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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES,)	
)	
PLAINTIFF)	Criminal Action
)	
-VS-)	No. 10-10294-NG
)	
FOREST PHARMACEUTICALS, INC.,)	November 19, 2010
)	
)	11:18 a.m.
DEFENDANTS)	

ARRAIGNMENT ON INFORMATION

BEFORE THE HONORABLE NANCY GERTNER
UNITED STATES DISTRICT COURT
JOHN J. MOAKLEY U.S. COURTHOUSE
1 COURTHOUSE WAY
BOSTON, MA 02210

VALERIE A. O'HARA
OFFICIAL COURT REPORTER
UNITED STATES DISTRICT COURT
1 COURTHOUSE WAY, COURTROOM 3204
BOSTON, MA 02210
E-mail: vaohara@gmail.com

1 A P P E A R A N C E S:

2 FOR THE PLAINTIFF:

3 United States Attorney's Office, by JAMES E. ARNOLD,
4 ASSISTANT UNITED STATES ATTORNEY, Suite 9200, Boston,
5 Massachusetts 02210, for the United States;

6 United States Department of Justice, by JEFFREY I.
7 STEGER, ESQ., 450 Fifth Street, N.W., P.O. Box 386,
8 Washington D.C., 20044, for the United States;

9 FOR THE DEFENDANT:

10 Debevoise & Plimpton, by ANDREW J. CERESNEY, ESQ. and
11 BRYAN P. KESSLER, ESQ., 919 Third Avenue, New York, New York
12 10022-3902, for the Defendant;

13 Sugarman, Rogers, Barshak & Cohen, P.C., by WILLIAM F.
14 BENSON, ESQ., 101 Merrimac Street, Boston, Massachusetts
15 02114-4737.

16 ALSO PRESENT: Herschel Weinstein, General Counsel for
17 Forest Pharmaceuticals
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P R O C E E D I N G S

THE COURT: Counsel, will you identify yourselves, please.

MR. ARNOLD: Good morning, your Honor, this is Assistant U.S. Attorney Jim Arnold for the United States. With me is Jeff Steger from the United States Department of Justice's Office of Consumer Litigation.

MR. STEGER: Good morning, your Honor.

MR. CERESNEY: Good morning, your Honor, Andrew Ceresney and Bryan Kessler from Debevoise & Plimpton in New York. With me today is also Bill Benson from Sugarman, Rogers, and seated with us today on behalf of Forest is Herschel Weinstein, the general counsel.

THE COURT: Is he the one who will be submitting the plea?

MR. CERESNEY: He will, your Honor.

THE COURT: All right. Then I suppose Mr. Weinstein should stand first. Before you take the plea, Mr. Weinstein, tell me again and put on the record what your position is and how you bind the company.

MR. WEINSTEIN: I am vice-president, general counsel of Forest Pharmaceuticals and its parent, Forest Laboratories.

THE COURT: So you have the authority to bind the company to this plea agreement and this plea?

1 MR. WEINSTEIN: Yes, I do.

2 MR. CERESNEY: Just for the record, your Honor,
3 Exhibit F to the plea agreement has a resolution of the
4 Board of Directors of Forest Pharmaceuticals which provides
5 Mr. Weinstein with that authority as well.

6 THE COURT: Exhibit F is dated September 14th,
7 2010. Do I have the right one?

8 MR. CERESNEY: Yes. Yes, that's correct.

9 THE COURT: The government is content that that in
10 fact gives Mr. Weinstein the authority to do what he's doing
11 today?

12 MR. ARNOLD: We are.

13 (Forest Laboratories, Inc. through
14 Herschel Weinstein was sworn.)

15 THE CLERK: Mr. Weinstein, as to Count 1,
16 obstruction of agency proceedings, Title 18, U.S.C.,
17 Section 1505; Count 2, distribution of an unapproved new
18 drug, all in violation of Title 21, Section 331, 333(a)(1)
19 and 355(a); as to Count 3, distribution of a misbranded
20 drug, inadequate directions for use, all in violation of
21 Title 21, U.S.C., Section, 331, 333(a)(1) and 3352(f)(1),
22 how do you plead to Counts 1, 2 and 3, guilty or not guilty?

23 MR. WEINSTEIN: Guilty.

24 THE CLERK: Okay.

25 THE COURT: Why don't you take the stand,

1 Mr. Weinstein. Do you want to stand with him, you certainly
2 can. Why don't you sit down. Before I begin, I note this
3 is an 11(c)(1)(c) plea; is that right?

4 MR. ARNOLD: That is correct, your Honor.

5 THE COURT: And further it has a waiver of appeal,
6 and while I ordinarily don't accept waivers of appeal, I
7 make an exception for 11(c)(1)(c), and I would particularly
8 make an exception in a situation where a corporation well
9 represented has entered into a waiver, so that won't be a
10 problem. Okay. So, Mr. Weinstein, you are the subject of
11 the resolution of the Board of Directors dated
12 September 14th, 2010?

13 MR. WEINSTEIN: Yes, I am.

14 THE COURT: And you're satisfied with your
15 lawyer's representation of the corporation?

16 MR. WEINSTEIN: Yes, I am.

17 THE COURT: I'm modifying the usual to tailor it
18 to this event.

19 MR. WEINSTEIN: I am.

20 THE COURT: How long has this been in negotiation?

21 MR. WEINSTEIN: Oh, I would say negotiations
22 probably started two years ago, 18 months to two years
23 ago.

24 THE COURT: Okay. And you are fully competent, I
25 take it, personally competent to make judgments today, that

1 is to say, you're not under the influence of any drugs,
2 you're not under the influence of any alcohol?

3 MR. WEINSTEIN: I'm good today, I'm fine. Yes,
4 thank you.

5 THE COURT: Counsel, will you give me a
6 description of what the charges are and what the facts are?

7 MR. ARNOLD: Surely, your Honor. With respect to
8 the charge is Count 1 charges Forest Pharmaceuticals with
9 obstruction of an agency proceeding in violation of
10 Title 18, United States Code, Section 1505, and the elements
11 of that offense are that there was an agency proceeding,
12 that the defendant was aware of that proceeding and that the
13 defendant intentionally endeavored corruptly to influence,
14 obstruct or impede the pending proceeding, and I'm also
15 going to give you Count 2 because I'm going to be discussing
16 certain facts pertaining to both Counts 1 and 2 together.

17 THE COURT: Okay.

18 MR. ARNOLD: Count 2 charges Forest with
19 introducing for delivery and into interstate commerce a drug
20 called Levothroid, which was an unapproved new drug in
21 violation of Title 21, United States Code, Sections 331(d),
22 333(a)(1) and 355.

23 This charge has the following elements: The
24 defendant introduced into interstate commerce or caused the
25 introduction or delivery for introduction into interstate

1 commerce the drug Levothroid; that Levothroid was a new drug
2 under the Food, Drug & Cosmetic Act and that it was a drug
3 that was not generally recognized among qualified experts as
4 safe and effective for use under the conditions prescribed,
5 recommended or suggested in the drugs labeling; and, 3, that
6 the United States Food & Drug Administration had not
7 approved the manufacture and distribution of Levothroid
8 pursuant to a new drug application or an investigational new
9 drug application.

10 With respect to the facts pertaining to those two
11 counts, had the case gone to trial, the United States would
12 have proven through a combination of witness testimony and
13 documents that Forest was a wholly-owned subsidiary of
14 Forest Laboratories, Inc. and had its principal place of
15 business in St. Louis, Missouri; Forest manufactured,
16 promoted and distributed in interstate commerce prescription
17 drugs intended for human use throughout the United States
18 including the District of Massachusetts; Forest had a
19 manufacturing and packaging facility in Cincinnati and a
20 distribution center in St. Louis.

21 Counts 1 and 2 that I just described both concern
22 a drug called Levothroid. Levothroid was an
23 orally-administered levothyroxine sodium drug product that
24 Forest marketed for the treatment of patients suffering from
25 hypothyroidism, which is a medical condition in which an

1 individual has a thyroid or hormone deficiency.

2 As background to these counts, the government
3 would have established that in or about 1991, Forest's
4 parent company, Forest Labs, bought the rights to
5 Levothroid. Forest later moved the manufacturing and
6 packaging of Levothroid to its Cincinnati plant and after
7 manufacturing and packaging, Forest transferred Levothroid
8 to its St. Louis distribution facility.

9 The United States would have established that at
10 no time through and including August 9th, 2003 did Forest
11 receive FDA approval of a new drug application, also known
12 as an NDA, to market and distribute Levothroid using the
13 formulation and manufacturing processes then being used at
14 its Cincinnati plant.

15 The United States would have further established
16 that the Levothroid product being manufactured and
17 distributed by Forest between August 14th, 2001 and
18 continuing through on or about August 9, 2003 was a new drug
19 under the Food, Drug and Cosmetic Act, the FDCA.

20 Specifically the United States would have
21 established that given the specific formulation and
22 manufacturing processes used by Forest during this time
23 period, there was not adequate data establishing that
24 Levothroid had consistent potency and stability to be
25 generally recognized by qualified experts as safe and

1 effective for use under its labeled conditions.

2 The government would have established that FDA is
3 the federal agency responsible for protecting the health and
4 safety of the public by enforcing the Food, Drug and
5 Cosmetic Act, ensuring the drugs intended for humans were
6 safe and effective for their intended uses and that the
7 labeling of those drugs bore accurate information.

8 The government would have introduced evidence
9 establishing that on August 14th, 1997, the FDA issued a
10 notice in the federal register announcing its conclusion
11 that all levothyroxine sodium drugs on the market, including
12 Levothroid, were new drugs within the meaning of the FDCA
13 because none of them had been shown to demonstrate
14 consistent potency and stability necessary to be generally
15 recognized as safe and effective.

16 The FDA announced in the federal register that
17 manufacturers of these drugs needed to file an NDA and
18 obtain FDA approval to permit continued marketing of the
19 products. The FDA stated that as a matter of enforcement
20 discretion, it would permit manufacturers to continue
21 distribution of their unapproved drugs until August 14th,
22 2000. The FDA later extended this grace period to
23 August 14th, 2001.

24 The United States would have introduced evidence
25 establishing that on July 13th, 2001, the FDA issued a

1 guidance for industry concerning levothyroxine sodium drugs.

2 The FDA announced that in the exercise of its
3 enforcement discretion, it was establishing a gradual
4 phase-down plan for the unapproved drugs remaining on the
5 market. The FDA repeated that the marketing unapproved
6 levothyroxine drugs without first obtaining an NDA approval
7 was illegal. The FDA advised, however, that it did not
8 intend to take enforcement action if the companies that did
9 not yet have an approved NDA complied with all aspects of
10 the phase-down plan.

11 With respect to Count 1, the United States would
12 have established that in response to the 1997 notice, Forest
13 and Forest Labs prepared an NDA for Levothroid or submitted
14 the NDA to the FDA on or about September 27th, 2000. Forest
15 knew and understood that the FDA needed stability data that
16 supported the expiration dates that the company was
17 proposing for its drug.

18 Stability testing was lab testing necessary to
19 demonstrate the shelf life of a drug, the length of time
20 during which the drug had the appropriate identity,
21 strength, quality, purity and potency. Forest knew and
22 understood that the FDA required that the stability data be
23 obtained under specific control temperatures and relative
24 humidity conditions, namely temperature between 25 plus or
25 minus 2 degrees Celsius and relative humidity between 60

1 percent plus or minus 5 percent. Those conditions are
2 referred to as ICH conditions.

3 The government would have proven that employees in
4 the Forest Cincinnati plant repeatedly submitted stability
5 data to Forest Labs for inclusion in the NDA in various
6 amendments to the Levothroid NDA that purported to have been
7 obtained under ICH conditions when in fact it was well-known
8 by plant management personnel and others within the
9 Cincinnati plant that serious equipment malfunctions had
10 resulted in humidity levels significantly below ICH
11 conditions for extended periods of time totaling hundreds of
12 days and thousands of hours.

13 These humidity excursions results in testing
14 results that misrepresented and overstated Levothroid's
15 potency relative to its expiration date. The government
16 would have shown that in an attempt to remedy these
17 significant humidity excursions on or around January 21,
18 2003 certain Forest Management personnel at the Cincinnati
19 plant decided to put a portable home humidifier in the room
20 where the stability testing was being conducted as a
21 temporary fix to the humidity problem.

22 Forest knew that this temporary fix would not
23 maintain the relative humidity at ICH levels as the portable
24 humidifier which required constant monitoring and refills of
25 water did not work effectively through the night or through

1 an entire weekend.

2 Between November 17th, 2003 and December 3rd,
3 2003, the FDA conducted a regulatory inspection of Forest's
4 facility in Cincinnati pursuant to the FDA statutory
5 inspection authority. During this inspection, the FDA
6 discovered the portable humidifier in the room Forest used
7 for its stability studies in support of the Levothroid NDA.

8 When the FDA investigators asked about this
9 portable humidifier, certain Forest management personnel at
10 the Cincinnati plant falsely stated that the portable
11 humidifier was being stored in the room and falsely denied
12 that the portable humidifier had ever been used for humidity
13 control.

14 The following day certain Forest management
15 personnel at the Cincinnati plant admitted to the FDA
16 investigators that the regular humidifier was not
17 functioning properly and that the portable humidifier had
18 been used to increase the humidity level in the room.

19 With respect to Count 2, the government would have
20 established that Forest took no affirmative steps to limit
21 its distribution of Levothroid in compliance with the FDA's
22 phased-down distribution plan in the guidance document that
23 the FDA issued in July of 2001.

24 The government would have established that Forest
25 initially hoped that it would through market forces alone

1 fall into compliance with the phase-down schedule and obtain
2 NDA approval quickly, however, by April, 2002, it was clear
3 to Forest that Levothroid NDA was not going to be approved
4 quickly.

5 As a result, on or about April 18th, 2003, Forest
6 had a meeting to determine whether to comply with the
7 phase-down schedule. The United States would have
8 introduced evidence establishing that Forest decided
9 internally not to comply with the guidance phase-down
10 schedule.

11 Thereafter Forest continued distributing its
12 unapproved Levothroid product at rates well over the levels
13 established in the Guidance. On August 7th, 2003, the FDA
14 issued a warning letter to Forest Labs addressing Forest's
15 failure to limit its distribution of its unapproved new drug
16 Levothroid consistent with the phase-down schedule.

17 The warning letter advised Forest Labs that FDA
18 had determined that Forest had deliberately decided not to
19 follow the agency's phase-out plan. As a result, the FDA
20 advised Forest Labs that "You are no longer entitled to the
21 enforcement discretion granted by the agency and are hereby
22 on notice that the distribution of your unapproved product
23 Levothroid remains in violation of Section 505 of the act."

24 The evidence would have established that Forest
25 received the warning letter by late morning on Friday,

1 August 8th, 2003. Rather than immediately stop Levothroid
2 distribution, Forest instead directed its employees to
3 continue shipping as much Levothroid product as possible.
4 Not until approximately 1 a.m. on August 9th, 2003 did
5 Forest stop packaging and shipping Levothroid to its
6 customers, and by that time Forest had filled the Levothroid
7 orders for all of its primary larger customers.

8 The United States would have further introduced
9 evidence establishing that Forest's gross gain from its
10 interstate distribution of its unapproved Levothroid product
11 was \$70,326,246 during the applicable time period.

12 With respect to Count 3, I'm going to ask that
13 Mr. Steger provide that to the Court.

14 THE COURT: That's fine. Go on.

15 MR. STEGER: Your Honor, Count 3 charges Forest
16 with introducing for delivery and for interstate commerce
17 Celexa, which was a misbranded drug in violation of 21,
18 U.S.C., Sections 331(a), 333(a)(1) and 352(f)(1). This
19 charge has the following elements: 1, that defendant
20 introduced into interstate commerce, delivered for
21 introduction into interstate commerce or caused the
22 introduction or delivery for introduction into interstate
23 commerce the drug Celexa; 2, that Celexa was a drug under
24 the Food, Drug & Cosmetic Act; and, 3, that Celexa was
25 misbranded in that it lacked adequate directions for use for

1 the uses intended by defendant.

2 Had the case gone to trial, the United States
3 would have proven the following through a combination of
4 witness testimony and documents: In 1998, FDA-approved
5 Celexa for the treatment of adult depression. The FDA never
6 approved Celexa for the treatment of any condition other
7 than adult depression or for any use in children or
8 adolescents.

9 Following FDA approval, Forest began promoting,
10 distributing and selling Celexa throughout the United
11 States, including in the District of Massachusetts. The
12 United States would have shown that Forest was aware that
13 the FDA had not approved Celexa for treatment of any
14 condition other than adult depression.

15 In or about April, 2002, Forest Labs in an attempt
16 to obtain, among other things, a pediatric indication for
17 Celexa submitted data to the FDA from two double-blinded
18 placebo controlled studies involving the use of Celexa in
19 children. One of these studies, the Forest study, was
20 sponsored by Forest Labs. The Forest study indicated that
21 Celexa was more effective than placebo in treating pediatric
22 patients suffering from depression.

23 The other study, the European study, had been
24 conducted in Europe and sponsored by the Danish company
25 that had developed and owned the rights to Celexa. The

1 European study had negative results, that is, the study did
2 not show Celexa to be any more effective than placebo in
3 treating pediatric depression.

4 On or about September 23d, 2002, the FDA denied
5 Forest Labs' request for a pediatric indication for Celexa.
6 If the case had gone to trial, the United States would have
7 introduced evidence establishing that Forest was aware that
8 promoting a drug product for indications other than those
9 approved by FDA was illegal.

10 The United States would have further demonstrated
11 that beginning in 1998 and continuing thereafter through at
12 least September, 2002, Forest promoted Celexa for use in
13 treating children and adolescents suffering from depression,
14 even though Celexa was not FDA approved for pediatric use.

15 Forest's off-label promotion consisted of various
16 sales techniques including directing Forest sales
17 representatives who promoted Celexa to make sales calls to
18 physicians who treated children and adolescents promoting
19 Celexa by various Forest's sales representatives for use in
20 children and adolescents, hiring outside speakers to talk to
21 pediatricians, child psychiatrists and other medical
22 practitioners who specialized in children and adolescents
23 about the benefits of prescribing Celexa to that patient
24 population and for publicizing and circulating the positive
25 results of the double-blind placebo controlled Forest study

1 on the use of Celexa in adolescents while at the same time
2 failing to discuss the negative results of the second
3 double-blind placebo controlled European study on the use of
4 Celexa in adolescents.

5 With respect to the speaking engagements, for
6 example, the United States would have introduced evidence
7 establishing that four sales representatives and division
8 managers identified speakers from lists maintained and
9 approved by Forest to organize promotional lunches and
10 dinners as part of which speakers were paid to give a talk
11 about Celexa. Certain of Forest approved speakers were
12 medical practitioners who specialized in treating children
13 and adolescents suffering from depression, and Forest paid
14 these practitioners to give promotional talks on the use of
15 Celexa in children and adolescents.

16 In or about mid-2001, Forest learned of the
17 positive results from the Forest study and the negative
18 results from the European study, and Forest Labs shared
19 these results with the FDA. Forest treated the studies
20 differently. Forest publicized and promoted the results
21 from the positive Forest study while at the same time Forest
22 did not publicize or disclose the results of the negative
23 study to persons outside the FDA or the Danish company which
24 sponsored the negative study.

25 Forest did this in various ways including via

1 certain discussions that Forest sales representatives had
2 with medical practitioners about the use of Celexa in
3 treating children, via certain promotional speeches made by
4 pediatric specialists who were hired by Forest to talk about
5 the use of Celexa in treating children and adolescents and
6 via letters sent by Forest Professional Affairs Department
7 to medical practitioners who had requested from Forest all
8 available information and data concerning the use of Celexa
9 in treating children and adolescents.

10 Lastly, the United States would have further
11 introduced evidence that this violation occurred beginning
12 as early as 1998 and continued through in or about December,
13 2002 and that during this time period Forest delivered for
14 introduction into interstate commerce and caused the
15 delivery for introduction in interstate commerce into
16 Massachusetts and elsewhere various quantities of Celexa for
17 unapproved use in pediatric and adolescent patients which
18 was misbranded in that Celexa's labeling lacked adequate
19 direction for such use.

20 Forest's pecuniary gain resulting from this
21 violation was \$28,040,000.

22 THE COURT: So there are two questions that I will
23 ask with respect to that presentation. Well, first of all,
24 what are the penalties, the maximum penalties with respect
25 to each of those charges?

1 MR. ARNOLD: The maximum penalties, your Honor,
2 with respect to Count 1 is a maximum fine of \$500,000, twice
3 the gross gain derived from the offense, twice the gross
4 loss to a person other than Forest, whichever is greatest,
5 in this case, the maximum fine is in fact \$500,000, a term
6 of probation of not less than one year and not more than
7 five years, restitution to any victims of the offense and a
8 mandatory special assessment in the amount of \$400.

9 With respect to Count 2, the maximum fine is a
10 fine of \$200,000 or twice the gross gain derived from the
11 offense or twice the gross loss to a person other than the
12 defendant, whichever is greatest, given that Forest's gross
13 gain from its sales of the unapproved new drug Levothroid
14 between August 14th, 2001 and August 9, 2003 totalled
15 \$70,326,246.

16 The maximum possible fine in connection with this
17 count is \$140,652,492, the term of probation of not more
18 than five years, one of the terms of which may include an
19 order of restitution and a mandatory special assessment of
20 \$125.

21 With respect to Count 3, which was the unapproved,
22 the promotion of Celexa that Mr. Steger described, the
23 maximum fine is a fine of \$200,000 or twice the gross gain
24 derived from the offense or twice the gross loss to a person
25 other than the defendant, whichever is greatest. Given that

1 Forest sales of the misbranded drug Celexa totalled
2 approximately \$28,040,000, the maximum possible fine in
3 connection with this count is \$56,080,000, a term of
4 probation of not more than five years, one of the terms of
5 which may include an order of restitution and a mandatory
6 special assessment of \$125.

7 Additionally, as is set forth in the plea
8 agreement, forfeiture is a potential punishment in this
9 case.

10 THE COURT: Okay. Mr. Weinstein, I'm obliged to
11 alert you on behalf of the corporation to the maximum
12 penalties, but I understand this is an 11(c)(1)(c) plea, so
13 the way this would work would be that if I accept the plea
14 terms, then that will be what the sentence for the
15 corporation will be. If I don't accept the plea terms, then
16 you are able to withdraw your plea and proceed with trial.

17 MR. WEINSTEIN: That's what I understand.

18 THE COURT: Then likewise the allegations that
19 were made by both counsel, are these facts true?

20 MR. WEINSTEIN: They're consistent with what I
21 believe the facts to be.

22 THE COURT: Okay. So essentially the corporation
23 is pleading guilty to these charges because it is guilty and
24 for no other reason?

25 MR. WEINSTEIN: That's correct.

1 THE COURT: This case is proceeded by way of a
2 waiver of indictment. You, of course, understand that by
3 proceeding by waiver of information, by information rather
4 than indictment, you give up your rights to have a grand
5 jury hear the government's case, determine if there's
6 probable cause to proceed. Do you understand that?

7 MR. WEINSTEIN: I do understand that.

8 THE COURT: Since you're a lawyer, this is a
9 little bit superfluous, but you also by pleading guilty, by
10 the corporation pleading guilty, you lose all the benefits
11 of a jury trial in which the jury would hear the
12 government's case, I have to go through this, the government
13 would have to prove to a jury the corporate guilt beyond a
14 reasonable doubt.

15 There's no obligation to mount a defense or to put
16 on witnesses or certainly to make any admissions, but you
17 could choose to put on witnesses, subpoena witnesses, make
18 whatever admissions you wish if you so chose, but you give
19 up all those rights when you plead guilty, when you, the
20 corporation pleads guilty. I don't want you to get
21 hysterical, you're not pleading guilty, you're pleading
22 guilty on behalf of the corporation.

23 Okay. The plea agreement is not binding on me
24 except in the way that I've just described, which it links
25 the plea to the sentence. If I reject the sentence, then

1 you can set aside your plea. There are a couple of
2 provisions of the plea. There was a reference, the plea
3 agreement is coupled with an agreement to not further
4 prosecute Forest for any additional federal charges, is that
5 right, this is page 6?

6 MR. ARNOLD: There were certain limitations, your
7 Honor. It's not a blanket.

8 THE COURT: Right.

9 MR. ARNOLD: Get out of jail free card.

10 MR. ARNOLD: No, it's not. It defines as set
11 forth in Section 5 of the plea agreement that the government
12 has agreed not to prosecute Forest for any additional
13 federal criminal charges with respect to conduct that falls
14 within the scope of the information to which Forest is
15 pleading guilty, was subject of the grand jury investigation
16 in the District of Massachusetts relating to Levothroid as
17 manufactured prior to August 14th, 2003 relating to the
18 sale, promotion or marketing of Celexa and Lexapro in the
19 United States, or it was not known to the United States
20 Attorney's Office for the District of Massachusetts or the
21 Office of Consumer Litigation of the Department of Justice
22 prior to the date of the agreement and which concerned the
23 sale, promotion, manufacture or marketing of Levothroid as
24 manufactured prior to August 14, 2003 in the United States
25 or which concerned the sale, promotion or marketing of

1 Celexa or Lexapro in the United States through December 31,
2 2005.

3 The declination is also expressly contingent upon
4 the guilty pleas of Forest to the information attached as
5 Exhibit A being accepted by the Court and not withdrawn or
6 otherwise challenged and Forest's performance of all its
7 material obligations as set forth in this agreement and the
8 attached civil settlement agreement.

9 THE COURT: Okay. I didn't mean to short-circuit
10 your carefully worked out plea, but essentially the document
11 defining this plea is the document that I've been given
12 dated September 15th, 2010 with a number of exhibits
13 attached to it. Perhaps that's the best way to proceed
14 rather than my trying to characterize anything, and this is
15 a document, this being the agreement September 15th, 2010 is
16 an agreement that the corporation has willingly entered into?

17 MR. WEINSTEIN: Forest Pharmaceuticals has, yes.

18 THE COURT: And Forest Pharmaceuticals has not
19 been threatened in any way to enter into this agreement?

20 MR. WEINSTEIN: Other than the prosecution
21 itself.

22 THE COURT: Yes.

23 MR. WEINSTEIN: Yes.

24 THE COURT: Okay. I mentioned the waiver of
25 appeal which I will accept. That would be a good thing for

1 Mr. Weinstein to sign now the waiver of indictment.

2 MR. CERESNEY: Your Honor, while we're doing this,
3 I wanted to raise one issue. We have now executed it. I
4 understand that your Honor had considered or had been
5 intending to order a pre-sentence report and order a
6 sentencing date in the future. I would just ask though if
7 your Honor is inclined, there is a provision under the
8 agreement which allows us to request, and I think the
9 government doesn't oppose, both plea and sentencing today
10 based upon the (c)(1)(c) plea obviously carefully negotiated
11 after a lengthy negotiation.

12 THE COURT: I wish I had some warning about that.
13 I don't want to do it now. I'm in the middle of another
14 jury trial, and I really don't want to proceed from one to
15 the other. I appreciate, that means everyone would have to
16 come back, but I don't necessarily -- does the government
17 take a position on whether you need a pre-sentence report
18 here?

19 MR. ARNOLD: The government pursuant to the plea
20 agreement stated that we don't object to the Court
21 proceeding to sentence immediately following the Rule 11
22 plea hearing or in the absence of a pre-sentence report. We
23 would note, however, that, for example, forfeiture documents
24 have not yet been prepared or submitted to the Court.

25 MR. CERESNEY: We would obviously, if there were

1 an open issue like forfeiture, which I understand you can
2 actually order and then have the paper done afterwards, we
3 would obviously be amenable to that. What we're trying to
4 avoid is obviously needing to return and also an obviously
5 carefully negotiated agreement.

6 THE COURT: I think needing to return would be
7 unavoidable under the circumstances because I really have to
8 conclude this. One other clarification for my purposes,
9 there is a civil settlement agreement, which is independent
10 of this, it's attached to it, but essentially a violation of
11 that settlement agreement doesn't trigger a breach of the
12 plea agreement. Is that correct? Did I read that
13 correctly? You haven't reduced this to your memory?

14 MR. ARNOLD: Well, your Honor, if you look at the
15 breach of agreement paragraphs, this is page 11, it does
16 indicate that Forest understands and agrees that this plea
17 agreement is an agreed criminal disposition are wholly
18 dependent upon Forest's timely compliance with the material
19 provisions of the attached civil settlement agreement.

20 THE COURT: Then it says, "failure to comply," oh,
21 failure to comply will constitute a breach.

22 MR. ARNOLD: Will constitute a breach.

23 THE COURT: Okay. I read that wrong.

24 MR. CERESNEY: Except for the corporate integrity
25 agreement.

1 MR. ARNOLD: Except for the CIA, right, the
2 corporate integrity agreement.

3 THE COURT: Okay. I see. My understanding of
4 this document is less significant than your understanding of
5 this document, and I assume that you were one of the
6 principal negotiators of it?

7 MR. WEINSTEIN: I was together with outside
8 counsel.

9 THE COURT: Okay. All right. I think that is
10 really all that I need to address.

11 MR. ARNOLD: Does the Court wish me to quickly
12 apprise it of what the terms of the (c)(1)(c) agreement are
13 with respect to the actual penalties?

14 THE COURT: We can do that.

15 MR. ARNOLD: The parties have agreed that the
16 appropriate resolution for this case would be a criminal
17 fine of \$150 million be imposed as follows: Count 1,
18 \$500,000; Count 2, \$110,000,000; Count 3, \$39,500,000. The
19 criminal fine is to be paid within one week of the date of
20 sentencing.

21 Mandatory special assessments totaling \$650 to be
22 imposed as follows: Count 1, \$400; Count 2, \$125; and
23 Count 3, \$125. Criminal forfeiture in the amount of
24 \$14,000,000, and in light of certain pending civil actions
25 identified in the plea agreement and the civil settlement

1 agreement between Forest and the United States, which
2 required payment of \$149,158,057.66 plus interest, the
3 parties have agreed that the complication and prolongation
4 of the sentencing process that would result from an attempt
5 to fashion a restitution order outweighs the need to provide
6 restitution to any nonfederal victims in this case given the
7 difficulty of determining whether and to what extent any
8 unknown individual payor suffered any injury as a result of
9 the offenses.

10 As a result, the United States agrees that it will
11 not seek a separate restitution order as to Forest as part
12 of the resolution of the information, and the parties agree
13 that the appropriate disposition of this case does not
14 include a restitution order.

15 THE COURT: All right. So, again, that's the
16 agreed upon disposition pursuant to 11(c)(1)(c). If I
17 accept that, that will be the sentence; if I don't, we can
18 begin again. I'm going to accept the plea. I find it
19 knowing and voluntary. You can go back to your seat. What
20 time do you need to do the forfeiture papers? What's an
21 appropriate time for everyone to have this sentence?

22 MR. ARNOLD: I think we had already been given a
23 date by your clerk of March 16th.

24 THE COURT: I don't believe that there's a
25 necessity for a pre-sentence report so that date could be

1 advanced if you wished.

2 MR. CERESNEY: I guess from our perspective, your
3 Honor, a date, we don't think there's a need, we agree to a
4 pre-sentence report for other submissions. We have an
5 agreement on the sentencing factors, and we would ask for a
6 date when the forfeiture papers are drawn.

7 THE COURT: What I propose is this so that we
8 don't deal with everyone's schedules, file a motion to waive
9 the pre-sentence report and to set a scheduling date and do
10 that as a matter of an agreement. We can fit in whenever
11 you can do it. Okay. Is there anything else I have to
12 address now?

13 MR. ARNOLD: No, your Honor, though the government
14 does reserve its right to submit a sentencing memorandum in
15 support of the plea agreement.

16 MR. CERESNEY: I understand that, but I would
17 imagine your Honor has plenty of paper on this case
18 already.

19 THE COURT: Yes. Essentially if the document says
20 I waive the pre-sentence report, here's the date we propose
21 for sentencing, and then if you wish to file something, you
22 may as well, put this all in the terms of the document so I
23 can just put that on my docket.

24 MR. ARNOLD: We will, your Honor. Thank you.

25 THE CLERK: All rise.

1 (Whereupon, the hearing was suspended at
2 11:48 a.m.)

3
4 C E R T I F I C A T E

5
6 UNITED STATES DISTRICT COURT)
7 DISTRICT OF MASSACHUSETTS)
8 CITY OF BOSTON)

9
10 I, Valerie A. O'Hara, Registered Professional
11 Reporter, do hereby certify that the foregoing transcript
12 was recorded by me stenographically at the time and place
13 aforesaid in No. 10-10294-NG, United States vs. Forest
14 Pharmaceuticals, Inc. and thereafter by me reduced to
15 typewriting and is a true and accurate record of the
16 proceedings.

17 /S/ VALERIE A. O'HARA

18
19 _____
20 VALERIE A. O'HARA

21 REGISTERED PROFESSIONAL REPORTER

22 DATED FEBRUARY 8, 2011
23 _____
24
25