDA application.	latery
11	
	C C
\mathcal{E}	
6 INDA and the NDA. As far as the 6 the people that were involved in t	
7 individuals that were responsible for 7 that had a high level, can you go	through
8 working on the INDA, can we talk about 8 their names and positions?	
9 any other names that you can think of 9 MS. JONES: Objection to to	the
outside of ones you've already provided? 10 form.	
11 I know we kind of went through the 11 A. Not beyond what I've alrea	ıdy
product team. 12 told you.	
13 A. Uh-huh. 13 BY MR. O'BRIEN:	
Q. And that was only really 14 Q. How about with the NDA?	
related to regulatory? 15 A. It's pretty much the same a	ıS
16 A. Yes. The INDs 16 what I've told you. I wasn't work	ing on
MS. JONES: Hold on just a 17 Cymbalta, so I'm just not familiar	with
second. You're asking about individuals 18 who was involved with it.	
second. You're asking about individuals 18 who was involved with it. outside of regulatory affairs? 19 Q. Let's just go through, let m	ie
outside of regulatory affairs? 19 Q. Let's just go through, let m	rom
outside of regulatory affairs? BY MR. O'BRIEN: Q. Let's just go through, let m make sure I've got all the names f perfore. Would you go through th	from le INDA,
outside of regulatory affairs? BY MR. O'BRIEN: Q. Let's just go through, let m make sure I've got all the names f perfore. Would you go through th	from le INDA,
outside of regulatory affairs? BY MR. O'BRIEN: Q. Let's just go through, let m make sure I've got all the names f before. Would you go through the names you've already told me	rom le INDA, l, make

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	Page 133		Page 135
1	complete list. I mean, I primarily know	1	addresses of the people responsible for
2	the regulatory folks who were involved,	2	the NDAs related to Cymbalta?
3	which at the time of approval would have	3	A. Well, not their addresses,
4	been Dr. Sharon Hoog and Dr. Ann Sakai at	4	certainly. The names I focused on
5	that time, now Robbins. The physicians	5	regulatory affairs quite honestly, so I
6	that I know were involved were Dr.	6	did not go beyond that.
7	Michael Robinson, Dr. Vladimir Skljarevski,	7	Q. Is it your understanding that
		8	` .
8	who is I'm not saying that correctly.		you have identified all the individuals
9	Dr. Arei Regev, and Dr. Joe Wernicke.	9	who were involved with the NDA as it
10	Q. How do you spell Joe's last	10	relates to regulatory affairs for
11	name?	11	Cymbalta?
12	A. W-e-r-n-i-c-k-e.	12	A. Well, those the two
13	Q. What was Joe Wernicke's	13	individuals I have called out, Dr. Hoog
14	involvement with the INDA?	14	and Dr. Robbins, were the primary
15	A. Well, I'm referring specifically	15	regulatory scientists. Dr. Brophy was
16	to the NDA now.	16	their supervisor at that time, so he
17	Q. Okay. Well, with regard to the	17	would have been involved. And there
18	NDA.	18	would have been involvement from chemistry
19	A. And that's actually only IND,	19	manufacturing controls, from labeling, and
20	there's no A on it. He was a global	20	I don't know those individuals at that
21	patient safety physician. Beyond that, I	21	point in time.
22	can't elaborate on what exactly he did.	22	Q. Does labeling fall under
23	Q. Does Lilly still employ global	23	regulatory affairs?
24	safety physicians?	24	A. Yes.
	The state of the s		
	Page 134		Page 136
-1	Page 134	4	Page 136
1	A. Yes.	1	Q. How would I obtain the identity
2	A. Yes.Q. And, typically, what does a	2	Q. How would I obtain the identity of individuals who were involved with
2 3	A. Yes.Q. And, typically, what does a global safety physician do?	2 3	Q. How would I obtain the identity of individuals who were involved with labeling in the NDA for Cymbalta?
2 3 4	A. Yes.Q. And, typically, what does a global safety physician do?MS. JONES: This is outside of	2 3 4	Q. How would I obtain the identity of individuals who were involved with labeling in the NDA for Cymbalta? A. I believe that's part of the
2 3 4 5	 A. Yes. Q. And, typically, what does a global safety physician do? MS. JONES: This is outside of the scope of the notice. Please note my 	2 3 4 5	Q. How would I obtain the identity of individuals who were involved with labeling in the NDA for Cymbalta? A. I believe that's part of the organizational charts that were provided.
2 3 4 5 6	A. Yes. Q. And, typically, what does a global safety physician do? MS. JONES: This is outside of the scope of the notice. Please note my objection. You can testify in your	2 3 4 5 6	Q. How would I obtain the identity of individuals who were involved with labeling in the NDA for Cymbalta? A. I believe that's part of the organizational charts that were provided. But, you know, we could refer to that or
2 3 4 5 6 7	A. Yes. Q. And, typically, what does a global safety physician do? MS. JONES: This is outside of the scope of the notice. Please note my objection. You can testify in your individual capacity to the extent that you	2 3 4 5 6 7	Q. How would I obtain the identity of individuals who were involved with labeling in the NDA for Cymbalta? A. I believe that's part of the organizational charts that were provided. But, you know, we could refer to that or we could speak to somebody within our
2 3 4 5 6 7 8	A. Yes. Q. And, typically, what does a global safety physician do? MS. JONES: This is outside of the scope of the notice. Please note my objection. You can testify in your individual capacity to the extent that you know.	2 3 4 5 6 7 8	Q. How would I obtain the identity of individuals who were involved with labeling in the NDA for Cymbalta? A. I believe that's part of the organizational charts that were provided. But, you know, we could refer to that or we could speak to somebody within our current labeling department.
2 3 4 5 6 7 8 9	A. Yes. Q. And, typically, what does a global safety physician do? MS. JONES: This is outside of the scope of the notice. Please note my objection. You can testify in your individual capacity to the extent that you know. A. We have ongoing safety	2 3 4 5 6 7 8 9	Q. How would I obtain the identity of individuals who were involved with labeling in the NDA for Cymbalta? A. I believe that's part of the organizational charts that were provided. But, you know, we could refer to that or we could speak to somebody within our current labeling department. MS. JONES: I think the
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	Page 137		Page 139
1	different components to an IND, much like	1	to that application. It would include
2	an NDA. But because, when you're	2	your risk management plan, your pediatric
3	typically filing an IND, it's primarily	3	plan, your patent information.
4	you've not you don't have any human	4	Module 2 would include the
5	data. So there is definitely a	5	multiple summaries. So that would include
6	toxicologist. There is a clinical	6	your clinical overview, which is really
7	pharmacologist. There we have ADME,	7	about the benefit risk of your compound.
8	which stands for "absorption, distribution,	8	It includes your summary of efficacy, your
9	* *	9	
10	metabolism, and excretion" scientists.	10	summary of safety, your summary of
	Usually a pharmacokineticist, regulatory,	l	clinical pharmacology, your summary of
11	and then medical as well as global	11	quality, which means CMNC, it also
12	patient safety and chemistry manufacturing	12	includes summaries of the nonclinical work
13	controls. There's also a legal review.	13	that was conducted.
14	BY MR. O'BRIEN:	14	Module 3 goes into a lot of
15	Q. Within those different	15	detail for chemistry manufacturing
16	categories, do you know any individuals	16	controls. It's broken out by drug
17	that were involved in the Cymbalta IND?	17	product and drug substance.
18	A. No.	18	Module 4 will include all the
19	Q. Now, I want to go back and	19	individual study reports of all the
20	talk about the NDA file.	20	nonclinical work that's been done.
21	A. Uh-huh.	21	And then Module 5 includes all
22	Q. What I know you mentioned	22	of the clinical study reports that have
23	some of the things that are recorded in	23	been conducted. And that includes
24	the NDA file. Can you give me a list of	24	statistical data sets and case report
	Page 138		Page 140
	- ago		
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1	the different areas that are recorded?	1	forms, a number in addition to the
2	A. Are you talking like the table	2	individual study reports.
2 3	A. Are you talking like the table of contents essentially or	2 3	individual study reports. BY MR. O'BRIEN:
2 3 4	A. Are you talking like the tableof contents essentially orQ. Like information that's	2 3 4	individual study reports. BY MR. O'BRIEN: Q. Now, you mentioned there's a
2 3 4 5	 A. Are you talking like the table of contents essentially or Q. Like information that's contained in an NDA file for Cymbalta. 	2 3 4 5	individual study reports. BY MR. O'BRIEN: Q. Now, you mentioned there's a risk management plan. Is that something
2 3 4 5 6	 A. Are you talking like the table of contents essentially or Q. Like information that's contained in an NDA file for Cymbalta. A. Okay. That's a pretty broad 	2 3 4 5 6	individual study reports. BY MR. O'BRIEN: Q. Now, you mentioned there's a risk management plan. Is that something that's updated every year?
2 3 4 5	 A. Are you talking like the table of contents essentially or Q. Like information that's contained in an NDA file for Cymbalta. A. Okay. That's a pretty broad question, so I'm not is there an area 	2 3 4 5	individual study reports. BY MR. O'BRIEN: Q. Now, you mentioned there's a risk management plan. Is that something
2 3 4 5 6	 A. Are you talking like the table of contents essentially or Q. Like information that's contained in an NDA file for Cymbalta. A. Okay. That's a pretty broad 	2 3 4 5 6	individual study reports. BY MR. O'BRIEN: Q. Now, you mentioned there's a risk management plan. Is that something that's updated every year?
2 3 4 5 6 7	 A. Are you talking like the table of contents essentially or Q. Like information that's contained in an NDA file for Cymbalta. A. Okay. That's a pretty broad question, so I'm not is there an area 	2 3 4 5 6 7	individual study reports. BY MR. O'BRIEN: Q. Now, you mentioned there's a risk management plan. Is that something that's updated every year? A. That is a newer document. It's
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. Are you talking like the table of contents essentially or Q. Like information that's contained in an NDA file for Cymbalta. A. Okay. That's a pretty broad question, so I'm not is there an area you would like me to focus on? Q. No, just generally. A. Okay. MS. JONES: Well, let me let me just say, that's obviously all governed by FDA regulations. To the extent that you want to give a sense of what that includes, but why don't you try to do that? A. Okay. In today's format, which	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	individual study reports. BY MR. O'BRIEN: Q. Now, you mentioned there's a risk management plan. Is that something that's updated every year? A. That is a newer document. It's actually required by European regulation, but it's not required by FDA. It is a document that we have for all of our molecules at Lilly and so we typically do provide that to the agency, to FDA. Those are risk management plans are subject to annual review and they can be updated more frequently if there are emergent new safety issues. Q. Now, it's strike that.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. Are you talking like the table of contents essentially or Q. Like information that's contained in an NDA file for Cymbalta. A. Okay. That's a pretty broad question, so I'm not is there an area you would like me to focus on? Q. No, just generally. A. Okay. MS. JONES: Well, let me let me just say, that's obviously all governed by FDA regulations. To the extent that you want to give a sense of what that includes, but why don't you try to do that? A. Okay. In today's format, which is the electronic common technical document, ECTD, format, Module 1 will include various administrative forms. It will include your draft label and your annotated draft label. It will include meeting minutes of previous meetings that	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	individual study reports. BY MR. O'BRIEN: Q. Now, you mentioned there's a risk management plan. Is that something that's updated every year? A. That is a newer document. It's actually required by European regulation, but it's not required by FDA. It is a document that we have for all of our molecules at Lilly and so we typically do provide that to the agency, to FDA. Those are risk management plans are subject to annual review and they can be updated more frequently if there are emergent new safety issues. Q. Now, it's strike that. What is regulatory's involvement on working with the risk management plan? I know there's some parts that's handled by the drug surveillance team. Can you explain to me the process on developing the risk management plan for Cymbalta?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Are you talking like the table of contents essentially or Q. Like information that's contained in an NDA file for Cymbalta. A. Okay. That's a pretty broad question, so I'm not is there an area you would like me to focus on? Q. No, just generally. A. Okay. MS. JONES: Well, let me let me just say, that's obviously all governed by FDA regulations. To the extent that you want to give a sense of what that includes, but why don't you try to do that? A. Okay. In today's format, which is the electronic common technical document, ECTD, format, Module 1 will include various administrative forms. It will include your draft label and your annotated draft label. It will include	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	individual study reports. BY MR. O'BRIEN: Q. Now, you mentioned there's a risk management plan. Is that something that's updated every year? A. That is a newer document. It's actually required by European regulation, but it's not required by FDA. It is a document that we have for all of our molecules at Lilly and so we typically do provide that to the agency, to FDA. Those are risk management plans are subject to annual review and they can be updated more frequently if there are emergent new safety issues. Q. Now, it's strike that. What is regulatory's involvement on working with the risk management plan? I know there's some parts that's handled by the drug surveillance team. Can you explain to me the process on developing

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	Page 141		Page 143
1	specifically, more maintaining the risk	1	postmarketing commitments outstanding, so
2	management plan. We are reviewing it	2	they are reviewed.
3	annually. That effort is initiated by	3	Q. And who participates in those
4	our global patient safety organization.	4	meetings?
5	So they're responsible for creating,	5	A. Those meetings are chaired by
6	initiating the review and the approval of	6	Dr. Rob Metcalf and Dr. Tim Garnett.
7	that document. Regulatory is involved in	7	There are also other medical personnel
8	reviewing the document and there are	8	involved as well as legal.
9	specific sections within the risk	9	
10	management plan for which regulatory	10	Q. And can you list the different
11		11	individuals and responsibilities that
12	personnel are responsible and that	12	attend those meetings?
	includes any regulatory interactions that	1	A. No, because I don't attend
13	have occurred over the last reporting	13	those meetings. I provide written input
14	period to do with safety. Were there any	14	to those meetings. I give status updates
15	drug safety communications? Were there,	15	on the various PMCs. And I've once been
16	you know, where we put on clinical hold	16	asked to go to the meeting to answer
17	for some safety issue, safety reason?	17	questions.
18	Was, you know, product withdrawn, that	18	Q. And what's a "PMC"?
19	kind of thing? And so my in my	19	A. Oh, postmarketing commitment.
20	tenure working on Cymbalta, I've not had	20	When a drug is approved by FDA, they
21	anything to list in that section.	21	often, in their approval letter, will
22	Q. Now, I want to turn our	22	issue certain postmarketing commitments.
23	attention to meetings in the regulatory	23	That could be to conduct a different
24	affairs department. Are there regular	24	study, to collect additional information
	Page 142		Page 144
1	meetings that happen on a scheduled basis?	1	from a registry, there can be multiple
2	As a director in U.S. regulatory affairs	2	different kinds of commitments that are
3	for Cymbalta and neuroscience, what	3	requested by FDA.
4	meetings do you attend on a regular	4	Q. And have you ever been required
5	basis?	5	to gather money sorry.
6	A. Could you be more specific?	6	Have you ever been required to
7	Q. Is there a department meeting	7	gather materials as it relates to Cymbalta
8			gamer materials as it relates to Cymbarta
_	that you have to attend every month?	8	for any sort of quarterly management
9	A. We have different okay. So	8 9	-
		1	for any sort of quarterly management
9	A. We have different okay. So we have GRAUS bio-medicines department	9	for any sort of quarterly management review?
9 10	A. We have different okay. So we have GRAUS bio-medicines department meeting.	9 10	for any sort of quarterly management review? A. Yes. Q. And when was that?
9 10 11	A. We have different okay. So we have GRAUS bio-medicines department meeting.Q. And let me help kind of	9 10 11	for any sort of quarterly management review? A. Yes. Q. And when was that? A. Well, I provide quarterly
9 10 11 12 13	 A. We have different okay. So we have GRAUS bio-medicines department meeting. Q. And let me help kind of streamline everything along. Any sort of 	9 10 11 12	for any sort of quarterly management review? A. Yes. Q. And when was that? A. Well, I provide quarterly updates on our postmarketing commitments,
9 10 11 12 13 14	 A. We have different okay. So we have GRAUS bio-medicines department meeting. Q. And let me help kind of streamline everything along. Any sort of meeting where Cymbalta could be on the 	9 10 11 12 13 14	for any sort of quarterly management review? A. Yes. Q. And when was that? A. Well, I provide quarterly updates on our postmarketing commitments, I do that routinely. And we also have a
9 10 11 12 13 14 15	 A. We have different okay. So we have GRAUS bio-medicines department meeting. Q. And let me help kind of streamline everything along. Any sort of meeting where Cymbalta could be on the agenda. 	9 10 11 12 13 14 15	for any sort of quarterly management review? A. Yes. Q. And when was that? A. Well, I provide quarterly updates on our postmarketing commitments, I do that routinely. And we also have a quarterly senior management report where
9 10 11 12 13 14 15	 A. We have different okay. So we have GRAUS bio-medicines department meeting. Q. And let me help kind of streamline everything along. Any sort of meeting where Cymbalta could be on the agenda. A. It would be the bio what I 	9 10 11 12 13 14 15 16	for any sort of quarterly management review? A. Yes. Q. And when was that? A. Well, I provide quarterly updates on our postmarketing commitments, I do that routinely. And we also have a quarterly senior management report where we provide the status of each of our
9 10 11 12 13 14 15 16	 A. We have different okay. So we have GRAUS bio-medicines department meeting. Q. And let me help kind of streamline everything along. Any sort of meeting where Cymbalta could be on the agenda. A. It would be the bio what I just was saying, the GRAUS bio-medicines 	9 10 11 12 13 14 15 16 17	for any sort of quarterly management review? A. Yes. Q. And when was that? A. Well, I provide quarterly updates on our postmarketing commitments, I do that routinely. And we also have a quarterly senior management report where we provide the status of each of our molecules. For me, I provide an update
9 10 11 12 13 14 15 16 17	 A. We have different okay. So we have GRAUS bio-medicines department meeting. Q. And let me help kind of streamline everything along. Any sort of meeting where Cymbalta could be on the agenda. A. It would be the bio what I just was saying, the GRAUS bio-medicines group meets monthly. Cymbalta may be on 	9 10 11 12 13 14 15 16 17 18	for any sort of quarterly management review? A. Yes. Q. And when was that? A. Well, I provide quarterly updates on our postmarketing commitments, I do that routinely. And we also have a quarterly senior management report where we provide the status of each of our molecules. For me, I provide an update on Cymbalta. I do that quarterly.
9 10 11 12 13 14 15 16 17 18	 A. We have different okay. So we have GRAUS bio-medicines department meeting. Q. And let me help kind of streamline everything along. Any sort of meeting where Cymbalta could be on the agenda. A. It would be the bio what I just was saying, the GRAUS bio-medicines group meets monthly. Cymbalta may be on the agenda. It frequently is not. 	9 10 11 12 13 14 15 16 17 18	for any sort of quarterly management review? A. Yes. Q. And when was that? A. Well, I provide quarterly updates on our postmarketing commitments, I do that routinely. And we also have a quarterly senior management report where we provide the status of each of our molecules. For me, I provide an update on Cymbalta. I do that quarterly. Q. And what is the name of that
9 10 11 12 13 14 15 16 17 18 19 20	 A. We have different okay. So we have GRAUS bio-medicines department meeting. Q. And let me help kind of streamline everything along. Any sort of meeting where Cymbalta could be on the agenda. A. It would be the bio what I just was saying, the GRAUS bio-medicines group meets monthly. Cymbalta may be on the agenda. It frequently is not. There is a quarterly management 	9 10 11 12 13 14 15 16 17 18 19 20	for any sort of quarterly management review? A. Yes. Q. And when was that? A. Well, I provide quarterly updates on our postmarketing commitments, I do that routinely. And we also have a quarterly senior management report where we provide the status of each of our molecules. For me, I provide an update on Cymbalta. I do that quarterly. Q. And what is the name of that document?
9 10 11 12 13 14 15 16 17 18 19 20 21	A. We have different okay. So we have GRAUS bio-medicines department meeting. Q. And let me help kind of streamline everything along. Any sort of meeting where Cymbalta could be on the agenda. A. It would be the bio what I just was saying, the GRAUS bio-medicines group meets monthly. Cymbalta may be on the agenda. It frequently is not. There is a quarterly management review of all postmarketing commitments	9 10 11 12 13 14 15 16 17 18 19 20 21	for any sort of quarterly management review? A. Yes. Q. And when was that? A. Well, I provide quarterly updates on our postmarketing commitments, I do that routinely. And we also have a quarterly senior management report where we provide the status of each of our molecules. For me, I provide an update on Cymbalta. I do that quarterly. Q. And what is the name of that document? A. Senior monthly management
9 10 11 12 13 14 15 16 17 18 19 20 21 22	 A. We have different okay. So we have GRAUS bio-medicines department meeting. Q. And let me help kind of streamline everything along. Any sort of meeting where Cymbalta could be on the agenda. A. It would be the bio what I just was saying, the GRAUS bio-medicines group meets monthly. Cymbalta may be on the agenda. It frequently is not. There is a quarterly management review of all postmarketing commitments that we have outstanding as a company, 	9 10 11 12 13 14 15 16 17 18 19 20 21 22	for any sort of quarterly management review? A. Yes. Q. And when was that? A. Well, I provide quarterly updates on our postmarketing commitments, I do that routinely. And we also have a quarterly senior management report where we provide the status of each of our molecules. For me, I provide an update on Cymbalta. I do that quarterly. Q. And what is the name of that document? A. Senior monthly management report, yeah, for bio-medicines. There's
9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	 A. We have different okay. So we have GRAUS bio-medicines department meeting. Q. And let me help kind of streamline everything along. Any sort of meeting where Cymbalta could be on the agenda. A. It would be the bio what I just was saying, the GRAUS bio-medicines group meets monthly. Cymbalta may be on the agenda. It frequently is not. There is a quarterly management review of all postmarketing commitments that we have outstanding as a company, that includes all approved drugs, of which 	9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	for any sort of quarterly management review? A. Yes. Q. And when was that? A. Well, I provide quarterly updates on our postmarketing commitments, I do that routinely. And we also have a quarterly senior management report where we provide the status of each of our molecules. For me, I provide an update on Cymbalta. I do that quarterly. Q. And what is the name of that document? A. Senior monthly management report, yeah, for bio-medicines. There's separate one for diabetes, a separate one
9 10 11 12 13 14 15 16 17 18 19 20 21 22	 A. We have different okay. So we have GRAUS bio-medicines department meeting. Q. And let me help kind of streamline everything along. Any sort of meeting where Cymbalta could be on the agenda. A. It would be the bio what I just was saying, the GRAUS bio-medicines group meets monthly. Cymbalta may be on the agenda. It frequently is not. There is a quarterly management review of all postmarketing commitments that we have outstanding as a company, 	9 10 11 12 13 14 15 16 17 18 19 20 21 22	for any sort of quarterly management review? A. Yes. Q. And when was that? A. Well, I provide quarterly updates on our postmarketing commitments, I do that routinely. And we also have a quarterly senior management report where we provide the status of each of our molecules. For me, I provide an update on Cymbalta. I do that quarterly. Q. And what is the name of that document? A. Senior monthly management report, yeah, for bio-medicines. There's

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	Page 145		Page 147
1	Q. And where would that be saved?	1	MS. JONES: I'm sorry.
2	A. I believe there is the GRAUS	2	September of 2010 to March 2010?
3	collaboration site. I think there's a	3	MR. O'BRIEN: I'm sorry.
4		4	September 2007 to March 2010.
5	senior management component to that that is restricted.	5	BY MR. O'BRIEN:
1		1	
6	Q. And you said there's also	6	Q. Do you remember attending any
7	you also said there's a GRUS [sic]	7	meetings where Cymbalta discontinuation
8	bio-medicines meetings?	8	syndrome was discussed?
9	A. Uh-huh.	9	A. No.
10	Q. And who attends those meetings	10	Q. And during that time frame,
11	and what are the purpose of those	11	were you attending regular department
12	meetings?	12	meetings?
13	A. So it's really Carl Garner and	13	A. Yes.
14	his staff. We talk about what's going	14	Q. Would it be the same type of
15	on, what hot topics are going on, their	15	meetings or what type what were those
16	updates on what's going on from a	16	meetings called during that time frame?
17	management perspective that we need to be	17	A. During that time frame, we were
18	aware of.	18	it was neuroscience focused. So we
19	Q. As it relates to regulatory	19	did have a monthly, you know, U.S.
20	issues or what type	20	regulatory neuroscience meeting. Dr. Brophy
21	A. Yes.	21	was in charge of that group. And it was
22	Q of issues do you discuss at	22	the same kind of meeting, talking about
23	those meetings?	23	the products, but it was a little more
24	A. Yeah, I mean, it's primarily	24	focused since it was just neuroscience.
	11. I can, I mean, it's primarily		locused since it was just neuroscience.
	Page 146		Page 148
1	regulatory. It's who recently had a	1	Q. Now, as we talked about
2	meeting with FDA, how did it go, that	2	earlier, there are CRFs [sic] that govern
3	kind of thing.	3	what information is placed into new drug
4	Q. Do you know if Cymbalta	4	applications, correct?
5	discontinuation syndrome has ever been	5	MS. JONES: Do you mean
6	addressed in one of those meeting?	6	provisions of the Code of Federal
7	A. Not while I've been on Cymbalta	7	Regulations?
8	and not that I'm aware of prior to that.	8	MR. O'BRIEN: Yes.
9	Q. And that would also be saved on	9	MS. JONES: You said "CRF."
10	the system?	10	THE WITNESS: That's CFR.
11	MS. JONES: Objection to form.	11	MS. JONES: That's CFR.
12	When you say "that," what are you talking	12	MR. O'BRIEN: Sorry.
13	about?	13	BY MR. O'BRIEN:
14		14	Q. Sorry. Strike that.
1	MR. O'BRIEN: I'm sorry. Let	15	•
15	me ask you a better question.	16	There are regulatory statutes
16	BY MR. O'BRIEN:	17	that govern what goes into an NDA,
17	Q. Would those materials used at	1	correct?
	the global regulatory bio-medicine meetings	18 19	A. Correct.Q. Has Lilly converted those
18	1 1 1 0		Q. Has Lilly converted those
19	be saved anywhere?		•
19 20	A. They are saved currently on a	20	regulatory statutes in any sort of SOPs
19 20 21	A. They are saved currently on a collaboration site.	20 21	regulatory statutes in any sort of SOPs or
19 20 21 22	A. They are saved currently on a collaboration site.Q. Now, you were the U.S.	20 21 22	regulatory statutes in any sort of SOPs or A. Yes.
19 20 21 22 23	A. They are saved currently on a collaboration site.Q. Now, you were the U.S. regulatory consultant in neuroscience from	20 21 22 23	regulatory statutes in any sort of SOPs or A. Yes. MS. JONES: Hold on. I'm
19 20 21 22	A. They are saved currently on a collaboration site.Q. Now, you were the U.S.	20 21 22	regulatory statutes in any sort of SOPs or A. Yes.

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1	You can answer.	1	personnel assigned within the quality
2	A. If you all of our SOPs	2	organization that will take the lead on
3	reference specific statutes and/or	3	updating or creating SOPs. And they will
	•		
4	guidance, whether they be FDA,	4	employ the appropriate experts in doing
5	international, that is part of the SOP	5	that and then they are approved.
6	and wherever that comes from is always	6	Ultimately by Dr. Metcalf or Dr. Forda,
7	referenced.	7	who is the vice president of international
8	BY MR. O'BRIEN:	8	regulatory affairs, as well as the quality
9	Q. Are there any other documents	9	organization. There's usually two
10	associated with those SOPs that provide	10	approvers.
11	any sort of direction, like some sort of	11	Q. Is there a copy of the CFRs in
12	job aid?	12	your department?
13	MS. JONES: Objection to the	13	A. Yes.
14	form.	14	Q. Where is it located?
15	A. You mean for an NDA?	15	A. We have individual copies on
16	BY MR. O'BRIEN:	16	the two nice little notebook things.
17	Q. Yeah, for an NDA. For	17	It's updated annually, includes 21 CFR,
18	instance, yesterday we had a deposition	18	312, 314, 50, just the ones that are most
19	with Dr. Knowles. He said some of the	19	relevant to our job. So we literally
20	SOPs had accompanying documents that	20	have a paper copy. You can also access
21	helped, you know, provide some guidance.	21	this online through the FDA website and
22	I was wondering if there's that with the	22	
23		23	get to any CFR.
23	SOPs as it relates to federal regulations?	24	Q. And other than job aids, are
∠ 4	A. There are some SOPs with job	<u>24</u> 	there any other documents that Lilly has
	Page 150		Page 152
1	aids or tools associated with them. I'm	1	produced that help provide guidance in
2	trying to think specifically around NDA if	2	interpreting the CFRs?
3	there was anything. Because I'm not sure	3	A. No. Well, let me take that
4	there's a job aid, but there is reference	4	back. We do look at FDA guidance
5	to the ECTD table of contents, which is	5	documents which will often extrapolate
6	very detailed as to what goes in what	6	from the CFRs. That's not something that
7	module and a description of those that is	7	Lilly provides, that's something that FDA
8		8	· · · · · · · · · · · · · · · · · · ·
	been harmonized that's been agreed to		provides and is publicly available. And
9	globally through the international council	9	then there may be webinars or webcasts
10	of harmonization.	10	that different organizations will host to
11	Q. Do you know who was responsible	11	elaborate on a specific regulation. Those
12	in entering the code of regulations into	12	are done by external parties, not by
13	SOPs?	13	Lilly.
14	A. It would have	14	Q. Now, I want to turn my
15	MS. JONES: Hold on. Objection	15	attention to technical writers. Were you
16	to the form. Go ahead.	16	one of your, I guess, earlier
17	A. It would have been the folks	17	positions in Lilly, was that part of a
18	involved with the regulatory quality	18	technical writing group?
19	system.	19	A. Medical writing, technical
20	BY MR. O'BRIEN:	20	writing, global scientific information and
21	Q. And what folks involved in	21	communications essentially mean the same
		l	•
22	regulatory quality system draft the SOPs?	22	thing, although technical writer can have
	regulatory quality system draft the SOPs? A. It's done by subject-matter	22 23	thing, although technical writer can have different connotations, so it would depend
22			thing, although technical writer can have different connotations, so it would depend on specifically what you're referring to.

	82	?15	
	Page 153		Page 155
1	Q. Were there technical writers	1	MR. O'BRIEN: Okay.
2	that were used to help draft Cymbalta's	2	BY MR. O'BRIEN:
3	label changes since 2004?	3	Q. I want to turn our attention to
4	A. No. The people that are	4	advertisements. Who creates a draft copy
5	involved with drafting the label, that	5	of Cymbalta ads?
6	effort is coordinated by our labeling	6	MS. JONES: I'm going to object
7		7	
l	department. So they would coordinate the	1	to this as outside the scope of the
8	writing of the label. The content comes	8	notice. You may answer in your
9	from the cross-functional team involved,	9	individual capacity.
10	including medical, GPS, statistics,	10	A. In general terms, marketing
11	toxicology, ADME, PK.	11	creates all of our promotional pieces.
12	Q. And that was a product team	12	BY MR. O'BRIEN:
13	that we talked about earlier?	13	Q. Do you know if marketing
14	A. That's correct.	14	employs any third parties that create the
15	Q. That would be the same team	15	advertisement or is that done in-house?
16	that would deal with the label changes?	16	MS. JONES: Same objection. Go
17	A. Yes. So in a way, you could	17	ahead.
18	call the labeling associate a technical	18	A. We do some in-house. I know
19	writer, but they do more than that. They	19	we've engaged other vendors for materials.
20	do research on FDA's expectations for	20	BY MR. O'BRIEN:
21	various parts of the label. That does	21	Q. Are ads sent to the FDA? I
22	change over time. The format of the	22	know before you kind of took me through
23	labeling changes over time and they keep	23	the process of approving ads. Once they
24	up with all of that and also will look	24	are, you know, used, are they sent to the
	up with an or that and also will rook		are, you mie w, asea, are arey sem to are
	Page 154		Page 156
1		1	
1	at, you know, competitor labels for	1	FDA?
2	consistency.	2	A. We have a regulatory
3	Q. Do you know who the labeling	3	affairs-U.S. ad promotional group. They
4	associate is for Cymbalta?	4	are responsible for working with marketing
5	A. Yes, Sara Mescher. That's	5	and the PCA review process to ensure
6	currently who was the labeling associate.	6	compliance with our SOPs as well as any
7	Q. And how long has Sara been in	7	applicable federal regulation. All of our
8	that position?	8	advertising materials are submitted to FDA
9	A. Several years. I don't know	9	per regulation. In some cases, direct to
10	specifically when she started working on	10	consumer information is precleared. Other
11	Cymbalta.	11	information is submitted with a Form 2253
12	Q. Has it been like five years	12	at the first time of use. But, yes, all
13	or	13	of that is provided to the agency.
14	A T 41 1	1 1 1	
T 4	A. I think so.	14	Q. Just so you understand, there's
15		15	
	Q. Next I want to turn do you	l	some advertisements that you can just
15		15	some advertisements that you can just start using and then you kind of send it
15 16	Q. Next I want to turn do you want to take would you like to take a break?	15 16 17	some advertisements that you can just start using and then you kind of send it to the FDA after the fact, correct?
15 16 17 18	Q. Next I want to turn do you want to take would you like to take a break? A. I'm okay. You can go.	15 16 17 18	some advertisements that you can just start using and then you kind of send it to the FDA after the fact, correct? A. You send it at the same time
15 16 17 18 19	 Q. Next I want to turn do you want to take would you like to take a break? A. I'm okay. You can go. Q. Okay. We'll keep on going 	15 16 17 18 19	some advertisements that you can just start using and then you kind of send it to the FDA after the fact, correct? A. You send it at the same time that you intend to use it.
15 16 17 18 19 20	 Q. Next I want to turn do you want to take would you like to take a break? A. I'm okay. You can go. Q. Okay. We'll keep on going then. 	15 16 17 18 19 20	some advertisements that you can just start using and then you kind of send it to the FDA after the fact, correct? A. You send it at the same time that you intend to use it. Q. That doesn't require some sort
15 16 17 18 19 20 21	 Q. Next I want to turn do you want to take would you like to take a break? A. I'm okay. You can go. Q. Okay. We'll keep on going then. MR. O'BRIEN: Phyllis, are you 	15 16 17 18 19 20 21	some advertisements that you can just start using and then you kind of send it to the FDA after the fact, correct? A. You send it at the same time that you intend to use it. Q. That doesn't require some sort of preapproval?
15 16 17 18 19 20 21 22	 Q. Next I want to turn do you want to take would you like to take a break? A. I'm okay. You can go. Q. Okay. We'll keep on going then. MR. O'BRIEN: Phyllis, are you good? 	15 16 17 18 19 20 21 22	some advertisements that you can just start using and then you kind of send it to the FDA after the fact, correct? A. You send it at the same time that you intend to use it. Q. That doesn't require some sort of preapproval? A. That's correct.
15 16 17 18 19 20 21 22 23	 Q. Next I want to turn do you want to take would you like to take a break? A. I'm okay. You can go. Q. Okay. We'll keep on going then. MR. O'BRIEN: Phyllis, are you good? MS. JONES: That's just fine 	15 16 17 18 19 20 21 22 23	some advertisements that you can just start using and then you kind of send it to the FDA after the fact, correct? A. You send it at the same time that you intend to use it. Q. That doesn't require some sort of preapproval? A. That's correct. Q. Are there certain ads that
15 16 17 18 19 20 21 22	 Q. Next I want to turn do you want to take would you like to take a break? A. I'm okay. You can go. Q. Okay. We'll keep on going then. MR. O'BRIEN: Phyllis, are you good? 	15 16 17 18 19 20 21 22	some advertisements that you can just start using and then you kind of send it to the FDA after the fact, correct? A. You send it at the same time that you intend to use it. Q. That doesn't require some sort of preapproval? A. That's correct.

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	Page 157		Page 159
1	A. Yes.	1	promotional piece.
2	Q. What type of ads are they?	2	Q. You said that's an untitled
3	A. Television direct-to-consumer	3	letter. Is there something called a
4	ads. We elect I mean, there are	4	"titled letter"?
5	· · · · · · · · · · · · · · · · · · ·	5	A. There's an untitled letter and
6	times when we preclear materials that	6	
7	don't require preclearance because we want	7	then there's a warning letter. I don't
	FDA's feedback on that.	l	know how they came up with the
8	Q. And where are these ads saved	8	terminology. An untitled it has to do
9	within regulatory?	9	with the severity of the violation, is my
10	A. All of the regulatory	10	understanding is the difference between
11	correspondence that we have with the	11	the two.
12	agency is maintained in e-files.	12	Q. Now, would a warning letter,
13	Q. And how long are they retained	13	would that would that come after
14	for? Are they retained for the life?	14	after an untitled letter or could a
15	A. Yeah, as long as yeah, as	15	warning letter come out for the first
16	long as we're marketing the compound or	16	time on an advertisement that the FDA had
17	the drug. Or if we divest it, we might,	17	a problem with?
18	you know, sell the product and with it we	18	A. A warning letter could come out
19	would give them the IND and NDA.	19	the first time.
20	Q. Has the FDA ever had an issue	20	Q. Okay. Do you know if Eli
21	with one of Eli Lilly's ads for Cymbalta?	21	Lilly has ever received a warning letter
22	MS. JONES: Objection to the	22	as it relates to a Cymbalta ad?
23	form; vague.	23	A. We have not.
24	A. What do you mean?	24	Q. Do you have an idea of how
	Page 158		Page 160
1	BY MR. O'BRIEN:	1	many untitled letters that Lilly has
2	Q. Meaning that maybe they thought	2	received from the FDA regarding Cymbalta?
2 3	Q. Meaning that maybe they thought that Eli Lilly was misrepresenting	2	received from the FDA regarding Cymbalta? A. I think it's four, maybe five.
2 3 4	Q. Meaning that maybe they thought that Eli Lilly was misrepresenting something in an advertisement for	2 3 4	received from the FDA regarding Cymbalta? A. I think it's four, maybe five. MS. JONES: And those have been
2 3	Q. Meaning that maybe they thought that Eli Lilly was misrepresenting something in an advertisement for Cymbalta?	2	received from the FDA regarding Cymbalta? A. I think it's four, maybe five. MS. JONES: And those have been produced, Kevin.
2 3 4 5 6	Q. Meaning that maybe they thought that Eli Lilly was misrepresenting something in an advertisement for Cymbalta? A. We have received a few	2 3 4 5 6	received from the FDA regarding Cymbalta? A. I think it's four, maybe five. MS. JONES: And those have been produced, Kevin. BY MR. O'BRIEN:
2 3 4 5 6 7	Q. Meaning that maybe they thought that Eli Lilly was misrepresenting something in an advertisement for Cymbalta? A. We have received a few "untitled letters," is what it's called,	2 3 4 5 6 7	received from the FDA regarding Cymbalta? A. I think it's four, maybe five. MS. JONES: And those have been produced, Kevin. BY MR. O'BRIEN: Q. Do you have a recollection of
2 3 4 5 6 7 8	Q. Meaning that maybe they thought that Eli Lilly was misrepresenting something in an advertisement for Cymbalta? A. We have received a few "untitled letters," is what it's called, if FDA has concerns about a specific	2 3 4 5 6 7 8	received from the FDA regarding Cymbalta? A. I think it's four, maybe five. MS. JONES: And those have been produced, Kevin. BY MR. O'BRIEN: Q. Do you have a recollection of what type of issues the FDA had with the
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	82	T	
	Page 161		Page 163
1	you know, it wasn't	1	wrong in producing those pieces and what
2	Q. It was taken back or whatever?	2	we could have done differently. We often
3	A. It was taken back, yes.	3	find it's a difference of interpretation
4	Q. What about the other, what did	4	and that what we provided in a
5	we say, four, you said four or five	5	promotional piece, we did believe was in
6	letters?	6	compliance with the regulations. And we
7	A. Yeah. I don't recall the	7	•
8		8	have so stipulated.
	details, but I do remember looking through	1	Q. Do you know if there's any
9	them briefly and there was nothing	9	changes to the regulatory process for
10	specific to discontinuation emergent	10	reviewing ads after the second, third,
11	adverse events.	11	fourth were pulled back from the FDA?
12	Q. Do you remember if the	12	A. No. I mean, we do periodically
13	advertisements were ultimately pulled in	13	review our processes, but not there is
14	those cases?	14	not changes specific to Cymbalta or
15	A. In all cases, we complied with	15	because of Cymbalta.
16	FDA's recommendation to cease	16	Q. I was wondering if you know the
17	dissemination. We responded to the	17	person that was reviewing those ads, that
18	letters in writing with whether or not we	18	gave approval to those ads that had to be
19	agreed with their characterization, of	19	pulled back from the FDA, if that person
20	whether or not we were in violation and	20	was maybe changed out or given new
21	but, yes, we did cease dissemination	21	instruction or extensive training due to
22	of the specific pieces that were noted.	22	the FDA's untitled letters?
23	Q. Do you know if within	23	MS. JONES: Objection to the
24	regulatory if there's any sort of	24	form.
	Page 162		Page 164
1	corrective action that got taken regarding	1	A. I don't know.
2	representations with the Cymbalta ads?	2	MR. O'BRIEN: Let's take a
3	Like was anybody disciplined for letting	3	ten-minute break.
4	an ad that had to be pulled back due to	4	MS. JONES: We are going off
	FDA cease and desist letters?	1	MS. JOINES. We are going on
		1 5	
5		5	the record. The time is 11:42 a.m.
6	MS. JONES: Objection to the	6	the record. The time is 11:42 a.m. (A recess was taken at
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	04	218	1
	Page 165		Page 167
1	change, we submit to the agency both a	1	considering a label change.
2	red-line version as well as a clean	2	Regardless of what initiated
3	version. So, yes, we do have records of	3	that trigger, the process is to review
4	those.	4	the information to understand why the
5	Q. I imagine that in the course of	5	change is being requested, what's the
6		6	rationale, what are the supporting data,
7	drafting a label, there may be different	7	and then we look at our core data sheet
	versions that take place. Do you know if		
8	different versions are saved before	8	to see, is it already covered in our core
9	they're submitted to the FDA?	9	data sheet, yes or no. If it's not, then
10	A. I do not know.	10	we would proceed with potential core data
11	Q. Do you know where that	11	sheet change which would be documented and
12	information would be if it did exist?	12	reviewed by our Global Product Labeling
13	A. If it does exist, it would be	13	Committee, GPLC. If that change is
14	within the global labeling archives.	14	approved, it will then be implemented
15	Q. And that would that would	15	locally and labeling according to that
16	include, if it does exist, rough drafts	16	region's local regulations. And then
17	of labels before they're actually	17	whatever change has been made will be
18	finalized?	18	submitted to the appropriate regulatory
19	A. Yes.	19	agency for approval.
20	Q. Is there somebody that's	20	Q. Now, with regard to a label
21	responsible for archives at global label?	21	change, let's say, for instance, as you
22	A. There is. I do not know.	22	know, there were label changes with regard
23	Nancy Allen is the senior director over	23	to Cymbalta discontinuation syndrome.
24	operations and labeling. So I expect she	24	A. Yes, there have been label
			,
	Page 166		Page 168
1	Page 166	4	Page 168
1	is ultimately responsible. I don't know	1	changes regarding that.
2	is ultimately responsible. I don't know if there's a specific individual within	2	changes regarding that. Q. When there's a label change
2 3	is ultimately responsible. I don't know if there's a specific individual within labeling that that is their	2 3	changes regarding that. Q. When there's a label change within Lilly, is there any sort of
2 3 4	is ultimately responsible. I don't know if there's a specific individual within labeling that that is their responsibility.	2 3 4	changes regarding that. Q. When there's a label change within Lilly, is there any sort of rationale for the label change?
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	Page 169		Page 171
1	(Record read.)	1	believe is what it's referred to.
2	MS. JONES: Okay. Let me just	2	Q. And what does that stand for?
3	make an objection to the form.	3	A. Oh, "Global Product Labeling
4	BY MR. O'BRIEN:	4	Committee."
5		5	
6			Q. Now, there's a product team,
	Cymbalta or any other sort of label	6	you know, right now there's a you said
7	change, if the product team creates	7	a neuroscience platform, correct?
8	materials that kind of discuss the	8	A. That's correct.
9	reasoning for the label change? Say	9	Q. Is there an interaction with
10	there's PowerPoint presentations to present	10	them in the global product labeling
11	to the group, do you know if those sort	11	committee?
12	of materials are created?	12	A. If there is a proposed label
13	MS. JONES: Objection to the	13	change, yes.
14	form.	14	Q. If there was a proposed label
15	A. Depends on what you mean	15	change, what type of interaction would
16	specifically. When we are changing our	16	there be? Or what was the proposed
17	core data sheet, there is a presentation,	17	what type of interaction was there when
18	although it's written, it's not	18	there actually were changes to the
19	PowerPoint. There's a template that's	19	
			Cymbalta label?
20	filled out with what is changing and why	20	MS. JONES: Objection to the
21	and the supporting documentation for that.	21	form.
22	BY MR. O'BRIEN:	22	A. Speaking in generalities, the
23	Q. Is that template for the FDA or	23	team has determined that there is a need
24	is that template for Lilly internally?	24	to change the core data sheet. They
	Page 170		Page 172
1	A. That template is for Lilly	1	that team, if it's a safety change, that
2		1	
3	internally for making core data sheet	2	goes through review by the safety review
	changes. When we submit a label change	3	committee, the SRC, which then makes a
4	to the FDA, we have to draft labeling,	4	recommendation to GPLC. So there is a
5	the red-line labeling, the annotated	5	preread, again, that says, "Here are the
6	labeling, and in some cases there may be	6	data, this is why we think the label
7	a supporting rationale document if it	7	needs the change," and then that's
8	if it's if it requires more	8	reviewed and approved or rejected by the
9	explanation than a simple annotation, and	9	global product labeling committee and the
10	that would include statistical figures,	10	reason for their approval or rejection is
11	tables, you know.	11	recorded in the minutes.
12	Q. What is the name of the	12	BY MR. O'BRIEN:
13	document that is the Lilly template for a	13	Q. Do you know if the GPLC has
14	label change?	14	ever rejected a proposed Cymbalta label
15	MS. JONES: Objection to the	15	change from the SRC?
16	form.	16	A. I don't know.
17		17	
l	,	l	Q. Do you know who would know
18	the USPI, for the SPC, could you be more	18	that?
19	specific?	19	A. Our GPS personnel.
20	BY MR. O'BRIEN:	20	Q. Is there a log of GPLC
21	Q. For the core data sheet.	21	rejections of labels proposals?
22	A. For the core data sheet there	22	MS. JONES: Excuse me.
22 23	A. For the core data sheet there is a template. What is it called? It's	23	Objection to the form.
22	A. For the core data sheet there	l .	

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	Page 173		Page 175
1	I don't know if there's a log that would	1	make recommendations for a different
2	provide exactly what you're asking for.	2	presentation of the data. So, yes, that
3			
	BY MR. O'BRIEN:	3	is all well within the rights to approve,
4	Q. Does the GPLC meet regularly,	4	reject, modify, ask for additional
5	like once a month, or only when there's a	5	information.
6	proposed label change?	6	Q. Now, if the GPLC were to
7	A. There's a standing meeting every	7	wordsmith the core data sheet for
8	two weeks that are cancelled if there's	8	Cymbalta, if that ever happened, where
9	no agenda items. If there's something	9	would I find that?
10	that's needed more urgently, there's an ad	10	A. That would be
11		11	
	hoc meeting scheduled.	1	MS. JONES: Hold on. Objection
12	Q. Who is on the GPLC?	12	to the form. Go ahead.
13	A. It is chaired by Tim Garnett,	13	A. That would be in the meeting
14	our chief medical officer. Other members	14	minutes.
15	include the vice president of global	15	BY MR. O'BRIEN:
16	regulatory affairs for the U.S., which is	16	Q. They would actually indicate the
17	currently Rob Metcalf. It also includes	17	language that got changed in the meeting
18	the vice president of global regulatory	18	minutes?
19	affairs international, Dr. Susan Forda.	19	A. I think so. At a minimum you
20	It includes legal. It includes quality.	20	would have the preread that went into
		1	
21	It includes medical as well as global	21	GPLC and what was ultimately approved.
22	patient safety and other functional area	22	Q. And where would the preread and
23	experts as needed.	23	the meeting minutes be located?
24	Q. And who is typically present	24	A. They do have a dedicated
	Page 174		Page 176
1	_	1	_
1	for quality and global patient safety?	1	collaboration site where that information
2	for quality and global patient safety? A. Quality is typically, at this	2	collaboration site where that information is housed.
2 3	for quality and global patient safety? A. Quality is typically, at this point in time, Nikki Mehringer. And then	2 3	collaboration site where that information is housed. Q. And that would be a
2 3 4	for quality and global patient safety? A. Quality is typically, at this point in time, Nikki Mehringer. And then from GPS, there's several different	2 3 4	collaboration site where that information is housed. Q. And that would be a collaboration site for the GPLC?
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	Page 177		Page 179
1	Q. So if the GPLC approved the	1	wording that makes sense, but then also
2	changes to the core data sheet, can the	2	looking at what are in the FDA guidance
3	label or the proposed label be submitted	3	documents as well as the CFR regulations
4	to the FDA?	4	around label content and format. And
5	A. The label would be modified	5	then we also look at similar labels to
6	according to the change in the core data	6	get a sense of the language that FDA
7	sheet and local regulations and then	7	prefers.
8	submitted to the FDA for approval.	8	*
9		9	Q. And the acronym "USPI," what does that stand for?
10	Q. Would there be a secondary	10	
11	review to ensure that the changes to the	11	ε
	core data sheet and the changes to the	12	Insert." If you refer to the U.S. label,
12	label based on the changes to the core	13	that's you know, we use those terms
13	data sheet were consistent?		interchangeably often.
14	A. Yes. There is a review	14	Q. With regard to Cymbalta, who is
15	process. I mean, whenever we make any	15	the person that's responsible for making
16	label change, there is a quality and a	16	sure that the core data sheet and the
17	content review involved with all of that	17	USPI are consistent?
18	prior to submission.	18	A. The labeling associate is
19	Q. So what would happen, say, the	19	responsible for performing that quality
20	core data sheet gets changed	20	check. Ultimately all changes to the
21	A. Uh-huh.	21	U.S. product information is approved by
22	Q and then, you know, the	22	the senior medical director for U.S.
23	department is going to change the label	23	medical.
24	to reflect the changes in the core data	24	Q. And do you have an
	Page 178		Page 180
1	sheet.	1	Page 180 understanding of who has been the labeling
1 2		1 2	
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1	MR. O'BRIEN: Yeah, let's mark	1	Q. It's my understanding there are
2	it. This is Exhibit No. 3.	2	changes in 2005, 2008, 2009, again later
3	(Plaintiff's Exhibit-3 was	3	in 2009, and then in 2012. The changes
4	marked for identification.)	4	are indicated by bold type, which you can
5	BY MR. O'BRIEN:	5	see in each one of those label changes.
6	Q. Now, Doctor, under each box it	6	A. Uh-huh.
7	kind of discusses the changes, however, I	7	Q. In preparation of your
8	think the actually language doesn't start	8	deposition today, I believe you had a
9	until it starts "discontinuation	9	conversation, was it Dr. Sara did you
10	symptoms."	10	have a conversation with somebody about
11	A. Okay.	11	the reasons for the label changes? I
12	Q. Now, there's kind of like some	12	have to check my notes.
13	under each label change there's kind	13	A. I did speak with Dr. Hoog and
14	of an entry where it kind of discusses	14	Dr. Ann Robbins about the initial
15	what the changes were. Here, let me	15	approvals. And I asked to speak with
16	, ,	16	Torkil Fredborg about changes to the SPC,
17	switch. Let me give you the marked copy.	17	which is the summary of product
18	A. Okay. So you are the bolded text are the changes from the	18	characteristics for Europe.
19		19	Q. Did you review these particular
20	previous version; is that correct?	20	• •
21	Q. Correct.	21	changes as shown in Exhibit 3 with Dr.
	MR. O'BRIEN: And, Phyllis, if	22	Hoog?
22	you have a different document that you	l .	A. No, not all of these, no. I
23	would like to use	23	really was focused on the initial
24	MS. JONES: Well, I'm not sure	24	approval.
	Page 182		Page 184
1	what you're planning to ask her. I'm	1	Q. Okay. And that's kind of what
2	going to hand her something just for her	2	I wanted to ask you. I wasn't sure if
3	reference, just to make sure that your	3	you went through the different label
4	understanding is aligned with	4	changes from 2005 to 2012 and discussed
5	THE WITNESS: Okay.	5	with Dr. Hoog the reasons for the change.
6	MR. O'BRIEN: Here, let me mark	6	A. No, she was no longer involved
7	that.	7	with Cymbalta as of early 2005.
8	MS. JONES: Okay.	8	Q. Okay. Are you able to testify
9	MR. O'BRIEN: I will mark this	9	today of why the changes were made with
10	as Exhibit No are we up to 4? I	10	regard to the changes in front of you
11	guess these are numbered?	11	from 2005-2012?
12	MS. JONES: The pages are	12	A. Yes.
13	numbered, yes.	13	Q. Can you discuss with us why the
14	(Plaintiff's Exhibit-4 was	14	changes were made? Let's begin in 2005.
15	marked for identification.)	15	MS. JONES: Just to be more
16	BY MR. O'BRIEN:	16	precise, is there a specific change that
17	Q. Here, Doctor, you can use this	17	you're interested in for 2005?
18	as your reference.	18	MR. O'BRIEN: Whatever the
19	A. Okay. Thank you.	19	bolding is. Each change
20	Q. Now, Doctor, here is a paper	20	THE WITNESS: Okay.
21	that kind of summarizes the	21	MR. O'BRIEN: is bolded.
	mat king of summanzes the	I	
22	discontinuation warning for Cymbalta	1 22	MS IONES: Olzozz Wall do
22 23	discontinuation warning for Cymbalta	22	MS. JONES: Okay. Well, do
23	since 2004.	23	you want to just state that for the
		I	•

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	Page 185		Page 187
1	record on what exactly she's explaining	1	Q. Now, in 2009, there was a
2	for you?	2	change that added tapered discontinuation
3	MR. O'BRIEN: Sure.	3	as opposed to just abrupt discontinuation.
4	BY MR. O'BRIEN:	4	Do you know why Lilly made the change to
5	Q. We're looking at the changes in	5	add "tapered discontinuation" to the label
6	the 2005 label which added MDD.	6	change as a warning?
7	A. FDA requested that change	7	A. This has always been part of a
8	because either well, either FDA or we,	8	warn this has always been a warning in
9	Lilly, put that in the legal because we	9	a label precaution or a warning. So this
10	had additional indications that were under	10	is in 2009. I don't know if that was
11	review. So it was being more specific to	11	something that we added or FDA added. We
12	specify that these trials were conducted	12	have done performed studies with abrupt
13	in patients with depression. Previously	13	discontinuation as well as tapered
14	when our label was first approved, it was	14	discontinuation. So it's possible this was
15	only reflecting depression data. So it	15	a consistency change.
16	was understood. It wasn't there was	16	Q. And you don't know if the
17	no need to call out that these were	17	impetus for this change was FDA initiated?
18	depression studies because that was the	18	A. I don't know.
19	only thing in the label at that point in	19	Q. Do you know who would know the
20	time.	20	answer to that question?
21		21	-
22		22	*
23	insomnia, diarrhea, anxiety, vertigo, and	l	department archives. It may also be in
23	hyperhidrosis were added. Do you	23	e-files.
24	understand why there was a label change	24	Q. I'm sorry, your GOLD department?
	Page 196		Dago 100
	Page 186		Page 188
1	there?	1	A. GOLD is "global operations
2	A. FDA changed the threshold for	2	labeling department."
3	reporting of specific symptoms for	3	Q. Okay.
4	discontinuation emergent adverse event	4	A. Sorry.
5	from the threshold of 2 percent or	5	Q. And then I guess later in 2009,
6	greater to 1 percent or greater.	6	the symptom fatigue was added.
7	Therefore, additional terms were added.	7	A. Yep.
8	Q. Was that did the FDA change	8	Q. Do you know if that was added
9	that threshold specifically for Lilly or	9	based on FDA requiring it or did Lilly do
10	across the industry?	10	that on their own?
11	A. I don't I can't comment on	11	A. We had additional information
12	across the industry because I haven't	12	added to our safety database and as such,
13	looked at all the labels. This was	13	the this symptom crossed the threshold
14	consistent with the fibro I believe,	14	of 1 percent or greater, so therefore it
15	with the fibromyalgia indication being	15	was added to the label.
16	approved and added to the label, at which	16	Q. Was that information, did that
17	point we had a larger database. The	17	come from a clinical trial or did it come
18	information was included from all of our	18	from some other source?
19	indications and FDA changed the threshold	19	A. This would have come from
20	from 2 percent to 1 percent, which,	20	clinical trials. That's what the you
21	again, is at a rate 2 percent or greater	21	know, this is the section of the label
22	was changed to a rate of 1 percent or	22	specifically refers to placebo-controlled
23	greater which is a more conservative	23	clinical trials.
24	threshold.	24	Q. Now, in 2012, it went from, I
<u> </u>			

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	Page 189		Page 191
1	guess, equal to 1 percent to at 1 percent	1	dizziness?
2	or greater. And then it added the	2	A. I don't believe so.
3	symptoms headache, nausea, diarrhea,	3	MS. JONES: I can tell you and
4	irritability, vomiting, and I guess it	4	answer that, it's no.
5	changed I guess fatigue, changed the	5	BY MR. O'BRIEN:
6	order	6	Q. So Lilly's labeling department
7	A. Uh-huh.	7	clearly has an indication of, you know,
8	Q of the side effects.	8	the incidence that occurs with each
9	A. So two things. Previously the	9	
10	•	10	symptom. A. Uh-huh.
11	label said, "at a rate greater than or	11	Q. Where would that information be
12	equal to 1 percent." And the wording was	12	`
	changed to "at 1 percent or greater."	13	located?
13	Those are the same. So it's actually a	l .	A. Well, the information to support
14	change of wording but not a change in	14	any label change is provided to the FDA.
15	threshold.	15	So the information around incidence of
16	Q. Do you know why it was	16	specific adverse events are included in
17	reworded?	17	the original NDA and all periodic safety
18	A. No, I don't. And then, again,	18	update reporting to the agency in the
19	we are always adding to our safety	19	annual reports. And then whenever a
20	database as new trials are completed. And	20	label change is made, it's annotated and
21	so we our database grew over time, had	21	the supporting data are provided. So FDA
22	new trials that were completed, and	22	has always had access to the specific
23	therefore the symptoms that occurred at	23	percentages of all of these adverse
24	the threshold of 1 percent or greater	24	events.
	Page 190		Page 192
1	were reflected and they're reflected in	1	Q. Thank you. I think that's all
2	the	2	I have, Doctor, with respect to that
3	Q. Rate of incidence?	3	sheet. You can put that away.
4	A. The incidence with the the	4	A. All right.
5	first one being the most frequent to the	5	Q. Now, Doctor, I just want to go
6	least frequent. That crossed that	6	over a couple of principles with you with
7	threshold.	7	regard to regulatory affairs. Is it your
8	Q. And that was my question. So	8	understanding that Lilly's regulatory
9	dizziness would be the would have the	9	department communicates with regulatory
10	highest incidence and that kind of, I	10	authorities in a truthful, responsible,
11	guess, then headache, then nausea, then	11	consistent basis?
12	diarrhea?	12	A. Yes.
13	A. Yes.	13	MS. JONES: Object. Well, hold
14	Q. When they rearranged the	14	on a second.
15	symptoms in 2012, they went from highest	15	THE WITNESS: Sorry.
16	incidence to lowest incidence, correct?	16	MS. JONES: Give me a chance
17	A. Uh-huh.	17	
18		18	to object. Objection to form. You may
19	Q. Was it always in that order	19	answer. BY MR. O'BRIEN:
	before or is that something that they	l .	
20	just decided to do in 2012?	20	Q. And does Lilly's regulatory
21	A. No, it's always been that	21	department feel that that's important?
22	order, that principle for the order, yes. Q. Anywhere in that chart does it	22 23	MS. JONES: Objection to the form.
	II Ansasanara in that chart does it	. / -<	TOPM
23	· ·	l .	
23 24	tell the percentage of incidence for	24	A. Yes, absolutely.

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1	BY MR. O'BRIEN:	1	determination of whether or not it impacts
2	Q. And does Lilly think it's	2	the core data sheet, or if it's a
3	important that a company be truthful in	3	regional label change only and why, if
		1	
4	what they tell the FDA?	4	needed, it undergoes GPLC review and
5	MS. JONES: Same objection.	5	approval before implementation locally.
6	A. Yes.	6	Q. And does Lilly believe it's
7	BY MR. O'BRIEN:	7	important to provide accurate and complete
8	Q. To your knowledge, has anybody	8	information in their package inserts?
9	in your department ever been untruthful to	9	A. Yes.
10	the FDA about Cymbalta?	10	Q. And that would be accurate and
11	MS. JONES: Objection to the	11	complete information, correct?
12	form.	12	MS. JONES: Objection to the
13	A. Not to my knowledge, no.	13	form.
14	BY MR. O'BRIEN:	14	A. We work on labels in
15	Q. Now, Doctor, we just just to	15	conjunction with FDA. A label is a
16	circle back, dealing with the label change	16	concise, succinct representation of all
17	of Cymbalta. All those label changes	17	the available data on the molecule.
18	would have happened with the product team,	18	There is judgment that is called in to
19	correct?	19	play when discussing the information that
20		20	is included in the label between FDA and
	MS. JONES: Hold on. Objection	21	
21	to the form; vague.	22	sponsor company.
22	A. I mean, the team has changed	1	BY MR. O'BRIEN:
23	over time, but the fundamental functions	23	Q. Do you think it's Lilly's
24	involved with any label change remain the	24	responsibility to provide accurate and
	Dago 104	l	Page 106
_	Page 194	_	Page 196
1	same, medical, GPS	1	complete information in package inserts
2	same, medical, GPS MS. JONES: I'm sorry. Could	2	complete information in package inserts regarding Cymbalta?
2 3	same, medical, GPS MS. JONES: I'm sorry. Could you read the question back, please?		complete information in package inserts regarding Cymbalta? MR. O'BRIEN: Objection to the
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	Page 197		Page 199
1	Q. Is that a "yes," do you think	1	MS. JONES: Objection to the
2	it's Lilly's responsibility to provide	2	A. No.
3	accurate and complete information in their	3	MS. JONES: Objection to the
4	package inserts concerning Cymbalta?	4	form.
5	MS. JONES: Objection to the	5	BY MR. O'BRIEN:
6	form. You may answer.	6	Q. Do you think it would ever be
7	A. We provide accurate and complete	7	appropriate for Lilly to mislead
8	information to the FDA. The label is a	8	physicians or patients about the risks of
9	distillation of the information, so it	9	discontinuating [sic] Cymbalta in their
10	does not include every piece of	10	package inserts?
11	information that we have about Cymbalta.	11	MS. JONES: Same objection.
12	If we did that, it would be five million	12	A. No.
13	pages long. That's where we work with	13	BY MR. O'BRIEN:
14	the agency to represent the safety	14	Q. Doctor, can you take us through
15	concepts and to provide the information	15	the different types of warnings that are
16	that a prescriber needs to safely	16	on a USPI?
17	administer the drug. It warns of the	17	A. Yes. There is FDA guidance
18	potential adverse effects, when they're	18	around warnings, precautions, and adverse
19	observed, what to do about them.	19	reactions that can be referred to. The
20	MR. O'BRIEN: Move to strike as	20	most current version of the USPI in the
21	nonresponsive.	21	sense of FDA changed from to a
22	MS. JONES: I'm going to oppose	22	physician's labeling rule format several
23	that motion. Go ahead.	23	years ago, 2007 time frame. So now
24	BY MR. O'BRIEN:	24	there's 17 sections of the label, one of
	Page 198		Page 200
1	Q. So Lilly doesn't think that	1	which is titled "warnings and
2	they have the responsibility to provide	2	precautions."
3	complete information in their package	3	Our warning regarding
4	inserts concerning Cymbalta?	4	discontinuating discontinuing treatment
5	MS. JONES: Objection;	5	with Cymbalta is included in that warning
6	mischaracterizes the testimony.	6	section.
7	A. No, that's not accurate. I'm	7	Q. Is there a higher level warning
8	trying to explain to you the process by	8	than a warning and precaution?
9	which we work with FDA to approve	9	A. Yes, there's a boxed warning.
10	labeling to informed prescribers.	10	Q. Is there any other elevated
11	BY MR. O'BRIEN:	11	warnings other than warnings and
12	Q. So Lilly does provide complete	12	precaution other than box warnings?
13	information in their package inserts	13	MS. JONES: Objection to the
14	concerning Cymbalta?	14	form. Go ahead.
15	MS. JONES: Objection; asked	15	A. In general, there is a
16	and answered, mischaracterizes the	16	contraindication. There's a
17	testimony. If you want to answer it	17	contraindication and a boxed warning.
18	again, go ahead.	18	BY MR. O'BRIEN:
19	A. There's no difference in my	19	Q. Is there a bold warning?
20	answer.	20	A. A boxed warning is a bold
21	BY MR. O'BRIEN:	21	warning.
22	Q. Do you think it would be ever	22	Q. So it is a black-box warning.
23	appropriate for Lilly to misrepresent data	23	Is there also a bold warning?
	1 F - F	~	is mere also a oold mailing:
24	about Cymbalta in their package inserts?	24	
24	about Cymbalta in their package inserts?	24	A. No, they're the same. Those

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	Page 201		Page 203		
1	terms are used interchangeably.	1	their drugs at any time subject to later		
2	Q. If at any time Eli Lilly wanted	2	FDA approval?		
3	to heighten their warning for Cymbalta	3	A. Yes.		
4	discontinuation syndrome, is there anything	4	Q. Can you tell us the process		
5	that would prevent that?	5	about how a drug company goes about		
6	A. We can we have the ability	6	giving a stronger and additional warning		
7	to propose different label changes to the	7	about their drug?		
8	agency, which would include the elevation	8	MS. JONES: Objection to the		
9	of a warning to a boxed warning. That is	9	form.		
10	always subject to FDA review and approval.	10	BY MR. O'BRIEN:		
11		11	Q. You mentioned there's a CBE?		
	Q. So you can add a warning or	12	`		
12	strengthen a warning without FDA approval?	13			
13	MS. JONES: Objection;	14	Q. Can you explain that process?		
14	mischaracterizes the testimony.	1	A. Whenever a company makes a		
15	A. A change's being effective	15	change to a label, it is submitted either		
16	label change based on safety can be made	16	as changes being affected or as a prior		
17	to strengthen or elevate a warning,	17	approval label supplement. There are		
18	however, that is always subject to FDA	18	certain regulations about what can be		
19	approval.	19	changed under the CBE regulations versus		
20	BY MR. O'BRIEN:	20	prior approval. There is guidance on		
21	Q. But they could change the	21	that. In any situation, whether it's CBE		
22	warning and get that out into the public	22	or prior approval, the proposed label		
23	without FDA approval at first, correct?	23	change as well as the rationale for the		
24	MS. JONES: Objection to the	24	change are provided and are subject to		
	Page 202		Page 204		
1	form. Who is "they"?	1	FDA approval.		
2	A. Who is the "they"?	2	Q. Do you agree that Lilly has the		
3	BY MR. O'BRIEN:	3	right to tell doctors and patients about		
4	Q. Do you not have an	4	a stronger warning for Cymbalta		
5	understanding of who "they is?	5	discontinuation syndrome at any time?		
6	A. No, I don't.	6	MS. JONES: Objection to the		
7	Q. If Lilly wanted to strengthen	7	form.		
8	the warning for Cymbalta discontinuation	8	A. We provide information to		
9	_ · · · · · · · · · · · · · · · · · · ·	l ,			
	syndrome, could Lilly do so and distribute	9	prescribers and patients in conjunction		
10	syndrome, could Lilly do so and distribute that warning before they obtained FDA	10	prescribers and patients in conjunction with our approved labeling.		
	syndrome, could Lilly do so and distribute that warning before they obtained FDA approval?		prescribers and patients in conjunction with our approved labeling. BY MR. O'BRIEN:		
10	that warning before they obtained FDA	10	with our approved labeling. BY MR. O'BRIEN:		
10 11	that warning before they obtained FDA approval? A. There is a mechanism called	10 11	with our approved labeling. BY MR. O'BRIEN: Q. But if Lilly thought it was		
10 11 12 13	that warning before they obtained FDA approval? A. There is a mechanism called "changes being affected" label supplement	10 11 12 13	with our approved labeling. BY MR. O'BRIEN: Q. But if Lilly thought it was really important to have a stronger label		
10 11 12 13 14	that warning before they obtained FDA approval? A. There is a mechanism called "changes being affected" label supplement that can be submitted to the agency at	10 11 12 13 14	with our approved labeling. BY MR. O'BRIEN: Q. But if Lilly thought it was really important to have a stronger label for Cymbalta discontinuation syndrome,		
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10 11 12 13 14 15 16 17 18 19 20 21 22	that warning before they obtained FDA approval? A. There is a mechanism called "changes being affected" label supplement that can be submitted to the agency at the same time that a company implemented a label change. It is still subject to FDA approval and can change based on their review. There also, when you are making changes to a warning, because it affects the highlights section of the USPI that's subject to prior approval by regulation.	10 11 12 13 14 15 16 17 18 19 20 21 22	with our approved labeling. BY MR. O'BRIEN: Q. But if Lilly thought it was really important to have a stronger label for Cymbalta discontinuation syndrome, that's something that they could do if they wanted to, correct? A. They MS. JONES: Objection hold on. Objection to the form; asked and answered. Go ahead. A. Yes. BY MR. O'BRIEN:		

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	Page 209		Page 211		
1	(Plaintiff's Exhibit-5 was	1	THE WITNESS: Yes. When you		
2	marked for identification.)	2	asked about the untitled letters that		
3	(Plaintiff's Exhibit-6 was	3	we've received for Cymbalta, one of them		
4	marked for identification.)	4	actually did reference and call out that		
5	THE WITNESS: I need to look	5	the safety information was not adequate		
6	at it just for a second.	6	with regards to discontinuation emergent		
7	MR. O'BRIEN: Okay.	7	adverse events. So I misspoke. However,		
8	THE WITNESS: And then I will	8	that was the untitled letter in which FDA		
9	give it back to you.	9	had mistakenly not included the important		
10	So in May 17th of 2007,	10	safety information which does address		
11	Lilly submitted a changes being affected	11	discontinuation emergent adverse events.		
12	labeling supplement for Cymbalta that	12	So that was the letter that was		
13	indicated one of the changes that it was	13	essentially rescinded by FDA.		
14	making, that Lilly was making voluntarily,	14	MS. JONES: And that's the		
15	was to change the threshold from 2	15	September 2010 letter that's publicly		
16	percent to 1 percent or greater when	16	available on the FDA's website. I'd also		
17	reporting discontinuation emergent adverse	17	like to mark as Exhibit No. 7 defendant's		
18	events for Cymbalta, and that was done	18	responses and objections to plaintiff's		
19	based on updates in the Periodic Safety	19	.30(b)(6) notice regarding regulatory		
20	Report No. 4, that covered the period of	20	affairs. This is the copy that's		
21	February to August 2006. So affectively,	21	captioned for the Herrera matter, but our		
22	Lilly made the threshold for reporting of	22	objections and responses are the same as		
23	discontinuation emergent adverse events	23	to each of the cases in which the		
24	more conservative at that time.	24	regulatory affairs notice has been served		
	Page 210		Page 212		
1	The second one is a CBE	1	and/or cross-noticed. That will be		
2	labeling supplement change that Lilly	2	Exhibit No. 7.		
3	provided on August 25th, 2007, among which	3	(Plaintiff's Exhibit-7 was		
4	one of the changes was to include	4	marked for identification.)		
5	"following abrupt or tapered	5	MS. JONES: We have no		
6	discontinuations" or adding "or tapered"	6	additional questions.		
7	and the rationale for that change was, I	7	MR. O'BRIEN: Thank you.		
8	had sort of halfway remembered it, but	8	THE VIDEOGRAPHER: This		
9	not completely.	9	concludes the deposition of Dr. Christine		
10	When we filed for approval of	10	Phillips. The time is 12:46 p.m., and		
11	the indication for fibromyalgia in 2007,	11	we're off the record.		
12	we had expanded the number of studies in	12	(Time noted: 12:46p.m.)		
13	our database that utilized both abrupt and	13	FURTHER THE DEPONENT SAITH NOT		
14	tapered discontinuation of Duloxetine,	14	CHRISTINE PHILLIPS, Ph.D.		
15	therefore we updated the label to reflect	15			
16	that.	16			
17	MS. JONES: And just for the	17			
18	record, can I see that one back too?	18			
19	Exhibit No. 5 is Bates numbered CYM	19			
20	.01111111, seriously. And Exhibit No. 6	20			
21	is Bates numbered CYM 01113163. And Dr.	21			
22	Phillips had one other clarification that	22			
23	she wanted to make to her earlier	23			
24	testimony.	24			
	costinony.		·		

Page 213 1 STATE OF INDIANA 2 **COUNTY OF HAMILTON** 3 I, Amy Doman, RPR, CRR, CSR 4 No. 10-R-3022, Notary Public in and for the County of Hamilton, State of Indiana, 5 at large, do hereby certify that CHRISTINE 6 7 PHILLIPS, Ph.D., the deponent herein, was 8 by me first duly sworn to tell the truth, 9 the whole truth, and nothing but the truth in the aforementioned matter; 10 That the foregoing deposition 11 12 was taken on behalf of the Plaintiff, at the offices of COHEN & MALAD, LLP, One 13 Indiana Square, Suite 1400, Indianapolis, 14 15 Indiana, on Friday, July 18, 2014, pursuant to the Indiana Rules of Trial 16 17 Procedure; 18 That said deposition was taken down in stenograph notes and afterwards 19 20 reduced to typewriting under my direction, 21 and that the typewritten transcript is a true record of the testimony given by the 22 23 said deponent; and that signature was 24 requested by the deponent and all parties Page 214 1 present; 2 That the parties were 3 represented by their counsel as aforementioned. 4 5 I do further certify that I am a disinterested person in this cause of 6 7 action, that I am not a relative or 8 attorney of either party or otherwise 9 interested in the event of this action, 10 and that I am not in the employ of the 11 attorneys for any party. IN WITNESS WHEREOF, I have 12 hereunto set my hand and affixed my 13 14 notarial seal this day of , 2014. 15 16 Amy Doman, RPR, CRR, CSR No. 10-R-3022 17 Notary Public My Commission Expires: October 1, 2017, 18 19 Residing in Hamilton County, Indiana 20 21 22 23 24