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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, . Case No. 06-CR-643 (AET)
. .
v. . 402 East State Street
. Trenton, New Jersey 08608
ALBERT POET, .
Defendant. .
. March 14, 2007
. 10:24 a.m.

TRANSCRIPT OF TRIAL
BEFORE HONORABLE ANNE E. THOMPSON
UNITED STATES DISTRICT COURT JUDGE and JURY

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1 that they have to show in their application is that the product
2 actually does -- is efficacious in -- or actually does, in
3 fact, cure short-sightedness.

4 A Yes, in the marketing application.

5 Q Right.

6 A Not in the investigational stage.

7 Q Oh, okay. Now, in -- for a new drug to come along, and I
8 realize your testimony about generics, there's no generic
9 biologics. And I understand that.

10 But I am going to talk about generics. Generally a
11 company that comes along and says, "We have a product which is
12 equivalent to this already approved product," a bio equivalent,
13 in general, is would that company -- that second company have
14 to show that indeed it is a bio equivalent, that it's made
15 consistently, that it's made safely and that it won't cause
16 other harm to the patient? Is that a general and fair
17 characterization?

18 A For a conventional type of drug, that would be a generally
19 fair characterization, yes.

20 Q And that doesn't apply to biologics, because there's no
21 such thing as a generic in biologics; is that correct?

22 A Correct.

23 Q Okay. And you learned that, again, through your 13 years
24 of experience in the Food and Drug Administration.

25 THE COURT: How much longer do you think you'll be,

1 Mr. Hughes?

2 MR. HUGHES: I'm going to be awhile, Your Honor.

3 THE COURT: I think that I'm going to -- I think
4 we've -- I'm timing both sides, and there's a certain amount of
5 time I'm allotting for both sides. So, I'm going to ask you to
6 see if you can't wrap it up now within the last -- next --
7 certainly 15 minutes.

8 MR. HUGHES: Okay.

9 BY MR. HUGHES:

10 Q A drug that has been approved by the Food and Drug
11 Administration has been approved for human use; is that
12 correct?

13 A There are also animal drugs, but for a drug that's been
14 approved for human medical use, then yes, it's for human use.

15 Q Okay, and so a drug that has not been approved has not
16 been approved for human use; is that correct?

17 A A drug that has not been approved by the FDA is not
18 approved for marketing for human use.

19 Q Right. A drug that has obtained FDA approval for human
20 use does not necessarily mean that the drug is indeed safe for
21 human use; is that a fair statement?

22 A A product that has an approved marketing application has
23 been judged safe and efficacious by which we mean that although
24 we understand its risks, we understand its benefits, and we
25 have a sound basis to believe that the benefits outweigh the

1 BY MR. HUGHES:

2 Q Let's talk about the --

3 MR. HUGHES: Your Honor, I have two areas that I
4 still have to go over.

5 MR. HUGHES: Well, you've got ten minutes.

6 BY MR. HUGHES:

7 Q We talked about the Botulinum toxin bacteria, correct?

8 A Yes.

9 Q Or actually Botulinum toxin substance. The substance
10 itself is an enzyme that is secreted from a bacteria; is that
11 correct?

12 A I don't think we would typically classify it as an enzyme,
13 but it's a protein.

14 Q It's a protein. And there's a lot of enzymes or amino
15 acids which are -- that make up that protein, correct?

16 A Yes, there are many parts to it.

17 Q And when we talk about the actual Botulinum toxin itself,
18 we're actually talking about an amino acid which has what is
19 called a heavy chain and a light chain; is that correct?

20 A A protein.

21 Q A protein.

22 A Yes, a protein that has a portion that we call the heavy
23 chain and a portion that we call the light chain.

24 Q And the Botulinum toxin Type A complex is actually this
25 heavy chain, this light chain and a whole bunch of other

1 Q Okay. Now, this article by Mr. Chance, did you read that
2 article?

3 A I believe I would have. I certainly cited it, so I'm sure
4 that I did read it at the time that I wrote this review.

5 Q Okay. And there's an article right up there called --
6 from Jancovic. Did you read that article?

7 A I'm sure that I read that article as well.

8 Q All right.

9 THE COURT: You know what, Mr. Hughes? I'm going to
10 take a short break now to give you a chance to look over what
11 -- how you would prioritize how you'd like to wind up your
12 cross examination.

13 MR. HUGHES: Your Honor, I still have much that I
14 have to go through.

15 THE COURT: No, no, Mr. Hughes. We -- you know,
16 cross examination is a cross of the direct by definition. So,
17 I want you to spend your break deciding how you're going to
18 prioritize so you can wind up.

19 Ladies and gentlemen, step down.

20 COURT OFFICER: All rise for the jury.

21 (Jury out)

22 (Recess)

23 (Jury in)

24 THE COURT: Please be seated, ladies and gentlemen.

25 All right, let's proceed.

1 A Actually I'm not sure. As I said, Dr. Jancovic is a very
2 well known, very prolific investigator and author, and I
3 actually would imagine he publishes several articles per year.

4 Q Okay.

5 A So, I cannot be sure that this particular article is the
6 same as the one that I relied upon. In fact, I suspect it was
7 not. The paragraph in which I cited -- that starts the bottom
8 of Page 10 to Page 11 is talking about cervical dystonia, and
9 the title of the article you have given me is on tremors, which
10 is broader than that. So, I am not sure that this actually
11 would necessarily be the same article.

12 Q Okay. With respect to -- are you aware that if articles
13 prior to the transfer of Occulinum to Allergan, if peer review
14 articles referred to Botulinum toxin as BOTOX?

15 A I think that there were at least some articles that may
16 have done that. I do not recall which specific ones and
17 whether -- and which specific preparation of a Botulinum toxin
18 they were referring to is not -- is certainly not within my
19 recollection. It may, in fact, have been the same product as
20 subsequently was marketed as BOTOX or not.

21 Q Well, the Anderson article -- referring to the Disport --
22 referred to Disport as BOTOX, did it not?

23 A I don't know. You did not give me enough time to actually
24 re-read the article. I could if you would wish.

25 Q Well, I --

1 A If that would help.

2 THE COURT: Mr. Hughes, it seems to me we're going in
3 no direction, if I sense the line of examination, that we have
4 discussed at pre-trial motions. And you'll have your
5 opportunity if I'm wrong.

6 MR. HUGHES: All right, I will move on.

7 BY MR. HUGHES:

8 Q You testified during direct examination that the TRI
9 substance did not -- the TRI substances manufacturing facility
10 was not investigated by the FDA for the manufacture of its
11 product; is that correct?

12 A Yes, we did not do any inspections of their facilities for
13 manufacturing purposes.

14 Q The manufacturing facilities.

15 A Yes, yes, I mean for the manufacturing of the product.

16 Q And you are aware who manufactured the TRI substance for
17 TRI, correct?

18 A Actually I know what I have been told by other people, but
19 I have no direct knowledge of exactly how that was done.

20 Q Well, you were called as an expert in the Florida case,
21 were you not?

22 A Yes.

23 Q And in that -- in your capacity as an expert -- and you're
24 called as an expert in this case, correct?

25 A Yes.

1 Q I have just a copy of the front page of that brochure on
2 the overhead, but can you just tell the jurors what color
3 appears on the brochure predominantly?

4 A The purple writing.

5 Q And what kind of information does the brochure offer?

6 A What BOTOX cosmetic is, what it isn't, is it right for
7 you, who should administer BOTOX cosmetic and what to expect
8 from BOTOX cosmetic, little before and after picture.

9 Go on?

10 Q That's fine.

11 A Okay.

12 Q Now, we've been talking a lot about BOTOX. At some point
13 in time did you become familiar with a substance made by a
14 company called TRI or Toxin Research International?

15 A Yes.

16 Q How did you learn about this substance from TRI or Toxin
17 Research International?

18 A Dr. Poet.

19 Q Do you recall when you learned about the TRI substance?

20 A The year 2003. The month I'm not sure.

21 Q What did Dr. Poet tell you about the TRI substance when
22 you first learned about it from him?

23 A Dr. Poet told me that he believed that it was in the FDA
24 process and that the stuff was more pure than BOTOX, and it
25 would have a longer shelf life after it was reconstituted.

1 A No, he did not.

2 Q Now, and your testimony about the not differentiating
3 between the product and the procedure and charging the patient,
4 was that true of all the procedures that Dr. Poet did?

5 A (No verbal response)

6 Q You've used the example of --

7 A Yes, a product, right. The price wasn't changed for a
8 procedure because a product that he used was more expensive
9 than another.

10 Q Now --

11 A With everything he does.

12 Q Now, you also stated that once in awhile you would order
13 Allergan's BOTOX, and when Dr. Poet wanted Allergan's BOTOX he
14 would say -- what would he ask you to do?

15 A He would say, "Call up Allergan and order BOTOX."

16 Q And you also stated previously that you had the TRI
17 substance used on you.

18 A I did.

19 Q And you stated that -- during direct that Dr. Poet had
20 indicated that he believed that the product was in the FDA
21 pipeline and purer than Allergan's BOTOX, correct?

22 A Correct.

23 Q And did he indicate to you where he learned this
24 information?

25 A I didn't --

1 MS. COWLES: Objection. Your Honor, I believe this
2 is based on hearsay.

3 THE COURT: I would agree.

4 MR. HUGHES: Your Honor, it goes to state of mind.
5 It goes to state of mind, and she asked the same exact question
6 in the grand jury.

7 THE COURT: Well, you know one thing, Mr. Hughes?
8 Not only is your statement inappropriate, but the rules are
9 different depending on which party is represented, as well you
10 know under the rules of evidence.

11 MR. HUGHES: Yes, Your Honor.

12 THE COURT: So, don't make a statement like that on
13 the floor of the courtroom unless I ask for an explanation.

14 MR. HUGHES: Yes, Your Honor.

15 BY MR. HUGHES:

16 Q To your knowledge, was any other BOTOX used at the office,
17 other than Allergan's BOTOX or the TRI BOTOX?

18 A No.

19 Q Did you ever see any BOTOX from China?

20 MS. COWLES: Objection to the form of the question.

21 MR. HUGHES: Your Honor --

22 THE COURT: Well, here's the problem. Only Allergan
23 BOTOX has been identified at this point. So, if you'd like to
24 -- it's beyond the scope of direct. Let's just stop it there.

25 BY MR. HUGHES:

1 Q So, the product was used on you, and you knew that you
2 were receiving the TRI substance.

3 A I did.

4 Q And if it did not work, you would have told Dr. Poet.

5 A Yes.

6 Q And if it worked you would have told Dr. Poet.

7 A Yes.

8 Q And what did you tell Dr. Poet?

9 A It worked great.

10 Q And how long did it last?

11 A About four months I think.

12 Q In relation to Allergan's BOTOX, how long did it last?

13 MS. COWLES: Objection. Your Honor, I believe this
14 is going to an area the Court has previously excluded through a
15 pre-trial motion.

16 THE COURT: Yes, the issue is not whether one was
17 more effective than the other. That's really not an issue.

18 MR. HUGHES: Well, actually, Your Honor --

19 THE COURT: It's not. It's not.

20 MR. HUGHES: May I please be permitted to respond?

21 THE COURT: No, no.

22 MR. HUGHES: Because it goes to state of mind.

23 THE COURT: No, no, absolutely not.

24 MR. HUGHES: All right.

25 BY MR. HUGHES: