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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: CELEXA AND LEXAPRO :MDL NO. 2067
MARKETING AND SALES PRACTICES :Master Docket No.
LITIGATION :09-MD-2067-(NMG)

DELANA S. KIOSSOVSKI and :Hon. Nathaniel M Gorton
RENEE RAMIREZ, on behalf of :
themselves and all others :Case No.
similarly situated, :14-CV-13848 (NMG)

Plaintiff,

v.

FOREST PHARMACEUTICALS, INC. :
and FOREST LABORATORIES, INC., :

Defendants.

-- --
OCTOBER 6, 2016

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Videotaped deposition of STEVEN L.

CLOSTER, held at DEBEVOISE & PLIMPTON, LLP, 919
Third Avenue, New York, New York, commencing at
9:27 a.m., before Margaret M. Reihl, a
Registered Professional Reporter, Certified
Realtime Reporter, and Notary Public.

GOLKOW TECHNOLOGIES, INC.
877.370.3377 ph/917.591.5672 fax
deps@golkow.com

1 Q. Who is Charles Flicker?

2 A. At the time he was the medical director
3 on the CNS group.

4 Q. What would his responsibilities involve
5 to the best of your knowledge personally?

6 A. To the best of my knowledge, you know,
7 conducting clinical trials, making sure they were
8 proceeding as planned, reviewing some of the documents
9 that would, you know, be developed as a result of a
10 clinical trial.

11 Q. Like, for example, a final study report?

12 A. Yes.

13 Q. Okay. Lawrence Olanoff is also listed
14 here.

15 Do you see that?

16 A. Yes.

17 Q. And he was the executive vice president
18 of scientific affairs at that time?

19 A. Right.

20 Q. Do you generally know what his
21 responsibilities were personally?

22 A. I believe at the time he was head of all
23 the R&D activities at the company.

24 Q. Okay. And then Ivan Gergel, who is he?

1 A. Similar, from what I recall, he reported
2 to Larry and Charles Flicker reported to Ivan. So
3 Ivan, I believe, at the time oversaw all the programs,
4 including CNS and other programs that we had ongoing at
5 the company.

6 Q. Now, correct me if I'm wrong, I'm not
7 trying to mischaracterize your testimony, but would it
8 be fair to say that at the top of the pyramid for these
9 three people, it would be Dr. Gergel, then Dr. Olanoff
10 and then Dr. Flicker?

11 A. No. It would be Dr. Olanoff, Dr.
12 Gergel, Dr. Flicker.

13 Q. Okay. Sorry. Thank you.

14 And then who are these other two people,
15 Edward Lakatos?

16 A. I believe he was in the stats
17 department.

18 Q. Okay. Did you know him personally?

19 A. I can't recall. Yeah, I don't know.

20 Q. And Keith Rotenberg, do you know who
21 that is?

22 A. Only by what it says on the page, that
23 apparently he was in regulatory affairs, perhaps the
24 head of regulatory affairs, I don't know.

1 Q. Okay. And you don't know either Edward
2 or Keith personally, correct?

3 A. Keith I don't. Edward it was a long
4 time ago, perhaps I do, but it's too long to remember.

5 Q. All right. Do you know what
6 Mr. Flicker's responsibilities were with regards to
7 Study 18 at that time?

8 A. No, not specifically.

9 Q. But he was overseeing -- would be
10 overseeing the clinical trials related to
11 antidepressants, correct?

12 MS. THORNE: Objection.

13 THE WITNESS: I believe that's true.

14 BY MR. WISNER:

15 Q. All right. On Page 6 here, there's the
16 objective of the clinical trial -- sorry, Page 3. I
17 felt my own mistake there. Page 3, Section 5 it says
18 Objective.

19 Do you see that?

20 A. Yes.

21 Q. And would it be fair to say that the
22 objective of this clinical trial was to measure the
23 efficacy and safety of citalopram in treating both
24 children and adolescents with major depressive

1 MS. THORNE: Objection.

2 THE WITNESS: Right.

3 BY MR. WISNER:

4 Q. So based on the results in these tables,
5 none of the secondary endpoints reached statistical
6 significance, correct?

7 MS. THORNE: Objection.

8 THE WITNESS: At Week 8, correct.

9 BY MR. WISNER:

10 Q. And the secondary endpoint was the
11 difference between citalopram and placebo at Week 8,
12 correct?

13 MS. THORNE: Objection.

14 THE WITNESS: Right.

15 BY MR. WISNER:

16 Q. All right. So none of the secondary
17 endpoints as pre-defined in the protocol met
18 statistical significance?

19 MS. THORNE: Objection.

20 THE WITNESS: That's right.

21 BY MR. WISNER:

22 Q. Turn to Page 14, Section "10.5 Efficacy
23 Conclusions."

24 You see that?

1 efficacy definition in a second. I haven't forgotten
2 about that.

3 You stated -- we've discussed this
4 potential unblinding that occurred in Celexa Study 18,
5 correct?

6 A. Right, right.

7 Q. Briefly, we didn't get into details, but
8 we discussed it briefly, right?

9 A. Yes.

10 Q. You understand that when those patients
11 who were the subject of that dispensing error are
12 removed from the primary efficacy results --

13 A. Right.

14 Q. -- the study is no longer statistically
15 significant, correct?

16 MS. THORNE: Objection.

17 THE WITNESS: I'm aware of that.

18 BY MR. WISNER:

19 Q. Okay. So if, in fact, the patients had
20 been removed from the study, the primary efficacy
21 endpoint would have ultimately been negative, right?

22 MS. THORNE: Objection calls for

23 speculation. That's outside the scope of the

24 30(b)(6) notice. It calls for a hypothetical.

1 To the extent that you have a personal opinion
2 on that topic, you can feel free to answer.

3 You're not answering on behalf of the company.

4 THE WITNESS: So the question is?

5 BY MR. WISNER:

6 Q. Well, Ms. Thorne is trying to instruct
7 you that it's a hypothetical, but it's not a
8 hypothetical, because they did conduct an analysis of
9 the primary efficacy endpoint, excluding those nine
10 patients that were subject to the dispensing error,
11 correct?

12 MS. THORNE: Objection.

13 MS. KIEHN: You had said they were
14 removed from the study.

15 MR. WISNER: Fair enough.

16 BY MR. WISNER:

17 Q. Can you answer that question I just
18 asked you?

19 A. If they were removed from the study, I
20 understand that the result would have been negative.

21 Q. Okay. And, in fact, when the dispensing
22 error occurred, Forest sent a letter to the Food and
23 Drug Administration; you're aware of that?

24 MS. THORNE: Objection, assumes facts