UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
CAUSE NO. 2:13cv2700-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.

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THE VIDEOGRAPHER: We are now on the video record. This is the video deposition of Christine Phillips taken by the plaintiff in the matter of Sidney Carter versus Eli Lilly & Company, in the United States District Court, Central District of California, Case No. 2:13cv2700-GHK.

This deposition is being held at the law offices of Cohen & Malad, One Indiana Square, Suite 1400, Indianapolis, Indiana, on Friday, July 18th, 2014, at 8:56 a.m.

I am Sara Williams, the videographer. The court reporter is Amy Doman. We represent James DeCrescenzo Reporting at 1880 John F. Kennedy Boulevard, Philadelphia, Pennsylvania. Counsel will now introduce themselves and state whom they represent.

MR. O'BRIEN: Kevin O'Brien on behalf of plaintiffs.

MS. JONES: Phyllis Jones on behalf of Eli Lilly and Company.

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 that.

MR. O'BRIEN: Okay.

BY MR. O'BRIEN:

Q. Hello, Dr. Phillips.

A. Hello.

Q. We had an opportunity to introduce each other earlier today. My name is Kevin O'Brien. I represent the plaintiffs in this action against Eli Lilly.

Could you please state your full name?

A. Christine Ann Phillips.

Q. And would you provide me your address?

MS. JONES: I'm sorry, do you want her work address?

BY MR. O'BRIEN:

Q. Business address would be fine.

A. Okay. Lilly Corporate Center, Drop Code 2653, Indianapolis, Indiana, .46285.

Q. And your current employer?

A. Eli Lilly.

Q. And your current title?

A. Advisor, global regulatory

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 somewhere that you're aware of?

A. Yes.

Q. Where do they exist?
A. I believe Lilly legal has them as well as Pepper Hamilton, which was the external counsel on that case.
Q. And that was my next question. In that matter you were represented by Pepper Hamilton?
A. Yes.
Q. Do you remember the name of the counsel from Pepper Hamilton that you were represented by?
A. Andy Kantra and John, began with a B, his last name.
Q. Are they local counsel?
A. No, they're based out of Philadelphia, I believe.
Q. I know you probably understand the basic instructions of depositions. And I just want to go over them again with you. I'm just going to ask that you let me finish my question before you provide a response. And I'll extend the same courtesy. If you do not understand my question, just let me know and I'll

repeat it or rephrase it as necessary. If at any time you need to take a break, please let me know. The only caveat is that I'd ask you to finish your question if there's any pending questions. Does that sound fair?
A. Yes.
Q. Are you on any medication or is there anything that would impair your judgment today?
A. No.
Q. I'd like to mark the 30(b)(6) notice for regulatory affairs. Here you go, Dr. Phillips. Will you take a chance to review that document.
(Plaintiff's Exhibit-1 was marked for identification.)
MS. JONES: Do you have a copy for us, Kevin?
MR. O'BRIEN: Yes, sorry, Phyllis.
MS. JONES: No problem.
MR. O'BRIEN: I wasn't expecting so many attorneys.

BY MR. O'BRIEN:
Q. Dr. Phillips, let me know when you've finished taking a look at the document.
A. Yes.
Q. Have you seen this deposition notice before?
A. I have.
Q. This deposition notice relates to areas of regulatory issues. Are you familiar with that area at Eli Lilly?
A. Yes, I am.
Q. Would you mind turning to page .8.
A. I'm there, yes.
Q. This begins a list of 11 topics that you have been designated by Eli Lilly to testify in the company's behalf. Would you please take a moment to review them if you haven't done so already.
A. I have already done so.
Q. Are you prepared to address each and every one of the topics addressed on page .8 and 9 of the

deposition notice?
A. Yes, I am.
MS. JONES: And let me just note for the record, Counsel, that Dr. Phillips is testifying today subject to the written objections and responses that we served on the 30(b)(6) notices on, I think, May the 23rd, 2014, and I'll mark those at the end of the deposition.
BY MR. O'BRIEN:
Q. Do you understand you're here as a 30(b)(6) deponent?
A. I do.
Q. And you understand that you're giving testimony as the voice of the corporation?
A. Yes, I do.
Q. And you're not appearing here -- strike that.
You're not testifying here individually as Dr. Christine Phillips. Do you understand that?
A. Yes, I do.
Q. And do you understand by being

designated by Eli Lilly, it requires you to testify about all information known or reasonably known to Eli Lilly?
A. Yes.
Q. Are you the person with the most knowledge at Eli Lilly regarding regulatory affairs?
MS. JONES: Objection to the form. You can answer.
A. Well, there are a number of folks in our regulatory affairs department. I am fairly experienced, so I know quite a bit about it.
BY MR. O'BRIEN:
Q. Would you mind providing me some names of other people who have a strong knowledge base of regulatory affairs in your department?
MS. JONES: Same objection.
A. Our vice president, Dr. Robert Metcalf. Are you referring specifically to U.S. regulatory affairs or --
BY MR. O'BRIEN:
Q. Let's start with U.S. regulatory

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 structure of all divisions of defendant wherein employees deal with regulatory

agencies concerning Cymbalta."
A. Okay.
Q. Can you give me the names of people that are most knowledgeable in that area?
A. Could you clarify? Are you asking about the divisions within regulatory?
Q. Yes, individuals.
A. Okay.
Q. Individuals within regulatory.
A. Okay. At present day or --
Q. Present day.
A. Present day. Okay. Well, I am the regulatory advisor responsible for Cymbalta currently in the U.S., although I am moving into a new position shortly. I report to Carl Garner, who is the senior director for the business -- bio-medicines business unit, which includes neuroscience. He reports to Dr. Robert Metcalf, who is the vice president of U.S. regulatory affairs. The other people within regulatory that work on Cymbalta include

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.
A. Okay.
Q. "Testimony on the name, address,

education, training, selection, job title, and responsibility of defendant's employees whose job includes dealing with regulatory agencies concerning Cymbalta."

Can you list other individuals that would have knowledge regarding that topic?

A. Not beyond the ones I just listed for you. There is one person I did not include that -- a regulatory associate, Victoria Papademas is also involved. She works with our registration group who actually submits a lot of the electronic documents to FDA.

Q. Would you spell Victoria's last name?

A. P-a-p-a-d-e-m-a-s.

Q. And would all the individuals that you listed under Topic 1 be knowledgeable on Topic 2?

A. Yes.

Q. Can you turn to -- sorry. With regard to Topic No. 3.

A. Uh-huh.

Q. "Testimony to identify written standard operating procedures pertaining to 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 operating procedures pertaining to defendant's regulatory affairs, who would

you direct me to?

A. Well, pretty much anybody in regulatory affairs will have knowledge of these written procedures. That's part of our training program, which we have a pretty robust training program. We do have quality directors that oversee that area.

Q. How about names of individuals that were responsible for creating those standard operating procedures or that are responsible for training people on those standard operating procedures?

A. There are a variety of folks. We have people in our quality group who oversee and then different subject matter experts contribute to those policies and procedures. They are ultimately approved by Robert -- Dr. Robert Metcalf, our vice president, or senior directors, such as Nancy Allen, who is responsible for operations and labeling within U.S. regulatory affairs, Nikki Mehringer oversees the quality systems within

regulatory.

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 advisory committee hearings held by the

FDA, if any, concerning Cymbalta and all issues involved in such hearings."

I want to start with individuals who may have attended or prepared for the attendance at an advisory committee meeting related to Cymbalta. Can you list those names and individuals and their titles for me, please?

A. Yes. Well, I am the subject-matter expert within our group for preparing for advisory committee meetings for FDA. There are other individuals who serve in that capacity. Jane Amos, she is with our submission, approval, and expert network, as well as Shelly Rickert, who is also involved in that capacity. I was involved with the team that was preparing for Cymbalta advisory committee meeting, although I was there as a consultant around process for that particular advisory committee meeting. So then within Lilly was a team of individuals working on Cymbalta that were actually at the FDA advisory committee

meeting.

Q. Can you identify that team and their titles?

A. Yes, Dr. Robert Baker was the executive sponsor for the team. Dr. Michael Robinson was one of the main -- he was the main speaker at the advisory committee meeting. There was Dr. Vladimir Skljarevski, and I'm probably pronouncing that incorrectly, and, no, I cannot spell it. He was our safety physician. And then we had an external expert, who I don't remember that individual's name. And then Claire Farrand was the project manager coordinating the internal team and there were several others involved.

Q. How do you spell Claire's last name?

A. F-a-r-r-a-n-d.

Q. Okay.

A. And then Matthew Kuntz was the regulatory scientist lead on Cymbalta at that time.

Q. And how do you spell his last

name?

A. K-u-n-t-z.

Q. And what is Michael Robinson's title?

A. He was a senior medical director for Cymbalta.

Q. Do you have an understanding of how many advisory committee meetings were held for Cymbalta?

A. Yes, there was only one.

Q. And would you go through Claire's title and Matthew's title?

A. Okay. Matthew was a principal consultant within regulatory affairs. Claire, I think she was -- her title is senior project management advisor.

Q. Are all the individuals you just listed still with the company?

A. No, they are not.

Q. Who is still there and who is not?

A. Dr. Baker is still there. Dr. Robinson is not. Dr. -- Dr. Vladimir Skljarevski is there, Claire Farrand is

there, Matt Kuntz is not.

Q. With regard to Dr. Robinson, Matt Kuntz, do you know where they -- where they went?

A. I don't know where Dr. Robinson is. I know Matt Kuntz is with AbbVie.

Q. Do you know where he is -- where he is physically located?

A. I believe in the Chicago area.

Q. And you mentioned you didn't -- not know where Dr. Robinson went, correct?

A. That's correct.

Q. Now, the titles that you reference attached to these individuals, do they -- the ones that are still at Lilly, do they still have the same role and job responsibilities?

A. Claire does. Dr. Robert Baker is now -- I think he's senior vice president over global patient safety. So that is the change from that position. And Vladimir, I believe, has been promoted but is fundamentally in the same role.

Q. I'll go back and ask more

questions regarding the advisory committee 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 Cymbalta."
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 scientists, such as myself, that were involved with the development of Cymbalta.
Q. Could you list some of those names?
A. Yes, Matt Kuntz, Isabelle Murray, Bryan Boggs, Ann Sakai now Robbins, Sharon Hoog.
MS. JONES: Hoog is H-o-o-g.

A. And then Richard Hoffman.
BY MR. O'BRIEN:
Q. Richard Hoffman. Doctor, do you know if you recently put together a list of those people that were involved in the development of Cymbalta?
A. Yes.
Q. Do you have the list available with you today?
A. I do not.
Q. With all the names that you just mentioned, could you go back and tell me their titles and their job responsibilities?
A. They -- so our job titles do vary by level. And so I'm not sure if I can get all of them correct.
Q. It doesn't have to be exact.
A. Okay.
Q. Just --
A. Isabelle is a principal consultant.
Q. During what time period was this?

A. She only supported Cymbalta for a short period of time. So let me go backwards if that would help. So I've been responsible for Cymbalta since August 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 six months. And then prior to that was Bryan Boggs, he had Cymbalta for several years, including through the chronic pain submission and approval. So I think he goes back quite a ways. And then Ann Sakai and Sharon Hoog were responsible for the molecule in the early 2000s through -- 2004 for Dr. Hoog and up until the transition to Bryan for Dr. Sakai.
Q. Is Dr. Hoog still with the company?
A. She is.
Q. Do you know what her current role is now?
A. Yes, she is a senior physician with global patient safety.

Q. Does she still have any responsibilities as it relates to Cymbalta?
A. She does not.
Q. Would you take a look at Topic 7 now. "Testimony on communication between the FDA and defendant concerning Cymbalta advertisements, promotional materials, or communications to the public or physicians."
A. Yes.
Q. And I think you provided me the name of the person that's responsible for advertising earlier.
A. Yes.
Q. Will you --
A. Currently just --
MS. JONES: I'm sorry, Dr. Phillips. When you say "responsible for advertising," you mean in the global regulatory affairs context?
MR. O'BRIEN: Correct.
A. Currently that's Josephine Secnik.

BY MR. O'BRIEN:
Q. Do you know who reports to Josephine?
A. I don't believe she has anybody that reports to her directly.
Q. So she handles all the Cymbalta advertisements on a day-to-day basis?
A. Yes, and currently there's none or very little.
Q. Is that her only job --
A. No, it's not.
Q. -- or is she -- and what are her responsibilities as they relate to Cymbalta advertisements?
A. In that role, the GRAUS advertising and promotional, she is -- would -- is -- excuse me -- is responsible for reviewing any promotional materials that are created by our marketing department to ensure compliance with our SOPs, with FDA regulations, consistency with our label, and she would be part of our formal review process that includes regulatory, medical, and legal.

Q. When you mean "formal review process," is it my understanding that Josephine takes a look at the label from marketing to see if there's -- if it needs to be changed or altered and then there is a team that kind of does a final approval?
MS. JONES: Objection to the form. Go ahead.
BY MR. O'BRIEN:
Q. She's going to object from time to time. If she doesn't want you to answer, believe me, she'll let you know.
A. Yes. Josephine, in her role, that role is not to change the label. The role is to ensure compliance with the label and that the marketing materials are appropriately in compliance. And then, also, she is responsible for regulatory submissions to the office of prescription drug -- OPDPM. I can't remember all the words. But they are the division of FDA that is responsible for promotional review.

Q. Just to understand the process, once Josephine receives a prospective advertisement from the marketing department, she takes a look, she sees if it's compliant or not. If she makes a determination if it's compliant, is there another review that goes on before it gets submitted to the office of prescription drugs?
A. Yes. She will make the initial determination, suggest revisions, if necessary, to bring the piece into compliance, and then it does go through a legal, medical, regulatory review that the acronym is PCA, it's prepare, create, and advise. I apologize. But there is a formal process. And that is the ultimate approval prior to submission to the agency and implementation of the materials.
Q. Now, part of the PCA --
A. Yes.
Q. Lilly loves acronyms.
A. We do.
Q. What individuals would

participate in a PCA review?
A. It will include the three functions that I listed; regulatory affairs, including the senior director, Dr. Michele Sharp; legal, I don't know -- I believe -- I'm not sure who the legal representative is on the group. But there would be at least one lawyer involved with that review that's familiar with the product; and then medical would include the brand medical, U.S. medical, currently the senior director for U.S. medical is Dr. Elizabeth Brunner.
Q. And does Dr. Elizabeth Brunner have responsibilities for Cymbalta?
A. Yes, as she is the U.S. affiliate responsible -- senior medical director.
Q. Do you know who held Josephine's position before she did?
A. I believe, and I'm not entirely positive, it was Dr. John Camacho.
Q. Do you have a time -- do you have a time frame of when he held that

position?
A. Not an exact one. I'd say, maybe 2010 to 2013, but I'm guessing honestly.
Q. Do you have any idea who held the position before John?
A. I don't.
Q. Is Josephine a physician?
A. No, she's not.
Q. Do you understand what her background is?
A. I don't.
Q. Once it goes through the PCA review, who is the individual that's responsible for submitting the advertisement to the office of prescription drugs?
A. It would be Josephine in this case.
Q. And what was the title of her position?
A. She's a principal consultant.
Q. And what department was that?
A. Global regulatory affairs-United

States, advertising and promotions.
Q. Are you aware of a contact 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 the foundation for all local labeling, which would include in this case the

United States prescribing information or, for example, the European summary product characteristics. The core data sheet is created by the Cymbalta team, which would include physician, statistician, global patient safety, regulatory affairs, labeling.
Q. Just to slow you down.
A. Okay.
Q. Can you explain to a jury what a "core data sheet" is?
A. Okay. It is a document, it's created in compliance with CIOMS' guidance. It's an international council that provides guidance on the structure of such documents. And it includes all the -- all the safety information around the product as well as efficacy information. And just to clarify, when I say "all," it is succinct, it is -- you know, it captures all the safety concepts associated with the product and it is the foundation for all local labeling. So it's the core but then the local labeling

implements the core according to their local regulations. So there may be 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.
Q. Is the global -- strike that.
Where is the global labeling

team located?
A. The global team is -- are located here in Indianapolis at Lilly Corporate Center.
Q. Who -- strike that.
Do you know the individuals that are on the global labeling team as it relates to Cymbalta?
A. Currently, that is Sara Mescher.
Q. And what's her position?
A. I believe she is a principal consultant.
Q. And who else would be on that team?
A. She -- Barbara Brown is the assistant that works on Cymbalta labeling as well.
Q. Is she an assistant and principal or just an assistant?
A. I don't know her exact title. It is -- I think she might actually be an associate. She is at a lower level than Sara.
Q. Okay. Is there anybody else on

that team?
A. No.
Q. Back -- if we go back in time to 2004 when Cymbalta was first on the market, would it have been a much larger team?
A. The product team, which by that I mean the Cymbalta product team, which is cross-functional, yes, the team was larger at that point in time.
Q. Okay. As far as individuals or teams responsible for labeling with Cymbalta, you have the global labeling team, which has Sara and Barbara, Barbara Brown and Sara Mescher?
A. Mescher.
Q. Mescher. Are there any other teams that are responsible for Cymbalta labeling?
A. No. I mean, it's -- when I -- it's hard because we use teams in multiple different ways. So we have a core team or a product team of which Sara is a member. So there's not really a

labeling team per se. It's individuals from labeling who are part of the team, just like there's individuals from regulatory, from medical, from patient safety.
Q. Fair enough. What is a Cymbalta product team?
A. The product team, it is a cross-functional group that's responsible for developing Cymbalta and the clinical program, conducting the clinical program, the approval of the initial indication as well as subsequent indications as well as the marketing aspects of the product. So because we're no longer actively developing Cymbalta, and the drug is off patent, that team is much smaller. We really are not doing any advertising at this point in time. So by virtue of that, the team is smaller now than it would have been in 2004.
Q. And does the Cymbalta product team, does that fall under regulatory?
A. No, like I said, it's a

cross-functional --
Q. Oh, cross-functional.
A. -- team and ultimately, you know, so their members, it's a matrix organization, so we have a product team leader that reports up through the vice president of the business unit and people come from different functions. So, for instance, me in regulatory, I report up through the regulatory department. I don't report up to the product team. And that would be true for the various functions, statistics, project management.
Q. Fair enough. Could you give me a picture of the Cymbalta product team now as far as the individuals, the departments that are involved and what those individuals' responsibilities are with regard to the product team? And then we'll go back in time and see how it's different.
A. Okay. Well, there's a global senior medical director, that is Rodrigo Escobar. We have a chief operating --

Q. Sorry, I just want to go one by one what they do.
A. Okay. Sorry. He -- actually, we have a slightly different structure now at Lilly than we did back in 2004. So Dr. Escobar is responsible for the neuroscience platform.
Q. And what does that mean?
A. That means all of the approved neuroscience products, so, for instance, that would include Cymbalta, Zyprexa, Prozac, Symbyax, Strattera.
Q. And when we talk about the Cymbalta product team, let's talk about how -- what specifically they do for Cymbalta.
A. Okay.
Q. Just to streamline things.
A. There is no Cymbalta product team anymore.
Q. Okay.
A. Because of the structure that we currently employ, it's the neuroscience platform.

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 Cymbalta, but they also likely have other products. And that's true for most functions.
Q. Okay. So how about we go through it the way you originally wanted to do it.
A. Okay. I'm sorry. I'm not sure what you wanted.
Q. Okay. You had the global science and medical officer, right, with Rodrigo Escobar?
A. He is the senior medical director from a global --
Q. Senior medical director. And then let's go next with the next --
A. Okay.
Q. -- department individual and what they do.
A. Okay. Laura Cox-Heuer, H-e-u-e-r, is the chief operating officer for the neuroscience platform. So she has the same responsibilities, if you will, as Dr. Escobar. I mean, she functions in a different capacity. She's kind of like the project manager in charge, making sure things get done as needed.
Q. And what are her day-to-day responsibilities on that team?
A. It's operations, making sure things get done that need to get done, that clinical trial, if there are issues, that they're getting addressed. We have regulatory responses to agencies, getting the right personnel in the room, the right resources to get that done.
Q. What type of -- can you give me examples of what type of regulatory responses would need to take place on that team?
MS. JONES: Objection to the form. Go ahead.

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 data sheet, to look at our label to see if that was consistent with our core data sheet, which it was. This has been a labeled warning for Cymbalta for some time. Actually, it's a contraindication. So what FDA was doing was fundamentally harmonizing the language across multiple labels. So that team reviewed that, responded to FDA accordingly.
BY MR. O'BRIEN:
Q. And other than Rodrigo and Laura, who are other members on the team?
A. We do have various project managers, including Dan White. He's the primary project manager I deal with on regulatory matters. I have a colleague in European regulatory, Beth Heaviside.

Q. And what are Dan White's day-to-day responsibilities on that team?
A. He's an extension of Laura and is really -- you know, he's scheduling meetings, getting people in a room, getting timelines together, making sure that the individual projects are getting done, an example of which is just the angle-closure glaucoma that I just mentioned.
Q. And then there's some -- you were about to mention some European counterparts?
A. Yes, European regulatory, that is Beth Heaviside, H-e-a-v-i-s-i-d-e. Because we do like global interactions. Statistics would be Na Cai, C-a-i, and Yoko Tanaka, T-a-n-a-k-a. We have lots of -- Iris Ferchland-Howe is our clinical project manager. She is based in Belgium. Do you want me to spell that too? Iris is I-r-i-s, her last name is F-e-r-c-h-l-a-n-d hyphen H-o-w-e.
Q. And, Doctor, what type of --

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.
A. That's correct.
Q. Is there some sort of

interaction between the product team and the drug safety surveillance team?
A. Yes.
Q. And can you give me an idea of what type of interaction there is?
A. Okay. Well, as I was just mentioning with the right-to-operate documents, that is the team working together with our safety organization. The safety -- the safety team for Cymbalta, they are responsible for literally the day-to-day surveillance of the safety, what's out there in the literature, what has been reported to Lilly, what has been reported to FDA to continuously monitor and they do this on a global basis.
Then when we do periodic reporting, so we have annual reports and we have also have periodic reports that are due at different points in time during the year. They lead that effort, but that involves, you know, folks from regulatory, from medical, from statistics

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.
Q. Is there a regular scheduled platform team meeting that occurs?

A. Yes. There are operation team meetings that are held every other week. There is a broader kind of management team meeting, which is about once a month, that's called G 10, but that's across the entire neuroscience platform, it's not just Cymbalta. And then there are ad hoc team meetings as needed for various topics.

Q. What types of issues get discussed typically at a G 10 meeting?

MS. JONES: Hold on just a second. Let me just lodge an objection. We've been outside of the scope of the notice for the last several questions, I think. So to the extent that you're going to pursue this, Dr. Phillips can answer the questions, but she's doing it in her capacity as an individual, not on behalf of the company. Go ahead.

A. Okay. We have several post-marketing commitments for Cymbalta. So we update the G 10 on the status of those commitments and any interactions

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 any materials produced for those G 10 meetings?

A. Yes.

Q. Who typically produces those materials?

A. Whoever is presenting. So it's really the team -- I keep using the word "team." The individuals who are presenting to G 10 to either update them or to gain alignment on new projects moving forward. So it would be a variety of individuals depending on the topic.

Q. And for members presenting regarding Cymbalta at the G 10 meeting, would it typically be people from the drug safety surveillance team or would it be people from the platform team?

A. It can be both quite honestly.

Q. Who would -- do you recall any

G 10 meetings where Cymbalta was discussed?

A. Yes. I mean, could you be more specific or, you know --

Q. I'm just asking, do you remember the individuals that spoke on behalf of Cymbalta?

A. Yes.

Q. Can you name them for me?

A. Well, Laura Cox-Heuer that I noted before, also Rodrigo Escobar. Iris has presented previously, that's Iris Ferchland-Howe that I had mentioned earlier. Those have been the primary folks that have been involved. I guess, actually, I have presented to them, so --

Q. Is there a share drive where some of these materials, presentation materials at these G 10 meetings are saved?

A. I believe there is a -- we have a collaboration site, a SharePoint site for the team. I believe they are housed there.

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 members will post various documents there to be shared amongst other team members. So that would include the G 10 slides that were in development. I believe there is a separate collaboration site more for the neuroscience platform, which is likely where the meeting minutes are housed for G 10. Although I'm not 100 percent certain.

And then safety personnel also may have information on a collab site for the team, but they have separate systems within GPS, our Lilly safety system and various regulatory systems where information would be housed.

Q. Okay. So there are minutes for the neuroscience platform meetings?

A. Yes.
Q. And do you understand if there's minutes for the G 10 meetings?
A. Yes, there are.
Q. And that would all be saved on a collaborative site?
A. I believe so.
Q. Usually in the neuroscience platform?
A. I don't know. I'd have to go and look.
Q. Let's go back to the notice. And let's talk about No. 10. "The testimony on the policy and procedures of defendants for pursuing the implementation of language into Cymbalta labeling, package insert, core data sheet, or summary of product characteristics."
Do you know individuals that could talk about the policy and procedures, are you able to identify the policies and procedures as it pertains to Topic No. 10?
A. Yes, I can do that.

Q. Thank you. Would you mind, 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 first approval. And that would involve

your product team at that point would put together that label with directions by our labeling department.
Q. Actually, sorry, Doctor, let me back up. So can we go back to the product team that would have existed back around 2004? Would there have been a Cymbalta platform? I mean -- strike that.
Would there have been a Cymbalta product team that only dealt with Cymbalta at that time?
A. Yes.
Q. Do you have any idea of the identities of the people that were on that team at that time?
A. I know some of them. I was not on the team at that time. I've only been recently responsible for Cymbalta. So I know the regulatory people who were involved at that time and primarily those folks. So I can't give you a complete list.
Q. That's fine. Can you just give

me the people that you understand that 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 just spelling "Robbins".

A. Oh, yeah, I was just -- yeah, sorry.
BY MR. O'BRIEN:
Q. Sorry. I've got acronyms on the brain.
A. Yeah, I'm trying to avoid that. It can be challenging. I can speak only in acronyms if you'd like. So those are the two regulatory leads at that point in time. Dr. Michael Robinson was involved in the team at that time. I'm not sure in exactly what capacity, but he was, at a minimum, one of the senior medical folks involved. Dr. Vladimir Skljarevski, whose name I can never pronounce correctly, was also involved with the team.
Q. Do you know how?
A. He has been primarily involved with the -- more the pain indications. So that would have been DPNP, diabetic peripheral neuropathic pain. Dr. Arei Regev, R-e-g-e-v, he is a safety physician with a specialty in hepatotoxicity. I

believe Dr. Wernicke, W-e-r-n-i-c-k-e, was involved with the team as a safety physician at that time. And that's -- I don't know beyond that who was involved.
Q. And of the names you listed, who is still with the company and what's their current capacity?
A. Dr. Hoog is with the company. She's a physician in global patient safety. Dr. Robbins is no longer employed by Lilly but she is a consultant and we do continue to work with her on certain projects.
Q. Where is she a consultant at?
A. She's an independent consultant, although I think she contracts through INC Research. Dr. Robinson is no longer with the company, and I am not sure where he 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 typically approved in the U.S. and Europe

first and then they go into the other regions of the world. So we do have active submissions in the other parts of the world. Dr. Arei Regev is still in Lilly. He is also in global patient safety in much the same capacity as he was at that point in time. Dr. Wernicke has retired.
Q. Dr. Phillips, what is the dynamic of the product team back in 2004? Are certain physicians assigned different assignments? You mentioned, I believe, Vladimir was responsible kind of for the pain indications. How are those assignments distributed?
MS. JONES: Objection to the form. You can answer.
A. It may vary from team to team. But with what was -- we had three indications under review for Cymbalta at the same time. So we had different physicians as the lead by indication. So Dr. Robinson was on depression. Vlad was probably on DPNP, I'm not sure.

Actually, I think it was Tim Garnett. Timothy Garnett was the lead physician for the stress urinary incontinence indication.
BY MR. O'BRIEN:
Q. And my understanding is Timothy Garnett is still with the company?
A. He is.
Q. And what's --
A. He is our chief medical officer.
Q. And did he have any other responsibilities as it relates to Cymbalta at the time that you know of?
A. No, I mean, when you're first getting a drug approved, it's pretty all consuming. You're only working on one product. And in this case only one part of the product by indication.
Q. Doctor, do you have an understanding that this case deals with Cymbalta discontinuation?
A. Yes.
Q. Do you have any knowledge of who worked on the discontinuation part of

the label from 2004 to present?
A. I know the regulatory personnel who have been involved with that.
Q. Was that piece of the label?
A. The discontinuation emergent adverse events, yes.
Q. Could you take me through their names of responsibilities and the dates?
A. Okay.
Q. And if you have -- do you have a list that you happen to have on you?
A. I don't.
Q. Okay.
MS. JONES: Let me just note, Kevin, to the extent that you're looking for lists of names and time frames for different positions, I believe we produced a set of organizational charts for global regulatory affairs and we can point you towards those afterwards if they would be useful to you.
MR. O'BRIEN: Okay. Phyllis, I wasn't -- thank you.
MS. JONES: Go ahead.

A. Okay. Dr. Sharon Hoog, I know, was involved with Cymbalta late '90s through 2005. The depression NDD application was filed in 2001.
BY MR. O'BRIEN:
Q. The ND --
A. The new drug application, the initial application for approval of Cymbalta.
Q. The INDA?
A. No, the NDA.
Q. Okay.
A. The IND, the investigational new drug application, was opened much earlier than that.
Q. And just to provide the jury some background, could you explain what an INDA is and what an NDA is?
A. Okay. When you would like to begin clinical trials in humans, you must file an investigational new drug application with the agency. That application includes information about all of the toxicology testing that's been

done, how the drug was developed, the chemistry manufacturing and controls, as well as your initial protocol and so that the agency can review to determine if it is safe enough to proceed into clinical trials with humans. So that is done before you can initiate any clinic trial in humans. And that's -- the IND is specific to FDA. So that's FDA terminology, but there are similar processes across the world with different names or acronyms, clinical trial application, or CTA, being the most common. So once FDA reviews and agrees that we can proceed with clinical testing, every protocol that we conduct is submitted to the agency under the IND and is subject to FDA regulation and oversight.
So those studies are conducted under the IND. They are reported to the IND, as well as any changes in chemistry, manufacturing, controls, along the way, as well as toxicology studies that are

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. When there's a supplement to the NDA at Eli Lilly, is it just called NDA, is it an -- I've seen sNDAs, I've seen supplemental NDAs.
A. Okay. Well, let me finish IND before we go to NDA because there are differences.
Q. Sorry.
A. So while the drug is under investigation, the information is going to the IND. When you have finished phase 3 testing, you submit a new drug application to the agency, the NDA, which, if approved, is then your -- you know, it's your approved application. And so our first indication for Cymbalta was for depression, major depressive disorder. So that application was submitted in 2001, reviewed, and then approved in 2004.
Subsequent to that approval, we

have submitted what are called "supplemental NDAs" or little S big NDA, which that can be labeling changes, that can be chemistry changes, it can be a new indication for the product. But everything that's submitted to the NDA outside of just routine correspondence is typically a supplement and is assigned a number and reviewed accordingly.

Q. Thank you, Doctor. And getting back to Dr. Hoog --

A. Uh-huh.

Q. -- you said she was involved in the late '90s to 2000 and we're just --

A. 2005.

Q. 2005. And just to go over her involvement with the discontinuation part of the Cymbalta label.

A. Okay. Well, she was part of the team that put together the NDA. She was the regulatory -- U.S. regulatory lead for the NDA and was responsible during the three-year review period as well as the -- just the initial approval of both

the NDA for depression as well as the NDA for diabetic peripheral neuropathic pain, which was approved shortly after the depression indication was approved. She was integral to working on and developing the core data sheet, which includes discontinuation emergent adverse events, has always included the phenomenon, those symptoms, and as an as a result, as I said, the core data sheet must be reflected in every local label. The label that was submitted to the FDA and the initial NDA did include information about the discontinuation syndrome as well as the specific symptoms and what to do about them should they be observed.

Q. Now, was Dr. Hoog involved in kind of revealing the work that was done on putting together the discontinuation part of the Cymbalta label or was she actually kind of working with the wording and doing the research behind it?

MS. JONES: Objection to the form. You can answer if you understand

the question.

A. I believe what you're asking is -- she was involved with compiling the NDA and working with the teams that were creating the integrated summary of safety. So that's looking at the safety across all of the trials that have been conducted for Cymbalta and looking at what are the key safety concepts that needed to be conveyed in labeling, one of which were discontinuation emergent adverse events. So while she was not the hands-on person doing the statistical analysis, she was part of the team interpreting the data, although that was led by GPS and our medical group. She is a physician, so she does -- she is a psychiatrist, and that had practiced extensively before coming to Lilly, so she did have an informed opinion as to that -- well, most of the label, so --

BY MR. O'BRIEN:

Q. Okay. And who would be the next person that would have

responsibilities with regard to the discontinuation part of the Cymbalta label?

MS. JONES: Objection to the form. Go ahead.

A. From a medical perspective, it would have been the medical director, it would have been the global patient safety physician, you know, and the statisticians who were involved with doing the analyses.

BY MR. O'BRIEN:

Q. And I'm just trying to get some names from the Cymbalta product team from .2004 to kind of present day that dealt with discontinuation label.

A. I don't know all the names. I mean, I've given you the names that I know from the time of the initial submission, including, you know, Dr. Robinson, Vladimir, and Dr. Regev. Through the years, it's the same functions that would be involved. That would be our senior medical director. It would be our global physicians. It would be our

global patient safety group.
Q. This -- sorry, Doctor. The senior medical director, is that under regulatory?
A. No. That position reports up through our medical organization and ultimately to Dr. Garnett as the chief medical officer now.
Q. Do you have an idea who the senior medical director was back in 2004?
A. I don't know.
Q. Do you have an idea -- strike that.
Can you think of anybody that was a senior medical director from 2004 to present day?
MS. JONES: Objection to the form.
A. I'm not sure I'm following.
BY MR. O'BRIEN:
Q. I'm just trying to get a list of individuals that you know of that held that position since Cymbalta has been on the market.

MS. JONES: Please also note my 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. Michael Robinson. And prior to that, I don't know.
BY MR. O'BRIEN:
Q. Doctor, let's turn our attention to Topic No. 11.
A. Yes.
Q. This is the "Testimony on the policy and procedures of defendant for creating, editing, reviewing, revising," and I believe that's supposed to be "filing all materials, documents, studies, or communication with the FDA concerning Cymbalta."
Are you prepared to testify as to that topic?
A. Yes, I am.
Q. Can you kind of take me through some of the policy and procedures?

A. Well, we have several. We have a regulatory quality system, RQS, that includes different SOPs regarding communicating with agencies and how to document those communications. For instance, we -- every time we have a phone call or an e-mail with somebody at FDA, we do a record of contact and that is logged in our electronic e-files.
Q. Where do the calls from the FDA come through? Is there a contact person at Lilly?
A. Yes. There is a contact person for each molecule. So for me, right now, I am the contact for Cymbalta. So FDA would call me first. My name is on the correspondence. And then I can direct them to other team members as needed. There may be occasions in which they contact our GPS physician or our CMNC lead in some situations. But the majority of the contact would go through me as the U.S. regulatory scientist.
Q. Does most of your contact with

the FDA, does that come through letters, 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 Cymbalta from the FDA, what's the process? Do you save it someplace?
A. Uh-huh.
Q. Did you forward it to somebody within regulatory? How does it work?
A. I would forward that to -- there's a certain mailbox that goes to our CRR group, our central registrations group. And they immediately upload that into e-files, which is our electronic repository of all incoming and outgoing correspondence, regarding our products and to FDA. And so that would be logged in that fashion. I would also log it as a record of contact regarding, you know, what our follow-up actions are going to be on that particular correspondence or if

there would be any follow-up, which is also logged into e-files.

Q. Now, the CRR group, is that a group that's put together kind of just save the communication, is that their function?

A. Well, they have a broader function than that. That's one of the things they do is, you know, they are responsible for ensuring that e-files is kept up to date, which includes records of contact, incoming, outgoing correspondence. They are responsible for submitting through the gateway to FDA. We submit everything electronically now. Previously it was on paper or some combination, but that group was always responsible for those submissions and making sure we're in compliance with the standards of the day for FDA.

Q. Now, all communication that is, I guess, covered in the e-files, is that saved on a certain database that's searchable?

A. Yes.

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 correspondence, outgoing correspondence, or records of contact.

Q. Okay. So you can search for all incoming correspondence from the FDA with regard to Cymbalta and you would see kind of -- would you see just a field of all the different letters and communications that have come in?

A. You would see a listing by date of the various submissions. And there'll be a brief description. It will be the date, the sequence number, the NDA number, and then you can click on that to get more information about the actual submission or what was received.

Q. And who provides the summary? What that be the CRR group or would it be you who did that before you sent the correspondence to the CRR group?

A. It would be one or -- of us, depending on what it was. So when we're submitting a protocol to the agency, the CRR associate would typically put that in. When it's a record of contact or incoming, I usually provide the summary for the group to, you know, to make that

searchable field. But it is a free text 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 submission to the FDA. Can you explain a little bit what it is and how it works?

A. Well, I'm not sure I can give you the inner workings, but we do submit --

Q. You can give me the CliffNotes version.

A. We -- all of our -- okay. So the IND and the NDA, they're separate applications but they essentially are a backbone, information goes into specific parts of it. There's modules that are standardized by FDA as well as -- actually a lot of the content has been globally harmonized so the idea is they have a common structure. It's an XML backbone and information gets slotted into certain sections within the NDA and then that is electronically submitted to the agency, they receive it in the same format, so they kind of have the same parallel structure so that we can see the same thing.

So, for instance, our annual reports go into Module 1. Study reports will go into Module 5. Chemical reports

go into Module 3. Toxicology reports go into Module 4. And within those modules, there's further breakdown as to what the structure is. But that way, FDA is receiving information in a common format from everybody that's submitting to them so that they have some consistency and where to locate information.

Q. Now, with regard to Cymbalta, do you have a contact at the FDA? Is there an individual employed by the FDA that you have day-to-day interaction with?

A. Yes, I actually work with several different project managers at FDA. They assign project managers by compound but then also by IND or NDA. So because we have multiple INDs and NDAs, I have different project managers that I interact with for those specific indications.

Q. Can you provide me a list of the project managers at the FDA that you may interact with regarding the Cymbalta discontinuation syndrome?

MS. JONES: Objection to the

form.

A. I -- there is -- I interact with various project managers on the basis of indications. And so there's not one person that I would talk to about any safety-related issue that -- let me take a step back. FDA is a very large organization.

BY MR. O'BRIEN:

Q. Yes.

A. And there are many different parts. There's different review divisions. So there's a division for psychiatry products. There's a division for anesthetics and analgesics. There is a division for reproductive health. So, for instance, our depression indications and anxiety indications are reviewed by the psychiatry division. Our pain indications, diabetic neuropathic pain, fibromyalgia, and chronic pain are within the anesthetics and analgesic division. So there's different review divisions based on their expertise who review them.

Separate from that is the office of surveillance and epidemiology, who are primarily responsible for safety, although the review division also has safety. They're equal but separate. The idea on FDA is to have a separate safety surveillance in addition to the review division and they concur on projects and then would recommend changes to the label.

So they work together to provide information to us or to request information from us about the label. That would ultimately get communicated to me through a specific project manager at FDA that are usually from the review divisions, although they do have project managers within OSC. So, most recently, I think it was Terry Henderson that communicated the example I gave before around the angle-closure glaucoma class-labeling changes.

Q. Now, do you have the contact of somebody that you have regular communications with from the FDA in the

office of surveillance?
A. I do not have a routine contact with that division office.
Q. Can you identify any project managers or employees from that division at the FDA that you've had contact with?
A. Just this most recent, Terry, and I think it's Henderson, but I'm not .100 percent sure.
Q. Does Lilly keep a log of contacts that they would have with the office of surveillance?
A. We keep a record of all contacts with FDA regardless of division or office.
Q. Is that contact list -- I mean, would it be searchable? So you want to go back and take a look of all the contacts you've had with the FDA but you really only wanted to look at contact you had with the office of surveillance, how would you go about doing that?
A. Within e-files, you can -- you could do a keyword search for records of

contact that involved OSC, because that is input as to what division so -- or part of FDA. However, that's a free text field, so it may not be always obvious, you know, sometimes you have to do a little bit of digging.
And then e-files has only been online since the end of 2010. So prior to that, notes to files were captured electronically in a Documentum database and also in our paper archive. And prior to 2010, our paper archive is the official repository of all communications between Lilly and FDA.
Q. So before 2010, all communications with the FDA were paper, most communications?
A. Most were. Well, we had electronic, they were often hybrid of paper and electronic. So there is electronic information that can be searched, but it is not a complete record. So if you want an absolutely complete record, you have to go to the

paper archives prior to December of 2010.
Q. So prior to December 2010, if you received an e-mail from the FDA, would that be printed and placed in the paper archives?
A. Yes.
Q. And where is the paper archives? Where does it exist?
A. It exists here in Corporate Center in Indianapolis, Lilly Corporate Center. That includes the most recent applications. We do have off-site storage for some of the older communications.
Q. And is it your understanding that Lilly no longer keeps a paper archive as in, you know, if you got an e-mail tomorrow, would it be printed and placed in the paper archive?
A. No, it would not. It would be electronic.
Q. Do you have an understanding how the paper archive system is indexed?
A. Uh-huh. Yes. It is indexed by NDA or IND by the number for that.

And it literally is a chronological record. So it's -- you -- literally, there are tabs within binders by date. There are different colored tabs that indicate different types of communication, whether it be incoming, outgoing, whether it be promotional types of communications. And the notes to file are kept in a separate binder, but they're also by chronology.
Q. At the time that Lilly made the decision or -- to go paperless, do you know if they scanned the old paper archives so they're available in electronic platform?
A. They have scanned quite a few of them. We had some summer interns that did a lot of that work. But it is not a complete record. So that's where, you know, if you want an absolutely, you know, complete record, you have to go to the paper. But, yes, there are quite a few documents that were scanned into the system and our searchable within e-files.

Some of them are scanned in, some of them only have the information to say "sequence No. XYZ from this date," but you still have to go to the paper to actually get the content.

Q. Now, Doctor, I want to turn our attention to --

MS. JONES: Is this a sensible time to take a break? We've been going about an hour and a half.

MR. O'BRIEN: Yeah. I mean, absolutely. I was just looking at the time. It looks like there's 12 minutes before the tape breaks.

MS. JONES: Oh, okay.

MR. O'BRIEN: We can go now and they can put in a new tape or --

MS. JONES: No, we can burn the tape, that's fine. Is that okay with you, Dr. Phillips?

THE WITNESS: That's fine.

BY MR. O'BRIEN:

Q. Doctor, can you give me an idea of the preparation that you did for

today's deposition?

A. Okay. I met with counsel to understand the content of the deposition, the information. I reviewed SOPs. I talked to a couple individuals who were involved with Cymbalta previously. And I reviewed some of the Cymbalta correspondence with FDA.

Q. And what individuals did you speak to regarding Cymbalta in preparation for your deposition? And can you list their names, you know, their titles, if you haven't told us already, their responsibilities as it related to Cymbalta?

A. Uh-huh. Well, I spoke with Dr. Hoog, who I have already described for you. I also spoke with Ann Robbins, Dr. Ann Robbins.

Q. And, also, would you mind telling me the type of information that you were trying to ascertain from Dr. Hoog and Dr. -- --

A. Uh-huh.

Q. -- Ann Robbins?

A. It was very similar, the two of them, when I was speaking to them since they were responsible for Cymbalta at the time of approval it was, you know, what was -- what information was provided in the NDA, what discussions were had with the FDA during the negotiation label process prior to approval, and some of the outcomes of those conversations. So I did speak to them about that. The creation of the core data sheet. I speak -- I spoke with Dr. Torkil Fredborg, he is an EU regulatory.

Q. Would you mind spelling that?

A. T-o-r-k-i-l. His last name is F-r-e-d-b-o-r-g. He was a European scientist involved with the initial Cymbalta submissions and approvals. So I did speak to him about language in the SPC.

Q. And would you mind telling the jury what the "SPC" is?

A. Sorry. That's the European

summary of product characteristics, so that's the equivalent of the USPI for Europe.

Q. And what was his day-to-day responsibilities as it related to Cymbalta back in 2004?

A. It was the same as the day-to-day responsibilities as what I described for Dr. Hoog and Dr. Robbins on the European side. They were global submissions, though, so he was involved with the creation of the -- the entire NDA or as it's called in Europe the "MAA," the marketing authorization application.

Q. And what type of information did you ascertain from Dr. Fredborg?

A. We talked about the approval, what was in the label, particularly regarding discontinuation emergent adverse events and how did that labeling change over time.

Q. And what did he tell you about that?

A. He went through the initial submission, which was very much based on the core data sheet as you would expect. And then just that there was a change for class labeling, much like in the U.S., in 2000 -- end of 2005, 2006 based on, you know, the European review of periodic safety update report and then their standardization of wording for discontinuation symptoms across the labels for all antidepressants. FDA did something very similar right as Cymbalta was initially approved in 2004, so you will see class labeling reflected in the initial label in addition to what was -- we initially provided.

Q. Where is Dr. Fredborg located?

A. He is located in the UK, in our offices there.

Q. So this was -- was this a phone conversation you had with him?

A. Actually, no, he was visiting Indianapolis. So I just happened to, you know, catch him when he was here locally.

Q. Did you guys review any documents?

A. We looked at the Rapporteur's assessment of our second PSUR, periodic update report. So the Rapporteur is the -- their reviewer. That's the name for their scientific medical reviewer.

Q. And when was the Rapporteur's assessment created?

A. It was in late 2005. That's when they made the change to their class labeling.

Q. Is that document publicly available?

A. No, it's not.

Q. If I wanted to obtain a copy of that assessment, if it hasn't already been produced, how would I go about asking for it?

MS. JONES: You would ask Lilly's lawyers.

A. Okay.

BY MR. O'BRIEN:

Q. I'm just trying to get the name of the -- the fact name of the document.

A. It's the Rapporteur's assessment of the second PSUR, periodic safety update report.

Q. Did you review any other documents with Dr. Fredborg?

A. We looked at the SPC itself, but -- which summary product characteristics.

Q. And how long was your meeting for?

A. It was like a half hour.

Q. And what about with Dr. Hoog?

A. Maybe an hour.

Q. And what documents did you review with Dr. Hoog?

A. We looked at the labeling for Cymbalta over time.

Q. And then she -- strike that.

Did Dr. Hoog have any comments of the label changes for Cymbalta over time?

MS. JONES: Objection to the form.

A. I mean, we did discuss when did this change and why, so, yes, we did have that conversation, specifically around discontinuation emergent adverse events.

BY MR. O'BRIEN:

Q. And did you have that conversation with anybody else, not including your lawyers?

A. I spoke with Dr. Robbins about the same thing because, although they were working in different indications, they were obviously coordinating because the label would be consistent across divisions with the exception of the actual indications and clinical study section.

Q. Did you meet with Dr. Hoog and Dr. Robinson -- Dr. Robbins at the same time?

A. No.

Q. When did you have those meetings?

A. Probably in June. I know I met with Dr. Robbins on July 1st.

Q. Dr. Phillips, do you have an

estimate of the number of documents that you looked at in preparation of today's deposition?
A. I didn't count them. I mean, I looked at some of the correspondence. I looked at versions of labels. I looked at SOPs. I had to do training anyway, so it was kind of timely. So -- and we have lots of SOPs. Maybe a hundred.
Q. Are there any other documents that you can think of you looked at other than SOPs, the label changes, and anything that you've already mentioned?
A. No.
Q. Without telling me what you spoke about with your attorneys, did you have an opportunity to meet with your attorneys in preparation of today's deposition?
A. Yes.
Q. And when did you meet with your attorneys?
A. I met with them in June and then earlier this week.

Q. And how much time did you spend with your attorneys?
A. A few hours each time. Met with them four times.
Q. Was it -- did you also meet with Dr. Knowles?
A. No, I did not.
Q. And which attorneys did you meet with?
A. I met with Ms. Jones, Ms. Martinez Resly, Ms. Dire, Dawne Dire, as well as Mr. Christopher Gramling of Lilly, and there was also a lawyer from Pepper Hamilton on the phone. And I'm not sure what the name was.
Q. Do you remember if it was a man or a woman?
A. It was a woman. Is it Alison or Nicole? Anyway, I'm not sure.
Q. It's okay. Did you gather any documents in preparation of today's deposition?
A. I gathered some SOPs and pointed -- I know Dawn had asked for

some, you know, the organizational charts. I pointed her to where they reside on the collaboration sites, that kind of thing.
MS. JONES: And those have been produced.
BY MR. O'BRIEN:
Q. Did you bring any documents here today with you?
A. I had kept an SOP binder that I brought with me. That's one of her binders.
Q. Anything else other than SOP documents?
A. No. I take that back. I think there was a timeline of when the various INDs were submitted and when the NDAs were submitted and approved. There was that timeline.
Q. Is that with you today?
A. Yes.
MR. O'BRIEN: Why don't we take our break?
MS. JONES: Okay.
THE VIDEOGRAPHER: We are going

off the record. The time is 10:25 a.m.
(A recess was taken at 10:25 a.m.)
THE VIDEOGRAPHER: This is the beginning of Tape 2 in the deposition of Dr. Christine Phillips. The time is 10:34 a.m., and we are back on the record.
BY MR. O'BRIEN:
Q. Dr. Phillips, I just want to take a moment and I'm going to mark your resume as Plaintiff's Exhibit 2.
(Plaintiff's Exhibit-2 was marked for identification.)
BY MR. O'BRIEN:
Q. Will you take a look at it?
A. Okay. I'm familiar with it.
MS. JONES: Do you have a copy for us, Counsel? Just one will do. We can share.
MR. O'BRIEN: I'm sorry, Phyllis.
MS. JONES: Thank you.
BY MR. O'BRIEN:
Q. Dr. Phillips, is this your most

recent resume? I see up top it looks like under parentheses on top by your name it says, "May of 2014." Is that the last time it was updated or reviewed?
A. Yes, it was.
Q. Has anything changed?
A. Well, I'm actually moving jobs currently, staying within regulatory affairs but I'm going to be focusing on devices. So I will no longer support Cymbalta or Zyprexa Relprevv as of Monday.
Q. So what will your new position be?
A. I will be in regulatory affairs for devices.
Q. Is that all devices or is there one in particular?
A. I will be working on several. We have --
MS. JONES: Let me just note for the record that if there is anything in development that you're not permitted to talk about because it's in development, please just be mindful of that. I defer

to your good judgment on that issue.
A. Okay. That's a very good point. We do have several marketed 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 there I completed a postdoctoral fellowship in biochemistry and molecular

genetics at the Medical University of South Carolina, which is located in Charleston. And that was up through early '97.
Q. So you're a doctor in biochemistry and molecular genetics, correct?
A. My doctorate is specifically in pharmaceutics.
Q. Pharmaceutics?
A. Yes.
Q. Not a medical doctor but in pharmaceutics?
A. That's correct. I'm not a medical doctor.
Q. And following college, would you take me -- or strike that.
Following your postgraduate degree, will you take me through your employment background?
A. Following my postdoctoral fellowship, I worked at a contract research organization called "PPD PharmaCo," located in North Carolina,

Research Triangle Park. I worked there as a medical writer.
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 regulatory response documents.
Q. And then you held that position

until June of 2000?
A. Yes.
Q. And from June of 2000, your resume indicates you were team leader in global science information and communications.
A. Yes. So we renamed medical writing to be global scientific information and communications. By "team leader," that meant I was a supervisor of about seven writers and two editors on the Prozac team. So that job was partly administrative, partly technical, and training new staff.
Q. And what were the writers -- what type of documents were the writers drafting?
A. The same as what I just described, you know, study protocols, clinical study reports, briefing documents, submission documents that would go into an NDA, that would include, you know, study reports as well as integrated summaries of safety or efficacy and also regulatory

response documents.
Q. And what other departments did you work with?
A. I worked closely with regulatory, medical, statistics, data sciences in some cases, our safety 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?
A. That's correct.
Q. And then you left that position

July 2002 and where did you go next?
A. I came into U.S. regulatory affairs at that time.
Q. And it says you were a U.S. regulatory scientist?
A. Yes.
Q. What does a U.S. regulatory scientist do?
A. It is very much the job I do today but at a lower level. I mean, as you get more experience, you get promoted kind of approach. So when I initially came into U.S. regulatory affairs, I was responsible for some early development molecules. I covered molecules in cardiovascular, some oncology, it was kind of a variety, some autoimmune sets.
Q. And you didn't have any involvement during that time with Cymbalta; is that correct?
A. That's correct.
Q. And then in October 2005, you left for Amgen?
A. That's correct, yes.

Q. And what was your position there?
A. I started as a senior manager and was promoted to director while I was at Amgen and I was a global regulatory 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.
Q. As a U.S. regulatory consultant?
A. Uh-huh.

Q. What does a U.S. regulatory consultant do?
A. Again, it's fundamentally the same job but our titles have changed over the years with different systems, but it's really on par with director level position that I had at Amgen. The difference being that we don't have a global regulatory leader role at -- well, that's not true. We have a global regulatory coordinator role at Lilly, which I also have served in that capacity.
Q. And then it looks like in March of 2010, you became a U.S. regulatory advisor director?
A. Yes.
Q. And same type of job responsibilities?
A. Yes. At that time things -- we restructured slightly and I had somebody reporting to me at one point in time. So we did -- regulatory and learning regulatory is somewhat of an apprenticeship so that's how you learn.

So although it's hard to describe at times, the fundamental job responsibilities, you increase in responsibility in taking the lead and you 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 States Regulatory Affairs." The reorganization changed so that everybody

is in Global Regulatory Affairs-U.S. So that is my title.
Q. So U.S. regulatory affairs and global regulatory affairs are synonymous?
A. No. Global regulatory affairs-U.S. is equivalent to U.S. regulatory affairs. We also have a vice president of global regulatory affairs-international that covers Europe, Japan, and essentially the rest of the world.
Q. Now, I kind of want to go through the corporate structure in the U.S. regulatory affairs. I really only want to focus on kind of the neuroscience. I know there's probably different divisions. You're in neuroscience regulatory affairs. Who do you report to?
A. I report to Carlos, Dr. Carlos Garner. And he is the senior director global regulatory affairs-U.S. for the bio-medicines business unit.
Q. The bio-medicines business unit?

A. Yes.
Q. And who does Carlos Garner report to?
A. He reports to Dr. Robert 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 the titles line up, if they're the same or -- I believe the chief medical officer

is kind of high up, though.
Q. Yeah, I wasn't sure if Dr. Garnett reported to David Ricks.
A. No, he does not. He reports to John Lechleiter, our CEO. Dave Ricks would also, I believe, report to Dr. Lechleiter.
Q. Okay.
A. And David Ricks is the president of the bio-medicines business unit.
Q. Yeah, he's still the -- he's a senior VP and I guess the president of -- president of the Lilly bio-medicines unit?
A. Yeah.
Q. Who reports to you?
A. No one.
Q. Are there other U.S. regulatory affairs directors for neuroscience currently?
A. Dr. Janice Hitchcock.
Q. Now, Dr. Janice Hitchcock, how long has she been in that position? Is she your replacement when you leave?

A. No. She's been in that position for quite some time. She's responsible for our Alzheimer's platform. And reporting to her is Mr. Ashraff 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 previously hold?
A. It's an extension of his current position, but he has responsibility for several of our more mature neuroscience products. So he currently has Prozac, Symbyax, and the oral forms of Zyprexa. And with my taking on a new role, he will also be responsible for Cymbalta and Zyprexa Relprevv.
Q. Do you have an understanding of who was the director of U.S. regulatory for neuroscience before you?
A. Uh-huh. Well, our organizational structure was different, of

course. Dr. Greg Brophy was the director, senior director of neuroscience in U.S. regulatory affairs for at least ten years.
Q. Dr. Brophy, you said?
A. Uh-huh.
Q. B-r-o-p-h-y?
A. Correct.
Q. And you believe he held that position since 2000 --
A. Early 2000s.
Q. Early 2000s?
A. He recruited me into regulatory affairs, so he's been there quite some -- he was there for quite some time.
Q. Is he still with the company?
A. No, he's retired.
Q. Did he have a medical degree?
A. No. He has a Ph.D. in toxicology.
Q. Is there anybody else that you can think of since 2000 in U.S. regulatory that had responsibilities as it relates to Cymbalta?

A. The individuals that I mentioned previously, Richard Hoffman, Isabelle Murray, Bryan Boggs, Sharon Hoog, Ann 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.
Q. And he had responsibilities as it relates to Cymbalta?
A. He was the senior director of the bio-medicines business unit. He is -- he is an MD, psychiatrist, so he had a particular fondness for neuroscience.
Q. And where is he currently now?
A. He is now the neuroscience platform leader at Lilly. So I spoke of Dr. Escobar previously as the senior medical director. Dr. Escobar reports to Dr. Conley.
Q. As far as regulatory affairs in the United States, is most of it based out of Indianapolis?

A. All of it is.
Q. All of it is?
A. Uh-huh.
Q. I wasn't sure if there was another office in the United States that deals with regulatory affairs.
A. Well, we have the YOS affiliate, but that's located here in Indianapolis as well.
Q. Is there an investigational side of regulatory?
MS. JONES: Objection to the form.
A. What do you mean by that?

BY MR. O'BRIEN:
Q. I guess if there were some sort of issues with a drug, that there's like a team that -- whose job it is to go out and investigate those issues.
MS. JONES: Same objection.
A. All safety issues are monitored and on a regular basis by our global patient safety organization.

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 surveillance team or if there is an investigational unit within regulatory.
A. I'm not sure what you mean by "investigational unit." Because that makes me think of CSI and, no, we don't have that, but we do -- I mean, our GPS group is responsible for monitoring and tracking down safety signals. Regulatory affairs is where -- the communication with the FDA, working with the teams to communicate the relevant information, including information gathered by GPS.
Q. Now, when somebody comes into the regulatory department, say they came in the U.S. regulatory, is there a certain training that takes place?
A. Oh, yes, yeah.
Q. Can you describe that training for me?
A. Yes, we have an individual

training plan, which includes, you know, reviewing various SOPs and then regulations from FDA including, you know, the 21 CFR, 312, 314, 201, you know, 600s, 800s. They are also assigned a mentor coach, because, as I was saying, there's a lot of on-the-job training. There's a lot of guidance documents, all of which are open to interpretation. And so there is that. And there's a series of one-on-one meetings with various experts within the regulatory organization, let's say orphan drugs, advisory committee meetings, that kind of thing, so they know who to go to. And then, you know, as you're -- well, all documents, when we're creating them to go to FDA, typically undergo a peer review. We do that regardless if you're new or not, just to -- you know, it's always good to have another pair of eyes and different experience looking at the documents and reviewing them.
Q. Is there an individual within

regulatory that's responsible for coordinating the training for new employees?
A. Yes, that's Janet Fourman, F-o-u-r-m-a-n.
Q. And what is her title?
A. I'm not entirely sure. She's just been the training person for a long time, so she --
Q. And --
A. She coordinates the training across regulatory.
Q. Is she part of the regulatory department or is she in a different department?
A. I think that might have changed recently, because she -- I consider her part of regulatory, but I know across Lilly, we've consolidated all the training people under one organization. So she may actually be reporting through a training organization now.
Q. Do you know who the trainer was before Janet Fourman?

A. No, she been in that position for as long as I can remember, as long as I've been in regulatory affairs.
Q. Now, with regard to SOPs and protocols, how would somebody in regulatory access them?
A. Well, we have our ITP, individual learning -- or training plan. And we can go to that electronically and tells you which one is due when, you can click on the link and go to the SOP. The SOPs are maintained electronically on the Lilly Intranet. So you go to a collab site for the regulatory quality system or the medical quality system and you can pull up SOPs there.
Q. You mentioned ITP, individual training program. What is an "ITP"?
A. It's by role. There is a specific training plan that you need to -- what SOPs are relevant for that role and what are the coursework you need to take to be qualified in that role. So that would be different for me as

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.
Q. And what's Dan Brady's position?
A. He is a senior advisor in U.S.

regulatory affairs oncology.
Q. Any other live training that you can think of, instructors?
A. Well, I instruct around advisory committee meetings as needed. When a team finds out they have an advisory committee meeting, I usually -- I go there and train. We have submission, a submission group led by Jane Amos who does training when you're a year or two out from submitting an NDA or a BLA, which is a biologics application. It's the equivalent, it's just not -- a small molecule on oral medication and biologic is usually injectable medication.
Q. Now, you've never attended a Cymbalta advisory committee, correct?
A. I viewed it through the webcast link, but I was not physically there in DC with the team. I did watch it. I helped the team prepare and then I watched it.
Q. Is there a transcript for that? Was it recorded?

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 documents, some tips on how to do slides. So it was process support, it wasn't

content support.
Q. Do you know if the materials or notes that were prepared in preparation of that meeting, are they saved anywhere?
A. There are some that were saved on the collab site for the team. The public record is the briefing documents submitted to the agency, the transcript, the slides, all of that is publicly available in the FDA website.
Q. I know you mentioned that there are SOPs for new employees that come into regulatory.
A. Uh-huh.
Q. Is there a handbook that employees receive?
A. Well, there's kind of the Lilly red book, which is, you know, our underlying philosophy and ethical standards, I guess is the way to put it. Our ITP is -- it's done electronically. And I think they now call it "success factors." They've changed the name recently. But basically the list of what

you're required to do in your position is 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 that they're trying to convey and that is, you know, kind of a testing system, "What would you do in this situation?"
Q. Is it -- is the -- the red book has different modulars [sic]?
A. Yes.
Q. In your position in U.S. regulatory in neuroscience, did you have any dealings with regulatory agencies other than the FDA?
A. Not directly. I would interact with my colleagues in Europe, but they

would be the primary contact to the European regulatory authorities.
Q. And who would be your colleagues in Europe that were the primary contacts with European regulatory authorities as it relates to Cymbalta?
A. Currently that's Beth Heaviside, who I mentioned earlier.
Q. Would you mind spelling that again?
A. Yeah, H-e-a-v-i-s-i-d-e.
Q. And where is Beth Heaviside located?
A. She's located in the UK.
Q. And what is her position in the UK?
A. I don't know her exact title. I think she's a principal consultant.
Q. And she deals with European regulatory bodies as they relate to Cymbalta?
A. Yes.
Q. Is there anybody else over there that you can think of?

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 UK?
A. Yes. Well, actually the European Union, not just the UK.
Q. Do you know if there's ever an issue with Cymbalta being denied approval in any international companies?
A. International companies?
Q. I'm sorry, international countries.
MS. JONES: I'm sorry. Could you read that question -- do you want to restate the question again?

MR. O'BRIEN: Let me restate it.
BY MR. O'BRIEN:
Q. Do you know if there was ever an issue with Cymbalta being denied approval in any international country?
MS. JONES: Objection to the form. You may answer.
A. Well, I guess I'm not sure exactly what you're asking.
MS. JONES: When you say "international countries," you mean outside of the U.S.?
MR. O'BRIEN: Outside of the U.S.
MS. JONES: Okay.
A. I don't have knowledge of every submission we've made outside of the U.S. So I don't think I can answer that question.
BY MR. O'BRIEN:
Q. Do you have any idea who would be able to answer that question?
A. Yes. We have a system called

"RAPT," regulatory activity and planning tracker, which does list all of the approved indications by country as well as the approved presentations in that country. And it will go through and list out if an application has been submitted, withdrawn, approved, et cetera, what is the status of those indications. So you can look at that by country.
Q. Now, earlier today, we discussed a little bit about what happens when you receive a phone call with the FDA and how that is recorded.
A. Uh-huh.
Q. Is there any policy and procedure if there's a meeting with the FDA as far as how that meeting is recorded?
A. Yes, there is an SOP about that.
Q. Could you tell me what the policy and procedure is, generally if you don't know specifically?
A. Okay. I think that it's called

"interactions with regulatory agencies," I think it is that simple as a title. And that -- and separate there is one for documenting interactions, which is more the record of contact. So the formal meetings, there is an SOP around -- around that interaction.
Q. Do you know any of the details of the -- what happens? Is it recorded on a certain form or is it saved? Who is it sent to?
A. Okay. I will commit specifically on FDA interactions because they do differ somewhat, but fundamentally it's the same concept. We submit a formal meeting request to FDA. There is a certain format specified by FDA that that meeting request is submitted that gives the agency an idea of what the topics are, background on the molecule, what questions you want to discuss with them. And then FDA either grants that meeting or they deny it. They can grant the meeting as a face-to-face, they can

grant the meeting as a teleconference, or they can grant it as meeting granted, written responses only. So they would only provide written feedback. Prior to -- they assign a date for the meeting. Prior to that meeting, we submit a briefing package to the agency, which outlines what we want to discuss, the relevant background, and what questions we specifically want them to answer for us.
And then during the meeting, there's a back-and-forth discussion, it's all based on the questions. There's no presentation. You assume everybody has done their homework, read the document, and that you really just go into the questions. There's a dialogue. Actually, let me back up.
Prior to the meeting, usually a few days prior to the meeting, FDA, through their good review practices initiative, will provide us with preliminary written meeting minutes. So basically their preliminaries 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 do focus on questions that require further resolution or clarification. And then following the meeting, we, Lilly, through the -- led by the regulatory scientists, will create our internal version of the meeting minutes which we then submit to the agency. And then they issue final official minutes within 30 days of the meeting. And those minutes will reflect the questions, the preliminary comments that FDA sent us prior to the meeting, as well as any discussion that happened at the meeting and kind of like their final answer to that specific question.

And that is your official record of the FDA meeting.

Q. And where would that record be

saved?

A. That would be in our e-file system.

Q. Now, I know we kind of went through and discussed a little bit of the INDA and the NDA. As far as the individuals that were responsible for working on the INDA, can we talk about any other names that you can think of outside of ones you've already provided? I know we kind of went through the product team.

A. Uh-huh.

Q. And that was only really related to regulatory?

A. Yes. The INDs --

MS. JONES: Hold on just a second. You're asking about individuals outside of regulatory affairs?

BY MR. O'BRIEN:

Q. Well, let's just go through individuals that worked on the INDA.

A. Okay.

MS. JONES: Well, to the extent

that you're asking about individuals outside of regulatory affairs, I'm going to object to the extent that it's outside the scope of the notice, but she can answer to the extent that she knows in her individual capacity.

A. That's a difficult question for me to answer because we have multiple INDs for Cymbalta because they are -- there's an IND for each indication that we have studied and evaluated over time. So we have an IND or depression, we have an IND for anxiety, we have an IND for diabetic peripheral neuropathic pain, for fibromyalgia, chronic pain, so we have several open INDs. They were opened at various points in time and I'd have to look at our list to know when the first IND was submitted, but that was probably in the '80s when I wasn't at the company, and I don't know who would have been involved. But that's -- drug development is a very long process. So that's when clinical trials would have started in

humans and then progressed ultimately resulting in an NDA application.

BY MR. O'BRIEN:

Q. Let's just take it back to before Cymbalta was approved. Some of the people that were involved in the INDA that had a high level, can you go through their names and positions?

MS. JONES: Objection to the form.

A. Not beyond what I've already told you.

BY MR. O'BRIEN:

Q. How about with the NDA?

A. It's pretty much the same as what I've told you. I wasn't working on Cymbalta, so I'm just not familiar with who was involved with it.

Q. Let's just go through, let me make sure I've got all the names from before. Would you go through the INDA, the names you've already told me, make sure we've got everybody.

A. Well, it's not going to be a

complete list. I mean, I primarily know the regulatory folks who were involved, which at the time of approval would have been Dr. Sharon Hoog and Dr. Ann Sakai at that time, now Robbins. The physicians that I know were involved were Dr. Michael Robinson, Dr. Vladimir Skljarevski, who is -- I'm not saying that correctly. Dr. Arei Regev, and Dr. Joe Wernicke.

Q. How do you spell Joe's last name?

A. W-e-r-n-i-c-k-e.

Q. What was Joe Wernicke's involvement with the INDA?

A. Well, I'm referring specifically to the NDA now.

Q. Okay. Well, with regard to the NDA.

A. And that's actually only IND, there's no A on it. He was a global patient safety physician. Beyond that, I can't elaborate on what exactly he did.

Q. Does Lilly still employ global safety physicians?

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 surveillance which is completed by our surveillance associates and then they provide that information to the global product safety physicians who meet regularly to review the safety of our products and they look at a variety of data sources for that including the literature, our clinical trial data, FDA databases, et cetera.

BY MR. O'BRIEN:

Q. Is Joe Wernicke still with the company?

A. No, he is retired.

Q. Did you make an effort to educate yourself about the name and

addresses of the people responsible for the NDAs related to Cymbalta?

A. Well, not their addresses, certainly. The names -- I focused on regulatory affairs quite honestly, so I did not go beyond that.

Q. Is it your understanding that you have identified all the individuals who were involved with the NDA as it relates to regulatory affairs for Cymbalta?

A. Well, those -- the two individuals I have called out, Dr. Hoog and Dr. Robbins, were the primary regulatory scientists. Dr. Brophy was their supervisor at that time, so he would have been involved. And there would have been involvement from chemistry manufacturing controls, from labeling, and I don't know those individuals at that point in time.

Q. Does labeling fall under regulatory affairs?

A. Yes.

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 organizational charts are going to answer that question.

BY MR. O'BRIEN:

Q. With regard -- with regard to drafting the IND for Cymbalta, what departments were involved other than regulatory?

A. Well, I'm going to speak in generalities because I can tell you the functions certainly involved.

MS. JONES: And I'm going to object to the extent that this is outside the scope of the notice. You can answer in your individual capacity.

A. Okay. Different -- there are

different components to an IND, much like an NDA. But because, when you're typically filing an IND, it's primarily -- you've not -- you don't have any human data. So there is definitely a toxicologist. There is a clinical pharmacologist. There -- we have ADME, which stands for "absorption, distribution, metabolism, and excretion" scientists. Usually a pharmacokineticist, regulatory, and then medical as well as global patient safety and chemistry manufacturing controls. There's also a legal review.

BY MR. O'BRIEN:

Q. Within those different categories, do you know any individuals that were involved in the Cymbalta IND?

A. No.

Q. Now, I want to go back and talk about the NDA file.

A. Uh-huh.

Q. What -- I know you mentioned some of the things that are recorded in the NDA file. Can you give me a list of

the different areas that are recorded?

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 have been held with FDA that are relevant

to that application. It would include your risk management plan, your pediatric plan, your patent information.

Module 2 would include the multiple summaries. So that would include your clinical overview, which is really about the benefit risk of your compound. It includes your summary of efficacy, your summary of safety, your summary of clinical pharmacology, your summary of quality, which means CMNC, it also includes summaries of the nonclinical work that was conducted.

Module 3 goes into a lot of detail for chemistry manufacturing controls. It's broken out by drug product and drug substance.

Module 4 will include all the individual study reports of all the nonclinical work that's been done.

And then Module 5 includes all of the clinical study reports that have been conducted. And that includes statistical data sets and case report

forms, a number -- in addition to the 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?

A. Uh-huh. For Cymbalta

specifically, more maintaining the risk management plan. We are reviewing it annually. That effort is initiated by our global patient safety organization. So they're responsible for creating, initiating the review and the approval of that document. Regulatory is involved in reviewing the document and there are specific sections within the risk management plan for which regulatory personnel are responsible and that includes any regulatory interactions that have occurred over the last reporting period to do with safety. Were there any drug safety communications? Were there, you know, where we put on clinical hold for some safety issue, safety reason? Was, you know, product withdrawn, that kind of thing? And so my -- in my tenure working on Cymbalta, I've not had anything to list in that section.

Q. Now, I want to turn our attention to meetings in the regulatory affairs department. Are there regular

meetings that happen on a scheduled basis? As a director in U.S. regulatory affairs for Cymbalta and neuroscience, what meetings do you attend on a regular basis?

A. Could you be more specific?

Q. Is there a department meeting that you have to attend every month?

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 Cymbalta is one of them. And we do have

postmarketing commitments outstanding, so they are reviewed.

Q. And who participates in those meetings?

A. Those meetings are chaired by Dr. Rob Metcalf and Dr. Tim Garnett. There are also other medical personnel involved as well as legal.

Q. And can you list the different individuals and responsibilities that attend those meetings?

A. No, because I don't attend those meetings. I provide written input to those meetings. I give status updates on the various PMCs. And I've once been asked to go to the meeting to answer questions.

Q. And what's a "PMC"?

A. Oh, postmarketing commitment. When a drug is approved by FDA, they often, in their approval letter, will issue certain postmarketing commitments. That could be to conduct a different study, to collect additional information

from a registry, there can be multiple different kinds of commitments that are requested by FDA.

Q. And have you ever been required to gather money -- sorry.

Have you ever been required to gather materials as it relates to Cymbalta 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 for oncology.

Q. And where would that be saved?
A. I believe there is the GRAUS collaboration site. I think there's a senior management component to that that is restricted.
Q. And you said there's also -- you also said there's a GRUS [sic] bio-medicines meetings?
A. Uh-huh.
Q. And who attends those meetings and what are the purpose of those meetings?
A. So it's really Carl Garner and his staff. We talk about what's going on, what hot topics are going on, their updates on what's going on from a management perspective that we need to be aware of.
Q. As it relates to regulatory issues or what type --
A. Yes.
Q. -- of issues do you discuss at those meetings?
A. Yeah, I mean, it's primarily

regulatory. It's who recently had a meeting with FDA, how did it go, that kind of thing.
Q. Do you know if Cymbalta discontinuation syndrome has ever been addressed in one of those meeting?
A. Not while I've been on Cymbalta and not that I'm aware of prior to that.
Q. And that would also be saved on the system?
MS. JONES: Objection to form. When you say "that," what are you talking about?
MR. O'BRIEN: I'm sorry. Let me ask you a better question.
BY MR. O'BRIEN:
Q. Would those materials used at the global regulatory bio-medicine meetings be saved anywhere?
A. They are saved currently on a collaboration site.
Q. Now, you were the U.S. regulatory consultant in neuroscience from September 2010 to March of 2010.

MS. JONES: I'm sorry. September of 2010 to March 2010?
MR. O'BRIEN: I'm sorry. September 2007 to March 2010.
BY MR. O'BRIEN:
Q. Do you remember attending any meetings where Cymbalta discontinuation syndrome was discussed?
A. No.
Q. And during that time frame, were you attending regular department meetings?
A. Yes.
Q. Would it be the same type of meetings or what type -- what were those meetings called during that time frame?
A. During that time frame, we were -- it was neuroscience focused. So we did have a monthly, you know, U.S. regulatory neuroscience meeting. Dr. Brophy was in charge of that group. And it was the same kind of meeting, talking about the products, but it was a little more focused since it was just neuroscience.

Q. Now, as we talked about earlier, there are CRFs [sic] that govern what information is placed into new drug applications, correct?
MS. JONES: Do you mean provisions of the Code of Federal Regulations?
MR. O'BRIEN: Yes.
MS. JONES: You said "CRF."
THE WITNESS: That's CFR.
MS. JONES: That's CFR.
MR. O'BRIEN: Sorry.
BY MR. O'BRIEN:
Q. Sorry. Strike that.
There are regulatory statutes that govern what goes into an NDA, correct?
A. Correct.
Q. Has Lilly converted those regulatory statutes in any sort of SOPs or --
A. Yes.
MS. JONES: Hold on. I'm sorry. Objection to the form. Go ahead.

You can answer.
A. If you -- all of our SOPs reference specific statutes and/or guidance, whether they be FDA, international, that is part of the SOP and wherever that comes from is always referenced.
BY MR. O'BRIEN:
Q. Are there any other documents associated with those SOPs that provide any sort of direction, like some sort of job aid?
MS. JONES: Objection to the form.
A. You mean for an NDA?
BY MR. O'BRIEN:
Q. Yeah, for an NDA. For instance, yesterday we had a deposition with Dr. Knowles. He said some of the SOPs had accompanying documents that helped, you know, provide some guidance. I was wondering if there's that with the SOPs as it relates to federal regulations?
A. There are some SOPs with job

aids or tools associated with them. I'm trying to think specifically around NDA if there was anything. Because I'm not sure there's a job aid, but there is reference to the ECTD table of contents, which is very detailed as to what goes in what module and a description of those that is been harmonized that's been agreed to globally through the international council of harmonization.
Q. Do you know who was responsible in entering the code of regulations into SOPs?
A. It would have --
MS. JONES: Hold on. Objection to the form. Go ahead.
A. It would have been the folks involved with the regulatory quality system.
BY MR. O'BRIEN:
Q. And what folks involved in regulatory quality system draft the SOPs?
A. It's done by subject-matter experts within the group. There are

personnel assigned within the quality organization that will take the lead on updating or creating SOPs. And they will employ the appropriate experts in doing that and then they are approved. Ultimately by Dr. Metcalf or Dr. Forda, who is the vice president of international regulatory affairs, as well as the quality organization. There's usually two approvers.
Q. Is there a copy of the CFRs in your department?
A. Yes.
Q. Where is it located?
A. We have individual copies on the two nice little notebook things. It's updated annually, includes 21 CFR, 312, 314, 50, just the ones that are most relevant to our job. So we literally have a paper copy. You can also access this online through the FDA website and get to any CFR.
Q. And other than job aids, are there any other documents that Lilly has

produced that help provide guidance in interpreting the CFRs?
A. No. Well, let me take that back. We do look at FDA guidance documents which will often extrapolate from the CFRs. That's not something that Lilly provides, that's something that FDA provides and is publicly available. And then there may be webinars or webcasts that different organizations will host to elaborate on a specific regulation. Those are done by external parties, not by Lilly.
Q. Now, I want to turn my attention to technical writers. Were you -- one of your, I guess, earlier positions in Lilly, was that part of a technical writing group?
A. Medical writing, technical writing, global scientific information and communications essentially mean the same thing, although technical writer can have different connotations, so it would depend on specifically what you're referring to.

Q. Were there technical writers that were used to help draft Cymbalta's label changes since 2004?
A. No. The people that are involved with drafting the label, that effort is coordinated by our labeling department. So they would coordinate the writing of the label. The content comes from the cross-functional team involved, including medical, GPS, statistics, toxicology, ADME, PK.
Q. And that was a product team that we talked about earlier?
A. That's correct.
Q. That would be the same team that would deal with the label changes?
A. Yes. So in a way, you could call the labeling associate a technical writer, but they do more than that. They do research on FDA's expectations for various parts of the label. That does change over time. The format of the labeling changes over time and they keep up with all of that and also will look

at, you know, competitor labels for consistency.
Q. Do you know who the labeling associate is for Cymbalta?
A. Yes, Sara Mescher. That's currently who was the labeling associate.
Q. And how long has Sara been in that position?
A. Several years. I don't know specifically when she started working on Cymbalta.
Q. Has it been like five years or --
A. I think so.
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 with me.

MR. O'BRIEN: Okay.
BY MR. O'BRIEN:
Q. I want to turn our attention to advertisements. Who creates a draft copy of Cymbalta ads?
MS. JONES: I'm going to object to this as outside the scope of the notice. You may answer in your individual capacity.
A. In general terms, marketing creates all of our promotional pieces.
BY MR. O'BRIEN:
Q. Do you know if marketing employs any third parties that create the advertisement or is that done in-house?
MS. JONES: Same objection. Go ahead.
A. We do some in-house. I know we've engaged other vendors for materials.
BY MR. O'BRIEN:
Q. Are ads sent to the FDA? I know before you kind of took me through the process of approving ads. Once they are, you know, used, are they sent to the

FDA?
A. We have a regulatory affairs-U.S. ad promotional group. They are responsible for working with marketing and the PCA review process to ensure compliance with our SOPs as well as any applicable federal regulation. All of our advertising materials are submitted to FDA per regulation. In some cases, direct to consumer information is precleared. Other information is submitted with a Form 2253 at the first time of use. But, yes, all of that is provided to the agency.
Q. Just so you understand, there's 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 require preapproval?

A. Yes.
Q. What type of ads are they?
A. Television direct-to-consumer ads. We elect -- I mean, there are times when we preclear materials that don't require preclearance because we want FDA's feedback on that.
Q. And where are these ads saved within regulatory?
A. All of the regulatory correspondence that we have with the agency is maintained in e-files.
Q. And how long are they retained for? Are they retained for the life?
A. Yeah, as long as -- yeah, as long as we're marketing the compound or the drug. Or if we divest it, we might, you know, sell the product and with it we would give them the IND and NDA.
Q. Has the FDA ever had an issue with one of Eli Lilly's ads for Cymbalta?
MS. JONES: Objection to the form; vague.
A. What do you mean?

BY MR. O'BRIEN:
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 advertisement. Yes, we've received a couple of these.
Q. As it relates to Cymbalta?
A. Yes.
Q. Do you know what happened -- strike that.
What is an "untitled letter"?
A. An "untitled letter" is a notice of violation that FDA provides to a sponsor, if they review a promotional piece that they think is not in compliance with their standards. That letter is sent to the company and will define what they believe is deficient and they add and ask us to ask the sponsor to cease dissemination and/or correct the

promotional piece.
Q. You said that's an untitled letter. Is there something called a "titled letter"?
A. There's an untitled letter and then there's a warning letter. I don't know how they came up with the terminology. An untitled -- it has to do with the severity of the violation, is my understanding is the difference between the two.
Q. Now, would a warning letter, would that -- would that come after -- after an untitled letter or could a warning letter come out for the first time on an advertisement that the FDA had a problem with?
A. A warning letter could come out the first time.
Q. Okay. Do you know if Eli Lilly has ever received a warning letter as it relates to a Cymbalta ad?
A. We have not.
Q. Do you have an idea of how

many untitled letters that Lilly has 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 Cymbalta representations?
A. I have a vague idea. So I can't speak to the details. I know a few of them involved promotional pieces regarding diabetic peripheral neuropathic pain that they -- well, in one case, a promotional piece, they found deficient with respect to safety information, however, it turned out that the FDA had been -- they had the wrong information. They literally had the advertisement without the important safety information. So they were wrong. The information had been provided. So once that was discovered, the letter was no longer -- I don't know what the right word is, but,

you know, it wasn't --
Q. It was taken back or whatever?
A. It was taken back, yes.
Q. What about the other, what did we say, four, you said four or five letters?
A. Yeah. I don't recall the details, but I do remember looking through them briefly and there was nothing specific to discontinuation emergent adverse events.
Q. Do you remember if the advertisements were ultimately pulled in those cases?
A. In all cases, we complied with FDA's recommendation to cease dissemination. We responded to the letters in writing with whether or not we agreed with their characterization, of whether or not we were in violation and -- but, yes, we did cease dissemination of the specific pieces that were noted.
Q. Do you know if within regulatory if there's any sort of

corrective action that got taken regarding representations with the Cymbalta ads? Like was anybody disciplined for letting an ad that had to be pulled back due to FDA cease and desist letters?
MS. JONES: Objection to the form.
A. Not that I'm aware of. We are constantly learning from our interactions with the agency as well as interactions of other companies. We routinely review untitled and warning letters, particularly for advertising and promotions, because FDA regulation and implementation of regulation, particularly for advertising and promotion, has changed dramatically over the years. So there is a -- it is an area that evolves quite frequently.
BY MR. O'BRIEN:
Q. Was Eli Lilly concerned about the untitled letters?
A. Yes. I mean, we take them very seriously and we go through and try to understand where we might have gone

wrong in producing those pieces and what we could have done differently. We often find it's a difference of interpretation and that what we provided in a promotional piece, we did believe was in compliance with the regulations. And we have so stipulated.
Q. Do you know if there's any changes to the regulatory process for reviewing ads after the second, third, fourth were pulled back from the FDA?
A. No. I mean, we do periodically review our processes, but not -- there is not changes specific to Cymbalta or because of Cymbalta.
Q. I was wondering if you know the person that was reviewing those ads, that gave approval to those ads that had to be pulled back from the FDA, if that person was maybe changed out or given new instruction or extensive training due to the FDA's untitled letters?
MS. JONES: Objection to the form.

A. I don't know.
MR. O'BRIEN: Let's take a ten-minute break.
MS. JONES: We are going off the record. The time is 11:42 a.m.
(A recess was taken at 11:42 a.m.)
THE VIDEOGRAPHER: This is the beginning of Tape 3 in the deposition of Dr. Christine Phillips. The time is 11:51 a.m., and we are back on the record.
BY MR. O'BRIEN:
Q. Dr. Phillips, I want to turn our attention to labeling. With regard to labeling, I think you mentioned earlier there's a -- there was a Cymbalta product team that would help develop and draft the labels, correct?
A. Correct.
Q. Do you know -- are you aware if Lilly keeps different drafts of labels, for instance, is there red-line labels, drafts that Lilly keeps?
A. Every time we make a label

change, we submit to the agency both a red-line version as well as a clean version. So, yes, we do have records of those.

Q. I imagine that in the course of drafting a label, there may be different versions that take place. Do you know if different versions are saved before they're submitted to the FDA?

A. I do not know.

Q. Do you know where that information would be if it did exist?

A. If it does exist, it would be within the global labeling archives.

Q. And that would -- that would include, if it does exist, rough drafts of labels before they're actually finalized?

A. Yes.

Q. Is there somebody that's responsible for archives at global label?

A. There is. I do not know. Nancy Allen is the senior director over operations and labeling. So I expect she

is ultimately responsible. I don't know if there's a specific individual within labeling that that is their responsibility.

Q. Are you familiar with the process of changing a drug's label?

A. Yes.

Q. Can you take us through it?

A. Okay. For any label change at Lilly, we -- there are many potential triggers for a label change. It could be through our safety surveillance that's ongoing, we've identified a new emergent safety signal. It could be -- it could come from that. It could come from the completion of a clinical study where either a safety or efficacy difference has been noted. So we're adding a new indication, for instance. It could come from new toxicology data, new clinical pharmacology data, PK data. We can get requests from various regulatory agencies to make a label change. So there are many different ways or triggers for

considering a label change.

Regardless of what initiated that trigger, the process is to review the information to understand why the change is being requested, what's the rationale, what are the supporting data, and then we look at our core data sheet to see, is it already covered in our core data sheet, yes or no. If it's not, then we would proceed with potential core data sheet change which would be documented and reviewed by our Global Product Labeling Committee, GPLC. If that change is approved, it will then be implemented locally and labeling according to that region's local regulations. And then whatever change has been made will be submitted to the appropriate regulatory agency for approval.

Q. Now, with regard to a label change, let's say, for instance, as you know, there were label changes with regard to Cymbalta discontinuation syndrome.

A. Yes, there have been label

changes regarding that.

Q. When there's a label change within Lilly, is there any sort of rationale for the label change?

A. Yes.

Q. Is that document submitted to the FDA?

A. Yes.

Q. Is there additional documents related to label change that aren't submitted to the FDA?

A. I'm thinking. No, I mean, there -- like I said, there could be different reasons for a label change, whether that be a new indication that we're adding to the label, a new safety finding, or an FDA request, specifically. I'm focusing on the U.S. in this situation. But whenever we submit a label to the agency for a review and approval, every change is annotated with supporting documentation.

MS. JONES: I'm sorry. Could you read the last question back, please?

(Record read.)
MS. JONES: Okay. Let me just make an objection to the form.
BY MR. O'BRIEN:
Q. Do you know, with regard to Cymbalta or any other sort of label change, if the product team creates materials that kind of discuss the reasoning for the label change? Say there's PowerPoint presentations to present to the group, do you know if those sort of materials are created?
MS. JONES: Objection to the form.
A. Depends on what you mean specifically. When we are changing our core data sheet, there is a presentation, although it's written, it's not PowerPoint. There's a template that's filled out with what is changing and why and the supporting documentation for that.
BY MR. O'BRIEN:
Q. Is that template for the FDA or is that template for Lilly internally?

A. That template is for Lilly internally for making core data sheet changes. When we submit a label change to the FDA, we have to draft labeling, the red-line labeling, the annotated labeling, and in some cases there may be a supporting rationale document if it -- if it's -- if it requires more explanation than a simple annotation, and that would include statistical figures, tables, you know.
Q. What is the name of the document that is the Lilly template for a label change?
MS. JONES: Objection to the form.
A. For the core data sheet, for the USPI, for the SPC, could you be more specific?
BY MR. O'BRIEN:
Q. For the core data sheet.
A. For the core data sheet there is a template. What is it called? It's within a specific -- the GPLC preread, I

believe is what it's referred to.
Q. And what does that stand for?
A. Oh, "Global Product Labeling Committee."
Q. Now, there's a product team, you know, right now there's a -- you said a neuroscience platform, correct?
A. That's correct.
Q. Is there an interaction with them in the global product labeling committee?
A. If there is a proposed label change, yes.
Q. If there was a proposed label change, what type of interaction would there be? Or what was the proposed -- what type of interaction was there when there actually were changes to the Cymbalta label?
MS. JONES: Objection to the form.
A. Speaking in generalities, the team has determined that there is a need to change the core data sheet. They --

that team, if it's a safety change, that goes through review by the safety review committee, the SRC, which then makes a recommendation to GPLC. So there is a preread, again, that says, "Here are the data, this is why we think the label needs the change," and then that's reviewed and approved or rejected by the global product labeling committee and the reason for their approval or rejection is recorded in the minutes.
BY MR. O'BRIEN:
Q. Do you know if the GPLC has ever rejected a proposed Cymbalta label change from the SRC?
A. I don't know.
Q. Do you know who would know that?
A. Our GPS personnel.
Q. Is there a log of GPLC rejections of labels proposals?
MS. JONES: Excuse me. Objection to the form.
A. There are GPLC meeting minutes.

I don't know if there's a log that would provide exactly what you're asking for.
BY MR. O'BRIEN:
Q. Does the GPLC meet regularly, like once a month, or only when there's a proposed label change?
A. There's a standing meeting every two weeks that are cancelled if there's no agenda items. If there's something that's needed more urgently, there's an ad hoc meeting scheduled.
Q. Who is on the GPLC?
A. It is chaired by Tim Garnett, our chief medical officer. Other members include the vice president of global regulatory affairs for the U.S., which is currently Rob Metcalf. It also includes the vice president of global regulatory affairs international, Dr. Susan Forda. It includes legal. It includes quality. It includes medical as well as global patient safety and other functional area experts as needed.
Q. And who is typically present

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 physicians that often attend our European -- there's a specific term in European regulatory affairs called the "QP," the qualified person. And that is Valerie Simmons, Dr. Valerie Simmons, and she is responsible -- she would be the one point person from the European perspective for all safety issues.
Q. Now, once they label -- a proposed label is submitted to the GPLC, can they edit that label or will they just reject the label and will go back to where it started?
A. GPLC will review the core data sheet. They do not review local labels. So they would not review the USPI or the European summary product characteristics. So they are reviewing changes to the core data sheet. They can definitely wordsmith, change the wording, and -- or

make recommendations for a different presentation of the data. So, yes, that is all well within the rights to approve, reject, modify, ask for additional information.
Q. Now, if the GPLC were to wordsmith the core data sheet for Cymbalta, if that ever happened, where would I find that?
A. That would be --
MS. JONES: Hold on. Objection to the form. Go ahead.
A. That would be in the meeting minutes.
BY MR. O'BRIEN:
Q. They would actually indicate the language that got changed in the meeting minutes?
A. I think so. At a minimum you would have the preread that went into GPLC and what was ultimately approved.
Q. And where would the preread and the meeting minutes be located?
A. They do have a dedicated

collaboration site where that information is housed.
Q. And that would be a collaboration site for the GPLC?
A. Yes.
Q. And could anybody within regulatory access that?
A. No, I don't believe so.
Q. Does it require a certain level of clearance?
A. Yes, and I believe it's maintained by our labeling department.
Q. If GPLC decides to wordsmith a label, can they approve it and send it off for FDA submission?
A. No. The GPLC reviews and approves or rejects the core data sheet language. The core data sheet is the basis of local labeling. Local labeling is not necessarily identical to what is in the core data sheet. It has to be conceptually consistent as well -- with the core data sheet as well as applicable local regulations.

Q. So if the GPLC approved the changes to the core data sheet, can the label or the proposed label be submitted to the FDA?
A. The label would be modified according to the change in the core data sheet and local regulations and then submitted to the FDA for approval.
Q. Would there be a secondary review to ensure that the changes to the core data sheet and the changes to the label based on the changes to the core data sheet were consistent?
A. Yes. There is a review process. I mean, whenever we make any label change, there is a quality and a content review involved with all of that prior to submission.
Q. So what would happen, say, the core data sheet gets changed --
A. Uh-huh.
Q. -- and then, you know, the department is going to change the label to reflect the changes in the core data

sheet.
A. Uh-huh.
Q. What happens next on its way to the FDA?
A. Are you asking what does the team do between core data sheet change and USPI change?
Q. Correct.
A. Okay. The labeling associate makes all of the affiliates, not just the U.S., aware of a core data sheet change. And there is a guideline for how quickly that needs to be implemented or acted upon and there are mandatory changes, nonmandatory changes, that's -- all that's detailed in SOPs.
So we find out, you know, that there's been a core data sheet change and we need to implement it in U.S. labeling. And then it's looking at what is being changed, looking at our label, understanding where it goes in the U.S. label. There's 17 sections to a USPI. Where does it go? And then we look at

wording that makes sense, but then also looking at what are in the FDA guidance documents as well as the CFR regulations around label content and format. And then we also look at similar labels to get a sense of the language that FDA prefers.
Q. And the acronym "USPI," what does that stand for?
A. The "United States Package Insert." If you refer to the U.S. label, that's -- you know, we use those terms interchangeably often.
Q. With regard to Cymbalta, who is the person that's responsible for making sure that the core data sheet and the USPI are consistent?
A. The labeling associate is responsible for performing that quality check. Ultimately all changes to the U.S. product information is approved by the senior medical director for U.S. medical.
Q. And do you have an

understanding of who has been the labeling associate since 2004 as it relates to Cymbalta?
A. I only know the current labeling associate and that's Sara Mescher. I'm not sure who preceded her in that role.
Q. Do you know if Sara Mescher has been the labeling associate for all the Cymbalta label changes?
A. She probably has not. I mean, she's been with the molecule for several years, but I don't think she's been part of every single label change.
Q. Let's take a look at the Cymbalta label changes.
MR. O'BRIEN: And, Phyllis, if you have a better representation of the --
MS. JONES: Let me see what you have.
MR. O'BRIEN: Yeah, I think --
MS. JONES: Are we marking this?

MR. O'BRIEN: Yeah, let's mark it. This is Exhibit No. 3.

(Plaintiff's Exhibit-3 was marked for identification.)

BY MR. O'BRIEN:

Q. Now, Doctor, under each box it kind of discusses the changes, however, I think the actually language doesn't start until -- it starts "discontinuation symptoms."

A. Okay.

Q. Now, there's kind of like some -- under each label change there's kind of an entry where it kind of discusses what the changes were. Here, let me switch. Let me give you the marked copy.

A. Okay. So you are -- the bolded text are the changes from the previous version; is that correct?

Q. Correct.

MR. O'BRIEN: And, Phyllis, if you have a different document that you would like to use --

MS. JONES: Well, I'm not sure

what you're planning to ask her. I'm going to hand her something just for her reference, just to make sure that your understanding is aligned with --

THE WITNESS: Okay.

MR. O'BRIEN: Here, let me mark that.

MS. JONES: Okay.

MR. O'BRIEN: I will mark this as Exhibit No. -- are we up to 4? I guess these are numbered?

MS. JONES: The pages are numbered, yes.

(Plaintiff's Exhibit-4 was marked for identification.)

BY MR. O'BRIEN:

Q. Here, Doctor, you can use this as your reference.

A. Okay. Thank you.

Q. Now, Doctor, here is a paper that kind of summarizes the discontinuation warning for Cymbalta since 2004.

A. Okay.

Q. It's my understanding there are changes in 2005, 2008, 2009, again later in 2009, and then in 2012. The changes are indicated by bold type, which you can see in each one of those label changes.

A. Uh-huh.

Q. In preparation of your deposition today, I believe you had a conversation, was it Dr. Sara -- did you have a conversation with somebody about the reasons for the label changes? I have to check my notes.

A. I did speak with Dr. Hoog and Dr. Ann Robbins about the initial approvals. And I asked to speak with Torkil Fredborg about changes to the SPC, which is the summary of product characteristics for Europe.

Q. Did you review these particular changes as shown in Exhibit 3 with Dr. Hoog?

A. No, not all of these, no. I really was focused on the initial approval.

Q. Okay. And that's kind of what I wanted to ask you. I wasn't sure if you went through the different label changes from 2005 to 2012 and discussed with Dr. Hoog the reasons for the change.

A. No, she was no longer involved with Cymbalta as of early 2005.

Q. Okay. Are you able to testify today of why the changes were made with regard to the changes in front of you from 2005-2012?

A. Yes.

Q. Can you discuss with us why the changes were made? Let's begin in 2005.

MS. JONES: Just to be more precise, is there a specific change that you're interested in for 2005?

MR. O'BRIEN: Whatever the bolding is. Each change --

THE WITNESS: Okay.

MR. O'BRIEN: -- is bolded.

MS. JONES: Okay. Well, do you want to just state that for the purposes of the record so we have a clean

record on what exactly she's explaining for you?

MR. O'BRIEN: Sure.

BY MR. O'BRIEN:

Q. We're looking at the changes in the 2005 label which added MDD.

A. FDA requested that change because either -- well, either FDA or we, Lilly, put that in the legal because we had additional indications that were under review. So it was being more specific to specify that these trials were conducted in patients with depression. Previously when our label was first approved, it was only reflecting depression data. So it was understood. It wasn't -- there was no need to call out that these were depression studies because that was the only thing in the label at that point in time.

Q. And in 2008, it looks like insomnia, diarrhea, anxiety, vertigo, and hyperhidrosis were added. Do you understand why there was a label change

there?

A. FDA changed the threshold for reporting of specific symptoms for discontinuation emergent adverse event from the threshold of 2 percent or greater to 1 percent or greater. Therefore, additional terms were added.

Q. Was that -- did the FDA change that threshold specifically for Lilly or across the industry?

A. I don't -- I can't comment on across the industry because I haven't looked at all the labels. This was consistent with the fibro -- I believe, with the fibromyalgia indication being approved and added to the label, at which point we had a larger database. The information was included from all of our indications and FDA changed the threshold from 2 percent to 1 percent, which, again, is at a rate 2 percent or greater was changed to a rate of 1 percent or greater which is a more conservative threshold.

Q. Now, in 2009, there was a change that added tapered discontinuation as opposed to just abrupt discontinuation. Do you know why Lilly made the change to add "tapered discontinuation" to the label change as a warning?

A. This has always been part of a warn -- this has always been a warning in a label precaution or a warning. So this is in 2009. I don't know if that was something that we added or FDA added. We have done -- performed studies with abrupt discontinuation as well as tapered discontinuation. So it's possible this was a consistency change.

Q. And you don't know if the impetus for this change was FDA initiated?

A. I don't know.

Q. Do you know who would know the answer to that question?

A. Should be part of our GOLD department archives. It may also be in e-files.

Q. I'm sorry, your GOLD department?

A. GOLD is "global operations labeling department."

Q. Okay.

A. Sorry.

Q. And then I guess later in 2009, the symptom fatigue was added.

A. Yep.

Q. Do you know if that was added based on FDA requiring it or did Lilly do that on their own?

A. We had additional information added to our safety database and as such, the -- this symptom crossed the threshold of 1 percent or greater, so therefore it was added to the label.

Q. Was that information, did that come from a clinical trial or did it come from some other source?

A. This would have come from clinical trials. That's what the -- you know, this is the section of the label specifically refers to placebo-controlled clinical trials.

Q. Now, in 2012, it went from, I

guess, equal to 1 percent to at 1 percent or greater. And then it added the symptoms headache, nausea, diarrhea, irritability, vomiting, and I guess it changed -- I guess fatigue, changed the order --

A. Uh-huh.

Q. -- of the side effects.

A. So two things. Previously the label said, "at a rate greater than or equal to 1 percent." And the wording was changed to "at 1 percent or greater." Those are the same. So it's actually a change of wording but not a change in threshold.

Q. Do you know why it was reworded?

A. No, I don't. And then, again, we are always adding to our safety database as new trials are completed. And so we -- our database grew over time, had new trials that were completed, and therefore the symptoms that occurred at the threshold of 1 percent or greater

were reflected and they're reflected in the --

Q. Rate of incidence?

A. The incidence with the -- the first one being the most frequent to the least frequent. That crossed that threshold.

Q. And that was my question. So dizziness would be the -- would have the highest incidence and that kind of, I guess, then headache, then nausea, then diarrhea?

A. Yes.

Q. When they rearranged the symptoms in 2012, they went from highest incidence to lowest incidence, correct?

A. Uh-huh.

Q. Was it always in that order before or is that something that they just decided to do in 2012?

A. No, it's always been that order, that principle for the order, yes.

Q. Anywhere in that chart does it tell the percentage of incidence for

dizziness?

A. I don't believe so.

MS. JONES: I can tell you and answer that, it's no.

BY MR. O'BRIEN:

Q. So Lilly's labeling department clearly has an indication of, you know, the incidence that occurs with each symptom.

A. Uh-huh.

Q. Where would that information be located?

A. Well, the information to support any label change is provided to the FDA. So the information around incidence of specific adverse events are included in the original NDA and all periodic safety update reporting to the agency in the annual reports. And then whenever a label change is made, it's annotated and the supporting data are provided. So FDA has always had access to the specific percentages of all of these adverse events.

Q. Thank you. I think that's all I have, Doctor, with respect to that sheet. You can put that away.

A. All right.

Q. Now, Doctor, I just want to go over a couple of principles with you with regard to regulatory affairs. Is it your understanding that Lilly's regulatory department communicates with regulatory authorities in a truthful, responsible, consistent basis?

A. Yes.

MS. JONES: Object. Well, hold on a second.

THE WITNESS: Sorry.

MS. JONES: Give me a chance to object. Objection to form. You may answer.

BY MR. O'BRIEN:

Q. And does Lilly's regulatory department feel that that's important?

MS. JONES: Objection to the form.

A. Yes, absolutely.

BY MR. O'BRIEN:
Q. And does Lilly think it's important that a company be truthful in what they tell the FDA?
MS. JONES: Same objection.
A. Yes.
BY MR. O'BRIEN:
Q. To your knowledge, has anybody in your department ever been untruthful to the FDA about Cymbalta?
MS. JONES: Objection to the form.
A. Not to my knowledge, no.
BY MR. O'BRIEN:
Q. Now, Doctor, we just -- just to circle back, dealing with the label change of Cymbalta. All those label changes would have happened with the product team, correct?
MS. JONES: Hold on. Objection to the form; vague.
A. I mean, the team has changed over time, but the fundamental functions involved with any label change remain the

same, medical, GPS --
MS. JONES: I'm sorry. Could you read the question back, please?
(Record read.)
MS. JONES: Okay. Objection to the form; vague as to "would have happened."
BY MR. O'BRIEN:
Q. Okay. My question is, there were label changes with Cymbalta from 2004 to 2012.
A. Uh-huh.
Q. Would it be the same type of people involved, like a Cymbalta product team or a neuroscience platform team that would have been involved with the label changes?
A. Yes.
Q. And that would have been consistent from 2004 to present, correct?
A. The same functions were involved -- are involved with any label change. A proposal for a label change with the supporting rationale is made, a

determination of whether or not it impacts the core data sheet, or if it's a regional label change only and why, if needed, it undergoes GPLC review and approval before implementation locally.
Q. And does Lilly believe it's important to provide accurate and complete information in their package inserts?
A. Yes.
Q. And that would be accurate and complete information, correct?
MS. JONES: Objection to the form.
A. We work on labels in conjunction with FDA. A label is a concise, succinct representation of all the available data on the molecule. There is judgment that is called in to play when discussing the information that is included in the label between FDA and sponsor company.
BY MR. O'BRIEN:
Q. Do you think it's Lilly's responsibility to provide accurate and

complete information in package inserts regarding Cymbalta?
MR. O'BRIEN: Objection to the form. You may answer.
A. We provide complete data to the agency on everything in our database and what we've seen our literature searches, all of that's done periodically. Lilly safety system, FDA safety system. That is distilled into label language. That is reflective of the information that is important to prescribers for prescribing a medication safely.
BY MR. O'BRIEN:
Q. Is that a "yes," that you think it's important --
A. Not every piece of information --
MS. JONES: Hold on. Wait. Hold on. Let him finish his question and then you can answer.
THE WITNESS: Okay. Sorry about that.
BY MR. O'BRIEN:

Q. Is that a "yes," do you think it's Lilly's responsibility to provide accurate and complete information in their package inserts concerning Cymbalta?

MS. JONES: Objection to the form. You may answer.

A. We provide accurate and complete information to the FDA. The label is a distillation of the information, so it does not include every piece of information that we have about Cymbalta. If we did that, it would be five million pages long. That's where we work with the agency to represent the safety concepts and to provide the information that a prescriber needs to safely administer the drug. It warns of the potential adverse effects, when they're observed, what to do about them.

MR. O'BRIEN: Move to strike as nonresponsive.

MS. JONES: I'm going to oppose that motion. Go ahead.

BY MR. O'BRIEN:

Q. So Lilly doesn't think that they have the responsibility to provide complete information in their package inserts concerning Cymbalta?

MS. JONES: Objection; mischaracterizes the testimony.

A. No, that's not accurate. I'm trying to explain to you the process by which we work with FDA to approve labeling to informed prescribers.

BY MR. O'BRIEN:

Q. So Lilly does provide complete information in their package inserts concerning Cymbalta?

MS. JONES: Objection; asked and answered, mischaracterizes the testimony. If you want to answer it again, go ahead.

A. There's no difference in my answer.

BY MR. O'BRIEN:

Q. Do you think it would be ever appropriate for Lilly to misrepresent data about Cymbalta in their package inserts?

MS. JONES: Objection to the --

A. No.

MS. JONES: Objection to the form.

BY MR. O'BRIEN:

Q. Do you think it would ever be appropriate for Lilly to mislead physicians or patients about the risks of discontinuating [sic] Cymbalta in their package inserts?

MS. JONES: Same objection.

A. No.

BY MR. O'BRIEN:

Q. Doctor, can you take us through the different types of warnings that are on a USPI?

A. Yes. There is FDA guidance around warnings, precautions, and adverse reactions that can be referred to. The most current version of the USPI in the sense of FDA changed from -- to a physician's labeling rule format several years ago, 2007 time frame. So now there's 17 sections of the label, one of

which is titled "warnings and precautions."

Our warning regarding discontinuating -- discontinuing treatment with Cymbalta is included in that warning section.

Q. Is there a higher level warning than a warning and precaution?

A. Yes, there's a boxed warning.

Q. Is there any other elevated warnings other than warnings and precaution other than box warnings?

MS. JONES: Objection to the form. Go ahead.

A. In general, there is a contraindication. There's a contraindication and a boxed warning.

BY MR. O'BRIEN:

Q. Is there a bold warning?

A. A boxed warning is a bold warning.

Q. So it is a black-box warning. Is there also a bold warning?

A. No, they're the same. Those

terms are used interchangeably.
Q. If at any time Eli Lilly wanted to heighten their warning for Cymbalta discontinuation syndrome, is there anything that would prevent that?
A. We can -- we have the ability to propose different label changes to the agency, which would include the elevation of a warning to a boxed warning. That is always subject to FDA review and approval.
Q. So you can add a warning or strengthen a warning without FDA approval?
MS. JONES: Objection; mischaracterizes the testimony.
A. A change's being effective -- label change based on safety can be made to strengthen or elevate a warning, however, that is always subject to FDA approval.
BY MR. O'BRIEN:
Q. But they could change the warning and get that out into the public without FDA approval at first, correct?
MS. JONES: Objection to the

form. Who is "they"?
A. Who is the "they"?
BY MR. O'BRIEN:
Q. Do you not have an understanding of who "they is?
A. No, I don't.
Q. If Lilly wanted to strengthen the warning for Cymbalta discontinuation syndrome, could Lilly do so and distribute 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.
Q. So a drug company can decide to give a stronger additional warning about

their drugs at any time subject to later FDA approval?
A. Yes.
Q. Can you tell us the process about how a drug company goes about giving a stronger and additional warning about their drug?
MS. JONES: Objection to the form.
BY MR. O'BRIEN:
Q. You mentioned there's a CBE?
A. Uh-huh.
Q. Can you explain that process?
A. Whenever a company makes a change to a label, it is submitted either as changes being affected or as a prior approval label supplement. There are certain regulations about what can be changed under the CBE regulations versus prior approval. There is guidance on that. In any situation, whether it's CBE or prior approval, the proposed label change as well as the rationale for the change are provided and are subject to

FDA approval.
Q. Do you agree that Lilly has the right to tell doctors and patients about a stronger warning for Cymbalta discontinuation syndrome at any time?
MS. JONES: Objection to the form.
A. We provide information to prescribers and patients in conjunction 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:
Q. And they could do that immediately pending FDA approval at a

later time?
A. Yes.
MS. JONES: Same objection.
BY MR. O'BRIEN:
Q. But to date, Lilly hasn't felt that it's important enough to do that --
MS. JONES: Hold on. Go ahead. Finish your question.
MR. O'BRIEN: Just add an objection to whatever I ask.
BY MR. O'BRIEN:
Q. To date, Lilly hasn't felt like it's necessary to add a stronger label for discontinuation syndrome related to Cymbalta?
MS. JONES: Objection to the characterization; asked and answered.
A. She said asked and answered.
BY MR. O'BRIEN:
Q. You have to answer it.
A. Okay. Sorry.
MS. JONES: You may still answer it.
A. Okay. Well, I mean, to

reiterate, we do ongoing safety surveillance. We update information in our label. We provide that to FDA on an ongoing basis. The warning and precaution for discontinuation emergent adverse events has been in our label since it was originally approved. It's been updated, as you've noted, with the various changes in symptomatology and the difference in threshold over time.
There has never been a need to strengthen that warning. It's been consistent. It's a well-known phenomena. There is class labeling regarding this. This happens with Cymbalta. It also happens with the entire class of antidepressants. It has been adequately warned. It's been reviewed multiple times by FDA. And it has -- there's never been a need to strengthen that warning.
MR. O'BRIEN: Move to strike as nonresponsive.
MS. JONES: And I oppose that motion.

MR. O'BRIEN: Let's take a ten-minute break.
MS. JONES: Okay.
MR. O'BRIEN: I'm probably getting close to being finished.
THE VIDEOGRAPHER: We're going off the record. The time is 12:33 p.m.
(A recess was taken at 12:33 p.m.)
THE VIDEOGRAPHER: We are back on the record. The time is 12:41 p.m.
MR. O'BRIEN: I don't have any more questions.
MS. JONES: We had a few, just -- I think there were a couple of things that Dr. Phillips wanted to clarify for the purposes of the record. And in connection with doing that, we're going to mark -- we'll do this in chronological order. This is the first one.
THE WITNESS: Uh-huh.
MS. JONES: This should be Exhibit No. 5. This should be Exhibit No. 6. And she'll explain.

THE WITNESS: These are two CBEs that we submitted to the agency. And you had asked me to specifically comment on when we changed the threshold from 2 percent to 1 percent.
MR. O'BRIEN: I'm sorry. Is there a pending question? Do you have any questions for her?
THE WITNESS: No, I'm clarifying my previous testimony.
MS. JONES: I indicated that she was going to clarify her previous testimony in response to questions that you had posed.
MR. O'BRIEN: Okay. Which one is 6 and which one is -- which one is 5, which one is 6?
THE WITNESS: That one is 5.
MS. JONES: 5 is the May 2007, .6 will be September 2007.
THE WITNESS: October.
MS. JONES: October 2007, excuse me. And these have both been produced.

(Plaintiff's Exhibit-5 was marked for identification.)
(Plaintiff's Exhibit-6 was marked for identification.)
THE WITNESS: I need to look at it just for a second.
MR. O'BRIEN: Okay.
THE WITNESS: And then I will give it back to you.
So in -- May 17th of 2007, Lilly submitted a changes being affected labeling supplement for Cymbalta that indicated one of the changes that it was making, that Lilly was making voluntarily, was to change the threshold from 2 percent to 1 percent or greater when reporting discontinuation emergent adverse events for Cymbalta, and that was done based on updates in the Periodic Safety Report No. 4, that covered the period of February to August 2006. So affectively, Lilly made the threshold for reporting of discontinuation emergent adverse events more conservative at that time.

The second one is a CBE labeling supplement change that Lilly provided on August 25th, 2007, among which one of the changes was to include "following abrupt or tapered discontinuations" or adding "or tapered" and the rationale for that change was, I had sort of halfway remembered it, but not completely.
When we filed for approval of the indication for fibromyalgia in 2007, we had expanded the number of studies in our database that utilized both abrupt and tapered discontinuation of Duloxetine, therefore we updated the label to reflect that.
MS. JONES: And just for the record, can I see that one back too? Exhibit No. 5 is Bates numbered CYM .01111111, seriously. And Exhibit No. 6 is Bates numbered CYM 01113163. And Dr. Phillips had one other clarification that she wanted to make to her earlier testimony.

THE WITNESS: Yes. When you asked about the untitled letters that we've received for Cymbalta, one of them actually did reference and call out that the safety information was not adequate with regards to discontinuation emergent adverse events. So I misspoke. However, that was the untitled letter in which FDA had mistakenly not included the important safety information which does address discontinuation emergent adverse events. So that was the letter that was essentially rescinded by FDA.
MS. JONES: And that's the September 2010 letter that's publicly available on the FDA's website. I'd also like to mark as Exhibit No. 7 defendant's responses and objections to plaintiff's .30(b)(6) notice regarding regulatory affairs. This is the copy that's captioned for the Herrera matter, but our objections and responses are the same as to each of the cases in which the regulatory affairs notice has been served

and/or cross-noticed. That will be Exhibit No. 7.
(Plaintiff's Exhibit-7 was marked for identification.)
MS. JONES: We have no additional questions.
MR. O'BRIEN: Thank you.
THE VIDEOGRAPHER: This concludes the deposition of Dr. Christine Phillips. The time is 12:46 p.m., and we're off the record.
(Time noted: 12:46p.m.)
FURTHER THE DEPONENT SAITH NOT
CHRISTINE PHILLIPS, Ph.D.
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STATE OF INDIANA
COUNTY OF HAMILTON)

I, Amy Doman, RPR, CRR, CSR No. 10-R-3022, Notary Public in and for the County of Hamilton, State of Indiana, at large, do hereby certify that CHRISTINE PHILLIPS, Ph.D., the deponent herein, was by me first duly sworn to tell the truth, the whole truth, and nothing but the truth in the aforementioned matter;

That the foregoing deposition was 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 Indiana Rules of Trial Procedure;

That said deposition was taken down in stenograph notes and afterwards reduced to typewriting under my direction, and that the typewritten transcript is a true record of the testimony given by the said deponent; and that signature was requested by the deponent and all parties

present;

That the parties were represented by their counsel as aforementioned.

I do further certify that I am a disinterested person in this cause of action, that I am not a relative or attorney of either party or otherwise interested in the event of this action, and that I am not in the employ of the attorneys for any party.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my notarial seal this _____ day of _____, 2014.

Amy Doman, RPR, CRR, CSR No. 10-R-3022
Notary Public
My Commission Expires: October 1, 2017,
Residing in Hamilton County, Indiana

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